Pressure Offloading Injectable System (POIS): Evaluating the use of an injectable dermal filler for offloading painful pressure points during weight bearing activities

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Fat pad atrophy is a condition characterized by the loss of natural fat on the plantar aspect of the foot. Fat pad restoration techniques directly address fat pad atrophy by increasing the overall thickness of subcutaneous tissue in the foot. Two subtypes of fat pad restoration, surgical dermal allograft and autolipotransplantation, are well-characterized treatment options for offloading high pressure regions of the foot. These methods have previously been shown to result in significant decreases in pain, improvement in the overall quality of life and decreases in the progression of dermal breakdown. However, the efficacy of a novel subtype of fat pad restoration, dermal injectables, is poorly characterized. This prospective, within-subjects design trial of thirty participants evaluated the safety and efficacy of an injectable hyaluronic acid dermal filler by measuring quality of life scores, ultrasound subcutaneous tissue thickness and gait pressure analysis. Each participant was followed for a one-year period with each study variable analyzed at 2 weeks, 12 weeks, 24 weeks and 54 weeks post-injection. Our study results revealed that a 1 milliliter injection of Juvederm® Voluma XC into regions of the foot with fat pad atrophy resulted in significantly higher Foot and Ankle Disability Index (FADI) scores over 54 weeks post-injection (p < 0.001, versus baseline), and significantly higher subcutaneous layer thickness over 54 weeks post-injection (p < 0.01, versus baseline), while no significant changes in the impulse gait percentages throughout the course of the study were evident (p >> 0.05, versus baseline). While follow-up studies are necessary, our preliminary study strongly suggests that Juvederm® Voluma XC (and other similar injectable dermal fillers) may present an efficacious, non-invasive, alternative treatment option to address fat pad atrophy.

Keywords: Foot and Ankle Disability Index (FADI) score, dermal filler, fat pad atrophy, fat pad restoration, foot pad cushioning, heel pain, Juvederm® Voluma XC, TOG GaitScan™, metatarsalgia, pressure ulceration.

Fat pad atrophy is defined as the loss of an individual's natural adipose tissue around the bones of the foot [1]. This condition is characterized by a patient's pain and discomfort in the plantar aspect of the foot while standing, walking, and performing certain weight bearing activities [2,3]. In severe cases of fat pad atrophy, dermal breakdown is the precursor to decubitus ulceration [4,5]. The loss of protective adipose cushioning can lead to an individual's decrease in activity level and eventually contribute to a decline in overall health.

Common causes of deterioration of fat in the foot include natural atrophy due to aging, foot type and gait pressure [6-10], systemic conditions such as thyroid and hormonal abnormalities [11], autoimmune and connective tissue disorders [12,13], smoking [14], and the iatrogenic overuse of cortisone injections [15,16]. Anterior displacement of the forefoot fat pad observed in a progressive cavus foot type diminishes the necessary adipose shock absorption at the metatarsal heads, resulting in pain with ambulation [17]. Generally, as individuals age, skeletal changes of the foot are seen in all genetic foot types and are aggravated by biomechanical forces placed upon the foot due to daily ambulation, physical weight bearing activity, and choice in shoe gear. As foot structure changes over time, bones can misalign, creating deformities such as a bunion or a hammered digit [18-21]. Foot musculoskeletal changes over time combined with external factors result in an increase in the pressure experienced by the foot while walking.
against the ground or shoe. Keratinocytes in the epidermal layer react to excessive friction by generating a buildup of keratin tissue as observed during the process of hyperkeratosis [22]. The accumulation of keratin subsequently leads to severe pain and discomfort during daily activities, such as walking and other forms of exercise. In the neuropathic population, high pressure during gait coupled with a loss of adipose shock absorption often leads to keratin breakdown and skin ulceration [23-25].

Antecedently, the most common treatments for fat pad atrophy have included offloading with sticker foot pads, orthotics, and surgical interventions [26-29]. Notably, fat pad restoration techniques have gained recent interest as viable, alternative treatment options for the repair of atrophied subcutaneous tissue. There are three common forms of fat pad restoration: injectables, surgical dermal allograft and autolipotransplantation [30-33].

Currently, dermal fillers are not FDA approved for use in the foot. This research study evaluated the efficacy of Juvederm® Voluma XC (Allergan, Irvine, California), a hyaluronic acid injectable, to alleviate the pain, discomfort, and high pressure experienced in the foot during gait. This was a single center, within-subjects design prospective trial that identified thirty qualified participants that met the criteria for inclusion. In this study, participants were evaluated both before and after they were injected with 1.0 mL of a hyaluronic acid dermal filler, in order to determine clinical progress at various time points (2 weeks, 12 weeks, 24 weeks, and 54 weeks post-injection), relative to the baseline level of disability. Each evaluation included the use of Foot and Ankle Disability Index (FADI) scores, ultrasound measurements of the plantar foot fat pad, and gait pressure analyses using a GaitScan™ (Markham, Ontario, Canada).

It was hypothesized that an injection of Juvederm® Voluma XC would significantly increase subcutaneous layer thickness in the plantar foot over the course of 54 weeks. In addition, this increase in the cushioning of the foot was hypothesized to decrease the participants’ pain with daily activities and improve overall quality of life. The primary objective of this prospective study was to assess whether a single 1 mL injection of Juvederm® Voluma XC in certain regions of the plantar foot would result in significant increases in subcutaneous layer thickness, increased comfort with daily activities, and decreases in gait peak pressures over a 54-week period.

Secondary objectives included evaluation of the subcutaneous thickness over the course of one year through ultrasound measurements and assessing the longevity of the effects of the dermal filler on pain reduction in high pressure areas.

Participants/Materials and Methods

This was a single center, within-subjects design, prospective trial of thirty participants (aged 40-75 years) who identified a localized area of pain in the foot, limiting their daily activities. Sub-investigators were responsible for the initial subject evaluations, data management, statistical analyses, and participated in a monitoring committee. One sub-investigator served as the outcome assessor and was blind to subject involvement. The primary material used in this research study was a hyaluronic acid dermal filler, Juvederm® Voluma XC (1 milliliter was injected into each patient). It was administered via injection to the affected foot region with a 25-gauge, 1.5-inch needle. The dermal filler was provided through a grant by Allergan (Batch Number: Lot # VB20A90454; GTIN # 10888628000018). Other equipment utilized for this study included a Terason Ultrasound, owned by the principal investigator (PI) and a TOG GaitScan™. The PI conducted clinical examinations in accordance with the inclusion and exclusion guideline criteria and patient medical history interviews, along with sub-investigators. The PI was also responsible for performing all injection procedures and ultrasound measurements. The study administrator was responsible for participant follow up scheduling and obtaining all FADI scores and gait pressure data. The study outcome assessor performed statistical analyses on the collected data and was blinded to anything related to the study except the collected data.

The inclusion criteria for participation included: being within the age range of 40-75 and presenting with a Foot and Ankle Disability Index (FADI) score of at least 55, as determined through FADI questionnaires. The degree of atrophy was determined via ultrasound measurements, and the peak pressure was identified through gait pressure mapping.

The exclusion criteria included: failing to present with high pressure fat pad atrophy, being treated for cancer, presenting with active skin infections and unhealed or acute foot fractures, displaying clinical
decreases in dorsalis pedis or posterior tibial pulses, being pregnant or breastfeeding, having previous injections with dermal fillers, nerve injury or nerve damage to the foot causing symptoms of numbness, tingling, burning, and sharp shooting or stabbing sensations, as well as any active and acute diabetic foot ulcers.

Any individual meeting the inclusion and exclusion criteria that was interested in the study and could commit to all the follow up evaluations throughout the course of the study was considered. The enrollment period was six months. Participants were recruited through a mass email sent to the PI’s patient database. This study consisted of thirty participants. IRB approval was obtained through Western IRB (wcrirb.com). We obtained approval from the institutional review board as a full review. The Food and Drug Administration also provided approval for the injection of Juvederm® Voluma XC in the foot. Furthermore, this study is registered on www.Clinicaltrials.gov.

Twenty-three women and seven men were enrolled in the study, with an average age of 61 years. One subject failed to follow up after the 24-week time point and was not responsive to various communication methods. Another subject missed the primary endpoint of 12 weeks but did present for evaluation at 24 weeks. This same participant did not complete the 54-week visit. This study was initiated just prior to the beginning of the COVID-19 pandemic. Some participants missed follow-up evaluations due to quarantine regulations, but if the participant was present for the primary endpoint evaluation at 12 weeks and the final evaluation at 54 weeks, they were still considered completed. The first subject was enrolled on October 30, 2019, and the final subject commenced evaluation in April of 2022.

Once it was identified that a subject met the initial inclusion criteria, each potential subject was given a randomized number between 1-30, as provided by the study administrator. Next, the participant met with the principal investigator and a medical history and clinical evaluation were performed. If any exclusion criteria were identified, the participant was not included in the study and the initial number assigned to the potential participant was placed back into the number pool.

Baseline FADI questionnaire, ultrasound measurement, and gait pressure data were subsequently collected from all qualified participants selected for the study. FADI scores were obtained as each participant completed their 26-item questionnaire, indicating their relative level of pain and disability at the start of the study [34]. FADI questionnaires are scored from 0-104, with 0 being equated with complete disability and pain with daily a, and 104 indicating complete function with the absence of pain. Ultrasound measurements were all performed by the same principal investigator to decrease variability in techniques. Using a 10Hz linear transducer, the probe was placed directly on the participants’ identified area of pain upon ambulation. With the participant placed in a supine position, the foot was slightly plantarflexed and the probe was positioned perpendicular to the underlying bone. The data were obtained by measuring the distance from the dermis to the echogenic signal of cortical bone. Gait pressure analysis was performed by the sub-investigators. Gait pressure data were obtained through an orthotic scanner. Each participant was required to take three steps on the floor prior to placing weight on the scanner in a forward locomotion. While the orthotic scanner solely provided qualitative data (rather than quantitative data), the percentage of the gait cycle in which the peak pressure is experienced still provides useful information regarding the efficacy of the treatment over 54 weeks.

Prior to injection, each participant was required to sign and submit photography release and procedure consent forms to the study administrator. Subsequently, the principal investigator performed injections on all study participants. A 25-gauge, 1.5-inch length needle was used to inject 1 milliliter of Juvederm® Voluma XC into the subcutaneous tissue. Care was taken not to inject superficially into the dermal layer, nor too deep into the capsule. The position of the needle was confirmed through syringe manipulation. Aspiration prior to injection was performed to ensure that none of the dermal filler material entered a blood vessel. Injection technique included a fan-like motion with the injection performed while backing out of the needle in a linear direction. Once the needle was close to the skin entry point, the syringe was moved approximately ten degrees, advanced into a new pathway, and negative pressure aspiration was subsequently performed immediately prior to dermal filler injection. The
injected area was then outlined with steri-strips in order to hold the dermal filler in the location of injection. The site of injection was then offloaded with a dural pad. Written instructions were provided and offloading with the dural padding was recommended for three days. Supportive shoe gear and limited physical activity were also recommended for two weeks. Participants were provided with precautions in the event of an adverse reaction, as well as relevant contact information.

Study participants were evaluated at 2 weeks post injection, 12 weeks post injection, 24 weeks post injection and 54 weeks post injection. The same protocols were performed during each follow up visit. FADI scores, ultrasound measurements, and gait pressure data were collected at each visit. If a participant could not be seen in the clinical setting due to COVID-19, they were provided solely with the FADI questionnaire to complete remotely.

In order to determine the statistical significance of the changes in FADI scores throughout the study (compared to baseline), we utilized Friedman’s ANOVA test followed by a non-parametric post-hoc test (Wilcoxon signed-rank test). Statistical significance was defined at the 5% (p ≤ .05) level.

For the ultrasound measurements, we utilized Friedman’s ANOVA test (followed by post-hoc Wilcoxon signed-rank tests) to determine whether there were statistically significant changes in subcutaneous layer thickness (compared to baseline). Statistical significance was defined at the 5% (p ≤ .05) level.

For the gait peak pressure measurements, we again implemented the Friedman’s ANOVA test (followed by post-hoc Wilcoxon signed-rank tests) to determine if there were statistically significant changes in the peak pressure percentage throughout the study. Statistical significance was defined at the 5% (p ≤ .05) level.

Throughout the study (compared to baseline), we utilized Friedman's ANOVA test followed by a non-parametric post-hoc test (Wilcoxon signed-rank test). Statistical significance was defined at the 5% (p ≤ .05) level.

Twenty-three women and seven men were enrolled in the study, with an average age of 61 years. Four participants presented with submetatarsal one pain, eleven participants indicated submetatarsal two pain, three participants had submetatarsal three pain, eight participants presented with submetatarsal five pain, two participants presented with hallux pain, and one subject had heel pain. Of the thirty participants enrolled, twenty-nine completed the study at 54 weeks (Table 1).

At 12 weeks post-injection, there were statistically significant improvements in pain and daily function, relative to both baseline levels (p < 0.001, Figure 1) and 2 weeks post-injection (p = 0.002, Figure 1). At 54 weeks post-injection, there was another statistically significant improvement in pain and daily function, compared to baseline levels (p < 0.001, Figure 1).

Furthermore, statistically significant increases in subcutaneous layer thickness were noted for patients with injections administered to submetatarsal 2. These increases were seen at 2 weeks (p= 0.006), 12 weeks (p=0.003), and 24 weeks (p=0.005) post injection, compared to pre-injection levels (Figure 2B). A statistically significant decrease in subcutaneous layer thickness was also evident between the 12-week and 54-week timepoints (p=0.007), suggesting a marked decline in the cushioning offered by Juvederm® Voluma XC beyond 12 weeks post-injection.

No other statistically significant changes in subcutaneous layer thickness were found between any timepoints for patients that were injected in submetatarsals 1, submetatarsals 3, submetatarsals 5, the hallux, or the heel. The most likely explanation for this result is the small sample size in each injection location group.

Gait pressure was also measured throughout this study. Our findings indicate that while there are upward trends in impulse percentage for subjects injected in the submetatarsal 1/hallux (any time point after baseline; Figure 3A), submetatarsal 2 (between 12 weeks to 24 weeks; Figure 3B), and submetatarsal 5 (between baseline and 2 weeks; Figure 3D), there are no statistically significant changes at any time point for any of the locations of Juvederm® Voluma XC 1cc injection (Figure 3).
Results

<table>
<thead>
<tr>
<th>Injection location</th>
<th>Hallux</th>
<th>Heel</th>
<th>Submetatarsal 1</th>
<th>Submetatarsal 2</th>
<th>Submetatarsal 3</th>
<th>Submetatarsal 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
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<td>4</td>
<td>11</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Female patients</td>
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<td>3</td>
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<td>0</td>
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<td>5</td>
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<tr>
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<td>3</td>
<td>7</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Left foot</td>
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<td>1</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 1 Baseline demographics and injection location groups (N=29).

![Figure 1](image)

**Figure 1** Mean increases in FADI score averages at 2 weeks, 12 weeks, 24 weeks, and 54 weeks post-injection (N=29).
Figure 2 Mean subcutaneous layer depth measurements before injection, immediately post-injection, 2 weeks, 12 weeks, 24 weeks, and 54 weeks post-injection. A) submetatarsal 1 [N=4], B) submetatarsal 2 [N=11], C) submetatarsal 3 [N=3], D) submetatarsal 5 [N=8], E) hallux [N=2], F) heel [N=1].
Figure 3 Impulse percentage measurements before injection, 2 weeks, 12 weeks, 24 weeks, and 54 weeks post-injection. A) submetatarsal 1/hallux [N=6], B) submetatarsal 2 [N=11], C) submetatarsal 3 [N=3], D) submetatarsal 5 [N=8], E) heel [N=1].

Discussion

As far as we know, this is the first clinical trial to directly assess the efficacy of a hyaluronic acid dermal filler (Juvederm® Voluma XC) in the treatment of plantar fat pad atrophy. In agreement with our initial hypothesis, a 1 cc injection of Juvederm® Voluma XC resulted in statistically significant increases in Foot and Ankle Disability Index (FADI) scores after 12 weeks. Also in alignment with our hypothesis were the statistically significant increases in the subcutaneous thickness of submetatarsal 2, beginning at 2 weeks and continuing until 24 weeks post-injection. Contrary to our hypothesis, our data indicated no significant increases in subcutaneous thickness for any other injection location in the study (submetatarsal 1, submetatarsal 3, submetatarsal 5, the hallux, and the heel). In addition, no significant changes were found in gait impulse percentage values throughout the duration of the study.

To date, there are few published studies that document the safety and efficacy of fat pad restoration treatments. Studies currently available in
the literature focus on silicone as the primary therapeutic agent. Balkin, et al., have published several papers on the use of subdermal silicone as a potential pressure offloading injectable system in the foot [30, 31, 35-43]. Additionally, a study from van Schie CH, et al., indicated that injectable silicone may significantly increase subcutaneous layer thickness and decrease peak pressure in diabetic foot patients over a 24-month period [44]. While injectable silicone demonstrates promise as a potential fat pad restoration treatment method, it is also known that the long-term therapeutic function of silicone is limited due to breakdown and fragmentation in the body over time [45,46]. Furthermore, silicone is not absorbed by the body, which may lead to certain noxious effects, such as encapsulation, calcification, fibroblast formation, and scarring [46]. As van Schie CH, et al., documented, the therapeutic effects of silicone injections in the plantar foot lasted approximately 24 months [44]. However, due to the adverse side effects and complications that also persisted for two years in study participants, our group hypothesized that the use of an absorbable material would ultimately be more efficacious for the long-term health of patients. Considering this, the use of an absorbable hyaluronic acid dermal filler in the foot may prove to be an ideal therapeutic candidate for fat pad restoration. In our prospective trial, there were no adverse reactions noted by any participant throughout the 54-week study.

Juvederm® Voluma XC is a dermal filler currently FDA approved for fine lines and wrinkles in the face. Like other dermal fillers on the market, Juvederm® Voluma XC possesses a highly crosslinked hyaluronic acid structure with the potential to absorb the plantar pressure experienced during gait. The longevity of the dermal filler’s effect on fine lines and wrinkles has been extensively evaluated in the face. However, there are no direct correlates from these studies with Juvederm’s ability to limit weight bearing forces upon the foot during gait. In our study, the 54-week duration was not sufficient to determine the specific range of time in which Juvederm® Voluma XC loses its therapeutic effect in the foot, as participants had not yet returned to baseline FADI scores by the time the study period concluded. Our findings suggest that the therapeutic effects of Juvederm® Voluma XC peak at 12 weeks, and may last beyond one year (Figure 1).

Ultrasound imaging was used to evaluate the overall subcutaneous thickness from the dermis to the cortical margin of the underlying bone where the hyaluronic acid was injected. The ultrasound scanning protocol was consistent throughout the length of the study. In addition, all ultrasound imaging was performed using a Terson 10Hz linear probe to scan the area being evaluated. There is minimal literature support for a standardized fat pad thickness depth for healthy individuals, relative to symptomatic individuals. However, Morrison, et al., reported a total soft tissue depth of 7.92 mm at the 2nd metatarsal head in non-diabetic patients, with an average age of 41.38 years [47]. They also evaluated the intra- and inter-reliability of ultrasound measurements of the foot and found consistency in total soft tissue measurements from the dermis to the associated metatarsal and calcaneal cortex. Our study demonstrated an average submetatarsal subcutaneous thickness of 7.63 mm. Future studies would be aided by a standardized range of ultrasound measurements for healthy individual’s subcutaneous layer thickness at various locations in the plantar foot, which would provide a well-characterized, objective metric of patient progress during different checkpoints of the trial. In our study, statistically significant changes in subcutaneous layer thickness were only found within the submetatarsal 2 subgroup (Figure 2B). The lack of statistical significance for our ultrasound data is most likely due to the low sample size for each location subgroup. For our submetatarsal 2 patients, statistically significant increases in subcutaneous thickness were measured at 2 weeks, 12 weeks, and 24 weeks post-injection, relative to baseline levels. This result may be due to the cell-proliferating effects of the hyaluronic acid filler, which could have stimulated the growth of the subcutaneous layer throughout the 12 weeks after injection. Nonetheless, a statistically significant decrease in subcutaneous thickness was also noted from 12 weeks to 54 weeks. This finding may suggest that the hyaluronic acid begins to break down on load-bearing surfaces after 12 weeks. Despite this decrease, the subcutaneous thickness at 54 weeks was still greater than baseline levels. Moreover, the FADI scores did not decrease in conjunction with the subcutaneous thickness levels. This could indicate that the therapeutic effects of hyaluronic acid fillers on the foot may last longer than the thickness of subcutaneous tissue suggests.
The final parameter evaluated in this study was gait pressure analysis. The physical quantity of impulse denotes the amount of force applied over time (Force x Time). In our study, a one-step gait scanner (TOG GaitScan) was used to measure the percentage of impulse experienced by the treated area. It is hypothesized that impulse percentage values will be positively correlated with FADI quality of life scores; an increase in the percentage of impulse experienced by a certain foot region would be associated with a decrease in pain and discomfort, due to the patient's ability to bear more weight comfortably while performing physical activities. However, our gait pressure findings were largely inconclusive due to a low sample size for each anatomical location subgroup. As a result, no statistically significant results were detected, though upward trends in impulse percentage values were noted for patients injected in submetatarsal 1/hallux, submetatarsal 2, and submetatarsal 5 (Figure 3A, 3B, 3D).

There are several limitations present in this study that can be addressed in subsequent trials. Firstly, this study utilized a small number of participants per subgroup. One reason for the small subgroup sample size was the selective study recruitment process, which limited the participant pool to a total of 30 subjects. These 30 participants were unevenly divided into various location subgroups, depending on which foot region they had reported experiencing pain. Of these 30 participants, only 2 had hallux discomfort, 3 had submetatarsal 3 discomfort, 4 had submetatarsal 1 discomfort, and 1 had heel discomfort. Follow-up trials should implement an optimized screening process in which a minimum number of participants reporting discomfort in a certain foot location is identified before proceeding with the study. A larger subgroup sample size would allow for greater statistical significance and would provide more conclusive results. The second limitation of this study is the lack of a positive (or active) control, which could have provided more useful data regarding the efficacy and strength of Juvederm® Voluma XC relative to other treatments currently available on the market. Certain alternative treatment options, like Radiesse® (a dermal filler) or Leneva® (an allograft adipose matrix) could be used in a separate control group to determine whether Juvederm® Voluma XC is less efficacious, equally efficacious, or more efficacious than therapies already available on the market. The third limitation of this study is the absence of an objective method to determine the

Another salient finding was that, despite diminished ultrasound subcutaneous thickness, skin quality improved throughout the duration of the study, relative to baseline conditions. Pre-injection hyperkeratotic lesions on certain patients were resolved by the end of the study, with noted improved quality of life (as measured by FADI questionnaire scales). One notable example was participant number 28, who had an initial complaint of a hyperkeratotic lesion on the right submetatarsal 2, causing pain and discomfort. At baseline, subcutaneous layer thickness was 6.7 mm (Figure 4). At the primary 12-week endpoint, thickness levels were 9.5 mm. At the conclusion of the study, subcutaneous layer thickness had diminished to 8.1 mm (Figure 5). The baseline, 12-week, and 54-week FADI scores for this subject were 96, 103, and 103, respectively. Upon clinical evaluation at the 54-week timepoint, the participant had no return of their hyperkeratotic lesion (Figure 5).
amount of dermal filler still localized in the region of injection at each timepoint during the study. Future studies would benefit from techniques such as histological analysis and biopsy examinations, which would aid in the determination of the exact length of time this specific hyaluronic acid filler remains in the foot. The fourth limitation of this study is the gait scanner technology utilized to measure impulse percentage. The TOG Gaitscan™ apparatus used in this study was solely capable of providing qualitative data, such as a color-coded map that displayed relative pressure readings as a patient ambulated across the scanner. The only numerical data provided by the scanner were the impulse percentage values, which are not direct correlates of peak pressure, and vary greatly between patients. Therefore, our gait scanner data should be taken with caution, as there is no conclusive evidence yet to confirm or disprove that Juvederm® Voluma XC significantly alters the peak pressure experienced during ambulation. Subsequent studies may achieve more useful information from the utilization of technology such as the TekScan® HR Mat™, which has been proven to collect precise pedobarographic data, including direct peak pressure measurements [26]. A fifth limitation found within our study is the potential for human error and variability in the clinical data collection techniques between the principal investigator and clinical coordinator. While ultrasound collection and gait scan data measurement protocols were identical between the PI and clinical coordinator, human error may have been introduced during the data-collection aspects of the study. Variability in the patient's position during ultrasound measurements, ultrasound sound probe pressure, and gait interferences may have also introduced a minimal amount of error into the final datasets. An additional limitation of our study is the possibility of the observer effect, in which study participants alter their behavior while being watched by study organizers. In the context of our study, this may have led to subjects overshothing or undershooting their true pain and disability levels while completing their FADI questionnaires at each follow-up visit.

In conclusion, our study indicates that a 1 cc injection of Juvederm® Voluma XC (a hyaluronic acid dermal filler) into the plantar aspect of the feet in patients with symptomatic fat pad atrophy is safe and effective to treat pain and disability over the course of 54 weeks. Juvederm® Voluma XC injection had less adverse effects than exogenous silicone over the course of one year and should be considered as a viable alternative treatment option for fat pad atrophy. While follow-up studies are necessary, our prospective clinical trial demonstrates the promise that hyaluronic acid dermal fillers have in the treatment of chronic foot pain and disability.

Acknowledgments

This research would not have been made possible without the assistance of our team, Heather Schultz, research coordinator and assistants Stephanie Kane, DPM and Robbie Caballes, DPM.

References


