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The Effects of a Designed Orthosis on Dynamic Plantar Pressure in Patients with Chronic Plantar Fasciitis: A Randomized Controlled Trial

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Abstract:	Background Plantar fasciitis is one of the most common causes of heel pain. Plantar fascia supports the longitudinal arch and absorbs ground reaction force during the static and dynamic phase(s) of weight-bearing. The purpose of this randomized controlled trial study was to determine the effects of a CAD/CAM foot orthoses that was designed based on the dynamic plantar pressure in patients with plantar fasciitis. Materials and Methods This study was performed on 34 patients with plantar fasciitis. Outcomes were compared based on plantar fascia thickness, peak pressure, mean pressure, maximum

	force, pain, activity daily living, quality of life, and sport activity that evaluated by ultrasound, plantar pressure platform, and the foot and ankle outcome score respectively. The patients were randomly assigned into two groups: the experimental group (CAD/CAM orthoses and night splint) and the control group (night splint only). All data was recorded again after four weeks. Results Pain (P = .002) and plantar fascia thickness (P = .001) has shown significantly decrease after one month of intervention. Activity daily living (P = .044) and quality of life (P = .001) showed significantly increase. There was a trend in increasing peak pressure in all masking regions in both groups. The maximum force remarkably reduced in the experimental group in all regions. Conclusions The results demonstrated that CAD/CAM foot orthoses designed based on dynamic plantar pressure with night splint can reduce the plantar fascia thickness and pain associated with plantar fasciitis and increases the activity daily living, quality of life, and sport activity.
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The effects of designed foot orthoses on dynamic plantar pressure in patients with chronic plantar fasciitis: A randomized controlled trial

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Conflict of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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The Effects of a Designed Orthosis on Dynamic Plantar Pressure in Patients with Chronic Plantar Fasciitis: A Randomized Controlled Trial

ABSTRACT

Background: Plantar fasciitis is one of the most common causes of heel pain. Plantar fascia supports the longitudinal arch and absorbs ground reaction force during the static and dynamic phase(s) of weight-bearing. The purpose of this randomized controlled trial study was to determine the effects of a CAD/CAM foot orthoses that was designed based on the dynamic plantar pressure in patients with plantar fasciitis.

Materials and Methods: This study was performed on 34 patients with plantar fasciitis. Outcomes were compared based on plantar fascia thickness, peak pressure, mean pressure, maximum force, pain, activity daily living, quality of life, and sport activity that evaluated by ultrasound, plantar pressure platform, and the foot and ankle outcome score respectively. The patients were randomly assigned into two groups: the experimental group (CAD/CAM orthoses and night splint) and the control group (night splint only). All data was recorded again after four weeks.

Results: Pain (P = .002) and plantar fascia thickness (P = .001) has shown significantly decrease after one month of intervention. Activity daily living (P = .044) and quality of life (P = .001) showed significantly increase. There was a trend in increasing peak pressure in all masking regions in both groups. The maximum force remarkably reduced in the experimental group in all regions.

Conclusions: The results demonstrated that CAD/CAM foot orthoses designed based on dynamic plantar pressure with night splint can reduce the plantar fascia thickness and pain

associated with plantar fasciitis and increases the activity daily living, quality of life, and sport activity.

Level of Evidence: Level I, Randomized controlled trial

Keywords

Plantar fasciitis; Ultrasonography; Plantar fascia thickness; Plantar peak pressure; Foot and ankle outcome score (FAOS), Orthoses

INTRODUCTION

Plantar fasciitis (PF) is one of the most common causes of plantar heel pain. The main complaint is typically a sharp pain in the inner aspect of the heel with the first few steps in the morning or after long periods of nonweightbearing.[1-4] It is estimated to affect 4% of the general population during their lifetime[5] and 7% in the older population.[6] Incidence of PF is higher in athletes especially in the runners, ranging from 8% to 22%.[7-9]

Plantar fascia supports the longitudinal arch and absorbs ground reaction force during the static and dynamic phase(s) of weightbearing.[10] Biomechanical, structural, and environmental factors and systemic diseases are the main risk factors that increase stress on the plantar fascia and cause PF.[11-13] The main biomechanical risk factors are excessive pronation, reduced ankle dorsiflexion, improper footwear, obesity, and extensive standing, walking, and running.[14-16] Tightness of the calf muscles, limited dorsiflexion of the ankle, and tightening of the plantar fascia that restrict the extension of the toes are other findings in physical examination.[16-18]

Pain starts with the first steps of gait[2-4] and worsens after long durations of standing or walking.[16] Objective dynamic evaluations of the plantar surface of the foot in PF patients, for

determining the impulse distribution, demonstrated that gait patterns were modified by a reduced hindfoot and an increased midfoot impulse.[19]

Orthotics treatments, i.e. foot orthoses and night splints, have been recommended for PF.[17,20-22] Foot orthoses have been manufactured in different ways; namely Plaster of Paris casting, impression foam methods, or scanning of the plantar surface of the foot. All these methods are static methods while shape of the foot changes during walking as a dynamic activity.[23] Custom insole designed based on the dynamic plantar pressure parameters[24] and finite element analysis[25,26] reduced high-pressure areas under the foot, during long-standing and walking.

The purpose of this randomized controlled trial study was to determine the effectiveness of a CAD/CAM foot orthoses designed based on the dynamic plantar pressure. To this end, plantar fascia thickness (PFT), plantar pressure parameters (peak pressure (PP), mean pressure (MP), maximum force (MF)), pain, activity daily living (ADL), quality of life (QOL), and sport activity were measured by ultrasound, plantar pressure platform, and the subscales of the foot and ankle outcome score (FAOS), respectively.

MATERIALS AND METHODS

This randomized controlled trial was performed on 34 patients with PF. It was approved by the Institutional Medical Ethics Committee and has been registered on the National Registry of Clinical Trials. Two groups of healthy participants (20 subjects in each group) were also included to assess reproducibility of ultrasound and plantar pressure platform, respectively. All participants signed the informed consent form after receiving information about the procedure of the study.

Reproducibility evaluation

Ultrasonography

Twenty healthy volunteers (10 female) were recruited to assess the reproducibility. Inclusion criteria were as follow: >18 years of age, no history of: surgery, fracture of the feet, and current or prior pain in the feet.

The subjects were positioned prone with a small cushion under the abdomen and a rectangular foam under the legs; the knee was positioned 30 degrees angled relative to the examination table with the feet hanging freely over the foam's edge and the ankle in a neutral position (0 degrees of plantarflextion and dorsiflexion).[27]

Ultrasound measurements were carried out with Sonoline G40 system (Sonoline G40, Siemens AG, Munich, Germany) equipped with a VF5-10 linear array transducer. All real-time sonographic examinations were performed by the same rater. Both heels of the participants were scanned in two-dimensional (2D) real-time B mode. The transducer was placed in the sagittal plane over the plantar aspect of the medial calcaneal tuberosity. The thickness of the plantar fascia was measured on a longitudinal view of the heel (in mm) at three points (point 1: the insertion point of the calcaneus, point 2: 5 mm from the insertion of the calcaneus, and point 3: 10 mm from the insertion of the calcaneus). Scan depth was set to 3 cm (Figure 1). As recommended by Rathleff et al.[28], to avoid errors due to transducer obliquity, three successive scans of each heel in every examination were taken and averaged. For each scan, the transducer was removed and repositioned again.

To assess within and between-day reliability, all healthy participants were rescanned on the same day with an hour interval and seven days later, respectively. It was randomly defined which side to measure first. All scans were performed between in the morning.

Plantar pressure platform

Twenty healthy volunteers (10 female) were recruited. Subjects were included if they were over 18 years of age with no history of surgery or fracture of the feet and current or prior pain in the feet.

To test maximum force (MF, %BW) and peak pressure (PP, kPa), emed-c50 system (Novel, Munich, Germany) was used. The emed-c50 system incorporates the Nicol capacitance pressure mat platform, which is a force transducer matrix consisting of a 610mm×323mm×15.5mm at 50/60Hz with 3792 sensors at a resolution of 4 sensors/cm^2 and accuracy of ±5% ZAS.

The emed platform was mounted in the center of a flat, 8 m walkway, at ground level. The participants were asked to walk barefoot at normal speed (mid-gait technique) while three left and three right footsteps were recorded. To assess within and between-day reliability, measurements were repeated on the same day with an hour interval and seven days later, respectively. It was randomly defined which side to measure first. All evaluations were performed between in the morning.

Based on automated masking technique (PRC), using Novel Database Pro software v.11 (Novel, Munich, Germany, novelelectronics.de), the foot was divided into 10 regions: medial hindfoot (M1), lateral hindfoot (M2), medial midfoot (M3), lateral midfoot (M4), first metatarsal (M5), second metatarsal (M6), third to fifth metatarsal (M7), hallux (M8), second toe (M9), and third to fifth toes (M10). The maximum force (MF, %BW) and peak pressure (PP, kPa) were calculated.

Randomized controlled trial design

The randomized controlled trial was performed on 34 patients (29 female) with PF. Inclusion criteria were clinical diagnosis of chronic PF (at least two months of plantar heel pain, point of

maximal tenderness on physical examination over the medial tubercle of the calcaneus). Patients with fractures, arthritis, or tumors of the foot or ankle, rheumatoid arthritis, generalized polyarthritis, neurologic impairments, diabetes mellitus, lower extremity nerve entrapment, vascular abnormalities, prior operative treatment of the foot, or current pregnancy were excluded. Those who received stretching exercises, physiotherapy, orthoses, corticosteroid, or other injections for PF during the past three months before study entry were also excluded.

The patients were randomly assigned into two groups through a block-style randomization scheme: the experimental group (CAD/CAM foot orthoses and night splint) and the control group (given just the night splint) (Figure 2).

Participant's characteristics such as sex, height, weight, duration of symptoms, and self-reported weight-bearing hours were recorded, and if there was pain on both sides, the dominant side was identified. The subjects were assessed at baseline (before intervention), and after four weeks of intervention both subjectively and objectively. Ultrasonography was assessed PFT. The PP, MP, and MF were evaluated with the emed-c50 platform. The validated version of FAOS[29] was used to evaluate pain, ADL, QOL, and sport activity.

The plantar pressure scanned files of the experimental group were sent to pedcad software for designing the foot orthoses. Then, the computer numerical control (CNC) machine was employed (Sadrafan-Gostar, Iran) for making the orthoses. The full length foot orthoses were shaved on a foam block made of ethylene-vinyl acetate (EVA) foam top layer (shore A durometer 30) (Figure 3A). They were placed in standard shoes of each participant by a podiatrist (with 1 inch heel and enough space in the toe box). Each individual walked with the foot orthoses in their shoes to confirm comfort. To increase the durability and hygiene of the foot orthoses, they were covered by a thin layer of leather.

Prefabricated night splint with 5 degrees ankle dorsiflexion and 5 degrees metatarsophalangeal dorsiflexion was given to all participants (Figure 3B). Night splints were fitted for each participant. The control group received the night splint at the initial visit and the experimental group received it when the foot orthoses were ready. Both groups were asked not to change their activity level and to wear the night splint at least 6 hours during night. The experimental group was asked to wear the foot orthoses at least 6 hours a day.

The follow-up time point was planned after four weeks at which full assessment of the patients was carried out by filling out the FAOS, evaluating and recording the PFT and plantar pressure parameters. It is worth mentioning that all evaluations at both baseline and follow-up time points were performed in the morning.

Statistical analysis

Descriptive statistics was used to examine the demographic data. Intra-class correlation coefficient (ICC) was used for analyzing the reliability of reproducibility assessments. Linear mixed model ANOVA analysis was used to evaluate the effect of time, side, and sex on sonographic measurements. Paired sample t-test was used to examine changes within groups and independent sample t-test was used to evaluate and compare changes between groups. Pearson correlation coefficient was used to evaluate the relationship between variables. All statistical analyses were performed using SPSS version 22.0 for Windows (SPSS, Inc., Chicago, IL, USA).

RESULTS

Reproducibility evaluation

Ultrasonography

Twenty healthy volunteers (10 female) participated in the ultrasonography reproducibility evaluation. The mean age was 27.9 ± 5.42 (range, 18-35) years, mean body mass index (BMI) was 22.24 ± 2.46 Kg/m^2. The subjects' demographic information is provided in Table 1.

The mean of PFT in three measurement points is showed in Figure 4A. The PFT for male participants was higher than that of females ($P < .01$).

Within and between-day ICCs at three points were very high for the left and right sides. (Figure 4B)

The linear mixed model ANOVA was used to calculate the difference between the mean of time-points and the difference between the mean of both sides in both sex. The linear mixed-effects regression results showed that the time and side did not affect the measurements ($P > .05$) and showed female's PFT was 0.63 mm thinner than that of males ($P = .0001$) (Table 2).

Plantar pressure platform

Twenty healthy volunteers (10 female) participated in plantar pressure platform for reproducibility evaluation. The mean age was 28.1 ± 4.48 (range, 22-35) years, mean BMI was 22.08 ± 2.76 Kg/m^2. The subjects' demographic information is provided in Table 3. The ICCs were calculated by three factors, (10 regions, three times, and both sides) for the PP and MF (Figure 5). The within-day reliability demonstrated a strong agreement between scan and re-scan. The mean of ICC for within-day measurement for PP and MF in 10 regions was 0.931 ± 0.064 and 0.922 ± 0.040 for the left and 0.991 ± 0.006 and 0.989 ± 0.012 for the right side, respectively.

For between-day reliability, ICC tests were performed on the mean of three examination time-points at 10 regions on both sides. High ICC values proved high between-day reproducibility for

PP and MF at both sides. The mean ICC was 0.944 ± 0.048 and 0.927 ± 0.045 for the left and 0.990 ± 0.008 and 0.989 ± 0.010 for the right side, respectively.

Randomized controlled trial

Thirty-four patients (29 female) with PF participated in the randomized controlled trial study. The mean age was 45.21 ± 8.51 (range, 27-64) years, mean BMI was 28.31 ± 4.46 (range, 21.30-40.23) Kg/m^2. The subjects' demographic information is provided in Table 4. One month post-intervention, PFT in both groups showed a significant decrease ($P < .05$) (Figure 6). Scores of pain, ADL, QOL, and sport activity subscales in both groups increased significantly ($P < .05$). (Figure 7). PP, MP, and MF were similar within and between groups. There was a trend in increasing PP in all masking regions in both groups (Figure 8A). The MP decreased in M1 and M2 in the experimental group after intervention (Figure 8B) and MF remarkably reduced in the experimental group in all regions (Figure 8C). The difference between two groups in PFT was significant at third point ($P = .004$). (Table 5) Additionally, the PFT had a moderate negative correlation with FAOS subscales ($P < .01$). Also, the pain had a moderate to strong positive correlation with other subscales of FAOS ($P < .001$). (Figure 9).

DISCUSSION

The purpose of this randomized controlled trial study was to investigate the effects of CAD/CAM-designed foot orthoses based on dynamic plantar pressure on PFT, PP, MP, MF, pain, ADL, QOL, and sport activity in patients with PF. To this end, first, within and between-day reliability of ultrasonography and plantar pressure platform were assessed. Then, in a randomized controlled trial PFT was assessed in three points by ultrasound before and after the intervention

using night splint only (as control group) and CAD/CAM-designed foot orthoses together with the night splint (as experimental group). In both groups, PFT and pain were decreased significantly and ADL, QOL and sport activity were increased significantly.

Reproducibility evaluation

The ICC for PFT showed high within and between-day repeatability in all three points bilaterally. The within-day repeatability ICC (> .951) was stronger than that found by Rathleff et al[28] (*ICC* > .770). A possible reason for lower ICC reported by Rathleff et al may be attributed to the effect of dorsiflexion in their measurements, putting the toes in dorsiflexion to get a higher clarity of the plantar fascia and thus causing variation of the thickness of plantar fascia due to changes in the angle of the metatarsophalangeal joints in each measurement. The between-day repeatability of the PFT in our experiments was similar to that of Cheng et al[30] (*ICC* > .925).

The mean of ICC for within and between-day measurement of PP and MF in 10 mask regions were *ICC* > .900 which is similar to Puttie's et al study[31], better than Gurny's et al[32] and Zemmit's et al study.[33] Gurny et al measured PP and MF by emed-AT with two sensors/cm^2 on nine volunteers which could compromise the accuracy. The difference between the results of Zemmit's et al. study and the present study may be due to differences in measurement systems, region masking, gait pattern, and evaluation of one foot.

Randomized controlled trial

Similar to the findings of our randomized controlled trial, a few studies also have shown decreased PFT and pain after interventions using orthosis. Chew et al[34] evaluated the efficacy of autologous conditioned plasma compared with extracorporeal shockwave therapy (ESWT) and

conventional treatments for PF in three groups. After 1 to 6 months pain improved and PFT was reduced. Yan et al[35] compared the therapeutic effect of ESWT and an orthopaedic insole separately and combined in three groups on PF. The PFT decreased significantly in the combined group.

In the present study pain and PFT were decreased after one month of intervention with the Pearson correlation indicating a good significant inverse correlation between them. Mahowald et al[36] and Moustafa et al[37] found a statistically significant relationship between the change in PFT and pain level after a variety of conservative modalities, i.e. rest, icing, ultrasound-guided corticosteroid injections, padding, shoe modifications, over-the-counter arch supports, and stretching, and dexam-ethasone (DXM) iontophoresis and DXM injection, respectively. Liang et al[38] also showed that PFT reduction and pain in a group of patients treated with ESWT had a positive correlation.

Data regarding the effects of foot orthoses on PP, MP, and MF during walking in patients with PF is limited. Most studies have used in-shoe-based devices to assess immediate effect. PP and MF reduced significantly when patients walked with foot orthoses.[39-41] In our study, these parameters were evaluated before and after intervention by a floor-based device and participants walked barefoot. One month after intervention, PP, MP, and MF did not show significant differences in neither of ten masking regions. However, the results showed remarkable reduction of MF in the experimental group in all regions after one month intervention, which is in line with other studies.[19,39] It could be potentially due to the foot adaptation to the CAD/CAM foot orthoses. There was a trend in decreasing MP in heel (M1 and M2) in the experimental group as also reported by studies in which in-shoe device was used.[39-41] PP, in our study, increased in all masking regions in both groups. Brachman et al[42] evaluated the effect of ESWT on gait parameters in patients with chronic PF on the treadmill barefoot. The gait parameters were improved and load and pressure

were increased. One reason for increased PP after interventions could be due to reduced pain and increased patient confidence.

One month after intervention scores of FAOS subscales significantly increased in both groups. No significant differences in pain, QOL, ADL, and sport activity were seen between two groups. Previous studies have shown that custom foot orthoses and night splints, together or alone, reduce pain[21,22,43-45] and improve QOL[44,46,47], ADL[44,48,49], and sport activity[44] in patients with plantar heel pain. Similar to our results, in a study by Roos et al[44] FAOS subscales scores were improved using orthotic treatments though not significantly.

Since the most common complain of patients with PF is pain, many studies have focused on changes in pain. Nakhaee et al[43] investigated the effects of orthotics in three groups (silicon heel pad, functional thermoplastic foot orthosis, night splint), on the first step, night and worst pain by Numerical Rating Scale (NRS) and Verbal Rating Scale (VRS). In all groups, pain was reduced but not significantly. Another study[15], using customized and prefabricated orthoses, showed similar effectiveness in pain and foot function in patients with PF. Fong et al[45] compared the immediate therapeutic effects of rocker sole shoes and CAD/CAM custom-made foot orthoses, individually and combinatorically on PF. Results showed that a combined prescription had greater immediate therapeutic effects on PF pain. In a systematic review and meta-analysis, Whittaker et al[22] reported that foot orthoses are effective at reducing pain in the medium term. Based on the findings of another systematic review[50], mechanical treatment can be effective in relieving symptoms related to PF. O'Malley et al[51] used VAS, FAOS, and SF-12 to document the clinical outcomes of patients with PF who were treated with Platelet-rich plasma (PRP) injections. All scores of outcomes were improved after 4 weeks. Here, one-month after intervention, all FAOS subscales were improved and results showed a strong to moderate correlation between subscales.

Pain showed a positive strong correlation with ADL, sport activity, and positive moderate correlation with QOL.

CONCLUSIONS

The results of this randomized controlled trial demonstrate that in both CAD/CAM foot orthoses designed based on dynamic plantar pressure combined with splint and splint-only groups PFT and pain associated with PF decrease and ADL, QOL, and sport activity increase. Although not significant, there was a trend in decreasing the MF in the experimental group. Further research with larger sample size and longer follow-up time is warranted to evaluate the added value of orthotics on dynamic plantar pressure parameters.

REFERENCES

1. Alghadir AH. *Conservative treatment of plantar fasciitis with dorsiflexion night splints and medial arch supports: A prospective randomized study*. University of Pittsburgh; 2006.

2. Campblle WC. *Campbll's operative orthopaeics*. 10th ed. vol 4. Mosby, Inc; 2003.

3. Hamblen DL, Simpson HRW. *Adams's outline of orthopaedics*. 14th ed. Elsevier; 2010.

4. Menz HB. *Foot problems in older people, assessment and management*. Elsevier; 2008.

5. Hill CL, Gill TK, Menz HB, Taylor AW. Prevalence and correlates of foot pain in a population-based study: the North West Adelaide health study. *J Foot Ankle Res*. 2008;1(1):2. doi:10.1186/1757-1146-1-2

6. Dunn JE, Link CL, Felson DT, Crincoli MG, Keysor JJ, McKinlay JB. Prevalence of foot and ankle conditions in a multiethnic community sample of older adults. *American journal of epidemiology*. Mar 1 2004;159(5):491-8. doi:10.1093/aje/kwh071

7. Rome K, Howe T, Haslock I. Risk factors associated with the development of plantar heel pain in athletes. *The Foot*. 2001;11:119-125. doi:10.1054/foot.2001.0698

8. Taunton JE, Clement DB, McNicol K. Plantar fasciitis in runners. *Can J Appl Sport Sci*. Mar 1982;7(1):41-4.

9. Taunton JE, Ryan MB, Clement DB, McKenzie DC, Lloyd-Smith DR, Zumbo BD. A retrospective case-control analysis of 2002 running injuries. *Br J Sports Med*. 2002;36:95-101. doi:10.1136/bjsm.36.2.95

10. Bolgla LA, Malone TR. Plantar fasciitis and the windlass mechanism: a biomechanical link to clinical practice. *J Athl Train*. Jan 2004;39(1):77-82.

11. Irving DB, Cook JL, Menz HB. Factors associated with chronic plantar heel pain: a systematic review. *J Sci Med Sport*. May 2006;9(1-2):11-22; discussion 23-4. doi:10.1016/j.jsams.2006.02.004

12. van Leeuwen KD, Rogers J, Winzenberg T, van Middelkoop M. Higher body mass index is associated with plantar fasciopathy/'plantar fasciitis': systematic review and meta-analysis of various clinical and imaging risk factors. *Br J Sports Med*. Aug 2016;50(16):972-81. doi:10.1136/bjsports-2015-094695

13. Di Caprio F, Buda R, Mosca M, Calabro A, Giannini S. Foot and lower limb diseases in runners: assessment of risk factors. *J Sports Sci Med*. 2010;9(4):587-596.

14. Gordon R, Wong C, Crawford EJ. Ultrasonographic evaluation of low energy extracorporeal pulse activated therapy (EPAT) for chronic plantar fasciitis. *Foot Ankle Int*. Mar 2012;33(3):202-7. doi:10.3113/FAI.2012.0202

15. Landorf KB, Keenan AM, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis: A randomized trial. *Archives of Internal Medicine*. 2006;166(12):1305-10. doi:10.1001/archinte.166.12.1305

16. Thomas JL, Christensen JC, Kravitz SR, et al. The diagnosis and treatment of heel pain: A clinical practice guideline–revision 2010. doi: 10.1053/j.jfas.2010.01.001. *J Foot Ankle Surg*. 2010;49(3):S1-S19. doi:10.1053/j.jfas.2010.01.001

17. Buchbinder R. Plantar fasciitis. *N Eng J Med*. 2004;350:2159-66. doi:10.1056/NEJMcp032745

18. Young CC, Rutherford DS, Niedfeldt MW. Treatment of plantar fasciitis. Review. *Am Fam Physician*. 2001;63(3):467-74.

19. Wearing SC, Smeathers JE, Urry SR. A comparison of two analytical techniques for detecting differences in regional vertical impulses due to plantar fasciitis. *Foot Ankle Int*. Feb 2002;23(2):148-54. doi:10.1177/107110070202300212

20. Martin RL, Davenport TE, Reischl SF, et al. Heel pain-plantar fasciitis: revision 2014. *J Orthop Sports Phys Ther*. Nov 2014;44(11):A1-33. doi:10.2519/jospt.2014.0303

21. Landorf KB. Plantar heel pain and plantar fasciitis. *BMJ clinical evidence*. Nov 25 2015;2015

22. Whittaker GA, Munteanu SE, Menz HB, Tan JM, Rabusin CL, Landorf KB. Foot orthoses for plantar heel pain: a systematic review and meta-analysis. *Br J Sports Med*. Mar 2018;52(5):322-328. doi:10.1136/bjsports-2016-097355

23. Štajer T, Burger H, Vidmar G. Influence of casting method on effectiveness of foot orthoses using plantar pressure distribution: A preliminary study. *Prosthet Orthot Int*. 2011;35(4):411-417. doi:10.1177/0309364611424521

24. Owings TM, Woerner JL, Frampton JD, Cavanagh PR, Botek G. Custom therapeutic insoles based on both foot shape and plantar pressure measurement provide enhanced pressure relief. *Diabetes Care*. 2008;31(5):839-44. doi:10.2337/dc07-2288

25. Chen W-P, Ju C-W, Tang F-T. Effects of total contact insoles on the plantar stress redistribution: a finite element analysis. doi: . *Clin Biomech*. 2003;18(6):S17-S24. doi:10.1016/s0268-0033(03)00080-9

26. Goske S, Erdemir A, Petre M, Budhabhatti S, Cavanagh PR. Reduction of plantar heel pressures: Insole design using finite element analysis. *J Biomech*. 2006;39:2363 – 2370. doi:10.1016/j.jbiomech.2005.08.006

27. Nakhaee M, Mousavi ME, Mohseni-Bandpei MA, et al. Intra- and Inter-Rater Reliability of Ultrasound in Plantar Fascia Thickness Measurement. Research Article. *Iranian journal of radiology : a quarterly journal published by the Iranian Radiological Society*. 2018;15(3):e59022. doi:10.5812/iranjradiol.59022

28. Rathleff MS, Moelgaard C, Lykkegaard Olesen J. Intra- and interobserver reliability of quantitative ultrasound measurement of the plantar fascia. *J Clin Ultrasound*. / 2011;39(3):128-134. doi:10.1002/jcu.20787

29. Negahban H, Mazaheri M, Salavati M, et al. Reliability and validity of the foot and ankle outcome score: a validation study from Iran. *Clin Rheumatol*. 2010;29:479-486. doi:10.1007/s10067-009-1344-3

30. Cheng JW, Tsai WC, Yu TY, Huang KY. Reproducibility of sonographic measurement of thickness and echogenicity of the plantar fascia. *J Clin Ultrasound*. Jan 2012;40(1):14-9. doi:10.1002/jcu.20903

31. Putti AB, Arnold GP, Cochrane LA, Abboud RJ. Normal pressure values and repeatability of the Emed® ST4 system. *Gait Posture*. 4// 2008;27(3):501-505. doi:10.1016/j.gaitpost.2007.06.009

32. Gurney JK, Kersting UG, Rosenbaum D. Between-day reliability of repeated plantar pressure distribution measurements in a normal population. *Gait Posture*. May 2008;27(4):706-9. doi:10.1016/j.gaitpost.2007.07.002

33. Zammit GV, Menz HB, Munteanu SE. Reliability of the TekScan MatScan® system for the measurement of plantar forces and pressures during barefoot level walking in healthy adults. *J Foot Ankle Res*. 2010;3(11)doi:10.1186/1757-1146-3-11

34. Chew KTL, Leong D, Lin CY, Lim KK, Tan B. Comparison of Autologous Conditioned Plasma Injection, Extracorporeal Shockwave Therapy, and Conventional Treatment for Plantar Fasciitis: A Randomized Trial. *PM & R : the journal of injury, function, and rehabilitation*. Dec 2013;5(12):1035-43. doi:10.1016/j.pmrj.2013.08.590

35. Yan W, Sun S, Li X. [Therapeutic effect of extracorporeal shock wave combined with orthopaedic insole on plantar fasciitis]. *Zhong nan da xue xue bao Yi xue ban = Journal of Central South University Medical sciences*. Dec 2014;39(12):1326-30. doi:10.11817/j.issn.1672-7347.2014.12.017

36. Mahowald S, Legge BS, Grady JF. The correlation between plantar fascia thickness and symptoms of plantar fasciitis. *J Am Podiatr Med Assoc*. Sep-Oct 2011;101(5):385-9. doi:10.7547/1010385

37. Moustafa AMA, Hassanein E, Foti C. Objective assessment of corticosteroid effect in plantar fasciitis: additional utility of ultrasound. *Muscles Ligaments Tendons J*. 2016/02/13/ 2016;5(4):289-296. doi:10.11138/mltj/2015.5.4.289

38. Liang H-W, Wang T-G, Chen W-S, Hou S-M. Thinner plantar fascia predicts decreased pain after extracorporeal shock wave therapy. *Clin Orthop Relat Res*. 2007/07// 2007;460:219-225. doi:10.1097/BLO.0b013e31804ffd19

39. Bonanno DR, Landorf KB, Menz HB. Pressure-relieving properties of various shoe inserts in older people with plantar heel pain. *Gait Posture*. 2011;33:385-389. doi:10.1016/j.gaitpost.2010.12.009

40. Phillips A, McClinton S. Gait deviations associated with plantar heel pain: A systematic review. *Clin Biomech*. 2017;42:55-64. doi:10.1016/j.clinbiomech.2016.12.012

41. Sullivan J, Burns J, Adams R, Pappas E, Crosbie J. Plantar heel pain and foot loading during normal walking. *Gait Posture*. 2015/02/01/ 2015;41(2):688-693. doi:10.1016/j.gaitpost.2015.01.025

42. Brachman A, Sobota G, Marszałek W, Pawłowski M, Juras G, Bacik B. Plantar pressure distribution and spatiotemporal gait parameters after the radial shock wave therapy in patients with chronic plantar fasciitis. *J Biomech*. 2020/05/22/ 2020;105:109773. doi:10.1016/j.jbiomech.2020.109773

43. Nakhaee M, Tahmasbi MN, Karimlo M, Vahab Kashani R. Comparison of three type orthoses effects on plantar fasciitis. *j rehab*. 2008-2009;9(35-36):8-15.

44. Roos E, Engstrom M, Soderberg B. Foot orthoses for the treatment of plantar fasciitis. Comparative Study

Randomized Controlled Trial

Research Support, Non-U.S. Gov't. *foot Ankle Int*. Aug 2006;27(8):606-11. doi:10.1177/107110070602700807

45. Fong DT-P, Pang K-Y, Chung MM-L, Hung AS-L, Chan K-M. Evaluation of combined prescription of rocker sole shoes and custom-made foot orthoses for the treatment of plantar fasciitis. *Clin Biomech*. Sep 3 2012;doi:10.1016/j.clinbiomech.2012.08.003

46. Gross MT, Byers JM, Krafft JL, Lackey EJ, Melton KM. The impact of custom semirigid foot orthotics on pain and disability for individuals with plantar fasciitis. *J Orthop Sports Phys Ther*. Apr 2002;32(4):149-57. doi:10.2519/jospt.2002.32.4.149

47. Rome K, Gray J, Stewart F, Hannant SC, Callaghan D, Hubble J. Evaluating the clinical effectiveness and cost-effectiveness of foot orthoses in the treatment of plantar heel pain: A feasibility study. *J Am Podiatr Med Assoc*. 2004;94(3):229-238. doi:10.7547/0940229

48. Moyne-Bressand S, Dhieux C, Dousset E, Decherchi P. Effectiveness of Foot Biomechanical Orthoses to Relieve Patients Suffering from Plantar Fasciitis: Is the Reduction of Pain Related to Change in Neural Strategy? *BioMed research international*. 2018;2018:3594150. doi:10.1155/2018/3594150

49. Oliveira HA, Jones A, Moreira E, Jennings F, Natour J. Effectiveness of total contact insoles in patients with plantar fasciitis. *J Rheumatol*. May 2015;42(5):870-8. doi:10.3899/jrheum.140429

50. Schuitema D, Greve C, Postema K, Dekker R, Hijmans JM. Effectiveness of Mechanical Treatment for Plantar Fasciitis: A Systematic Review. *J Sport Rehabil*. Jul 1 2020;29(5):657-674. doi:10.1123/jsr.2019-0036

51. O'Malley MJ, Vosseller JT, Gu Y. Successful use of platelet-rich plasma for chronic plantar fasciitis. *HSS journal : the musculoskeletal journal of Hospital for Special Surgery*. Jul 2013;9(2):129-33. doi:10.1007/s11420-012-9321-9

LEGENDS

Figures

Fig. 1. Normal plantar fascia. A longitudinal sonogram shows the thickness of plantar fascia at three points.

Fig. 2. Flow chart demonstrating study design

Fig. 3. Representative A) CAD/CAM foot orthosis, B) prefabricated night splint

Fig. 4. A) Mean of plantar fascia thickness in reproducibility evaluation of ultrasonography, B) Repeatability of within and between-day measurements of the plantar fascia thickness. (1st-2nd: within-day reliability, 1st-3rd and 2nd-3rd: between-day reliability) (**: $P<0.01$)

Fig. 5. Within and between-day ICCs for maximum force and peak pressure at both sides. (PP: peak pressure, MF: maximum force, L: left, R: right, M1: medial hindfoot, M2: lateral hindfoot, M3: medial midfoot, M4: lateral midfoot, M5: first metatarsal, M6: second metatarsal, M7: third to fifth metatarsal, M8: hallux, M9: second toe, M10: third to fifth toes, 1st-2nd: within-day reliability, 1st-3rd and 2nd-3rd: between-day reliability)

Fig. 6. Changes of plantar fascia thickness in patients with plantar fasciitis (*: $P<0.05$)

Fig. 7. Changes of subscales of FAOS in patients with plantar fasciitis

(*: $P<0.05$, FAOS: foot and ankle outcome score, ADL: activity daily living, QOL: quality of life)

Fig. 8. Changes of a) peak pressure b) mean pressure, and c) maximum force in patients with plantar fasciitis. (M1: medial hindfoot, M2: lateral hindfoot, M3: medial midfoot, M4: lateral midfoot, M5: first metatarsal, M6: second metatarsal, M7: third to fifth metatarsal, M8: hallux, M9: second toe, M10: third to fifth toes)

Fig. 9. Correlation between different parameters measured. (FAOS: foot and ankle outcome score, ADL: activity daily living, QOL: quality of life, PFT: plantar fascia thickness)

Tables

Figure 1

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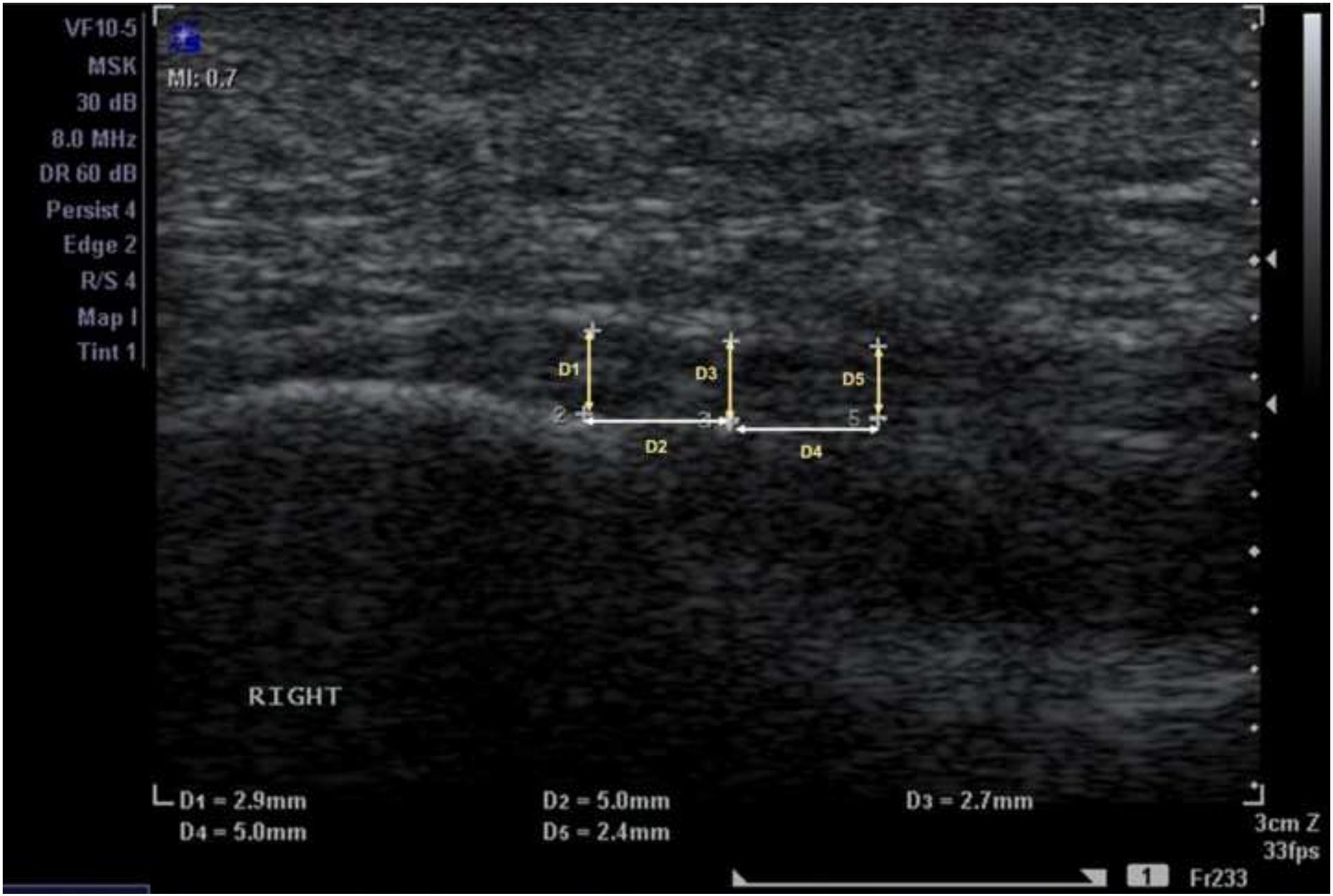

Figure 2

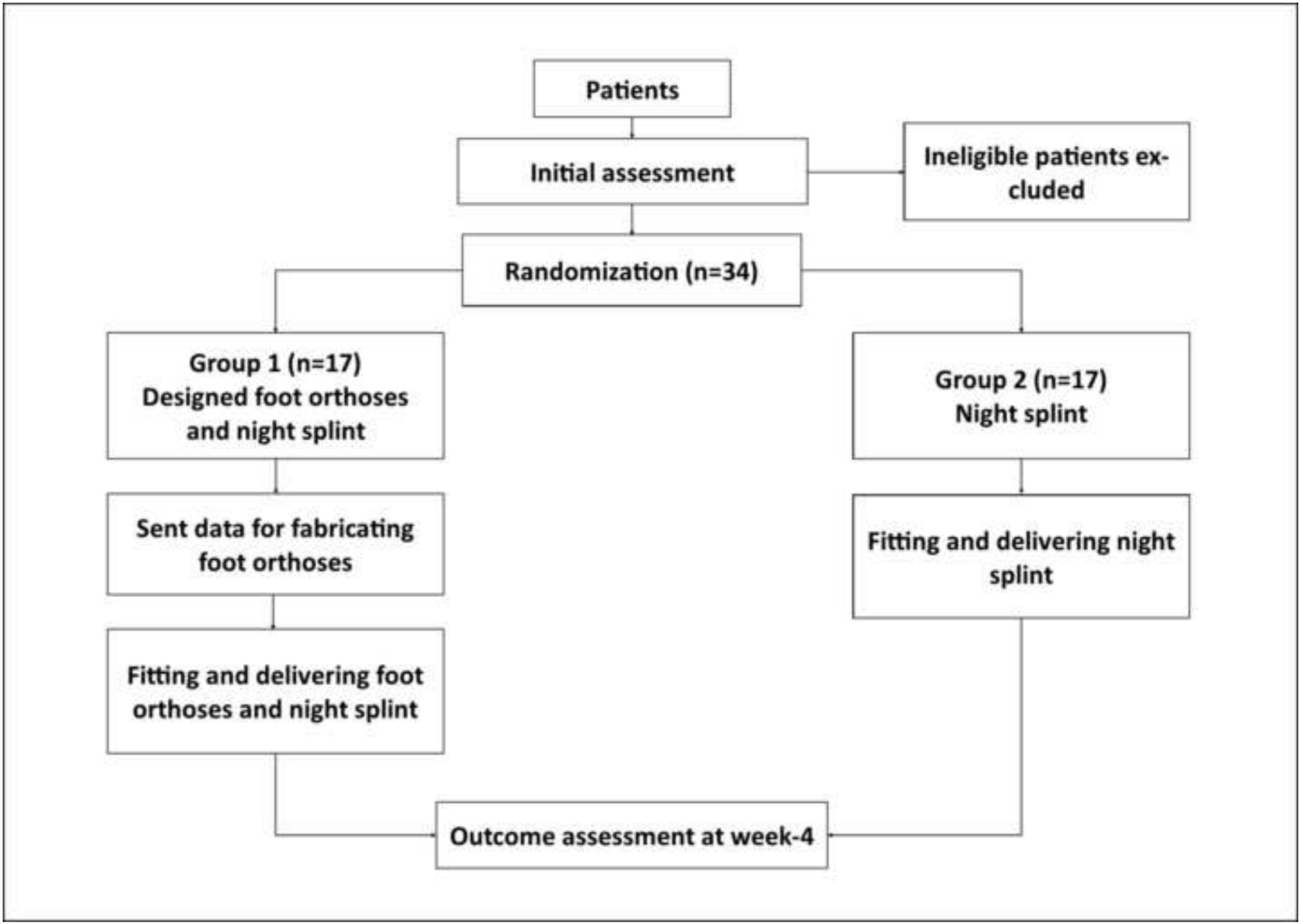

Figure 3A

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Figure 3B

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Figure 4A

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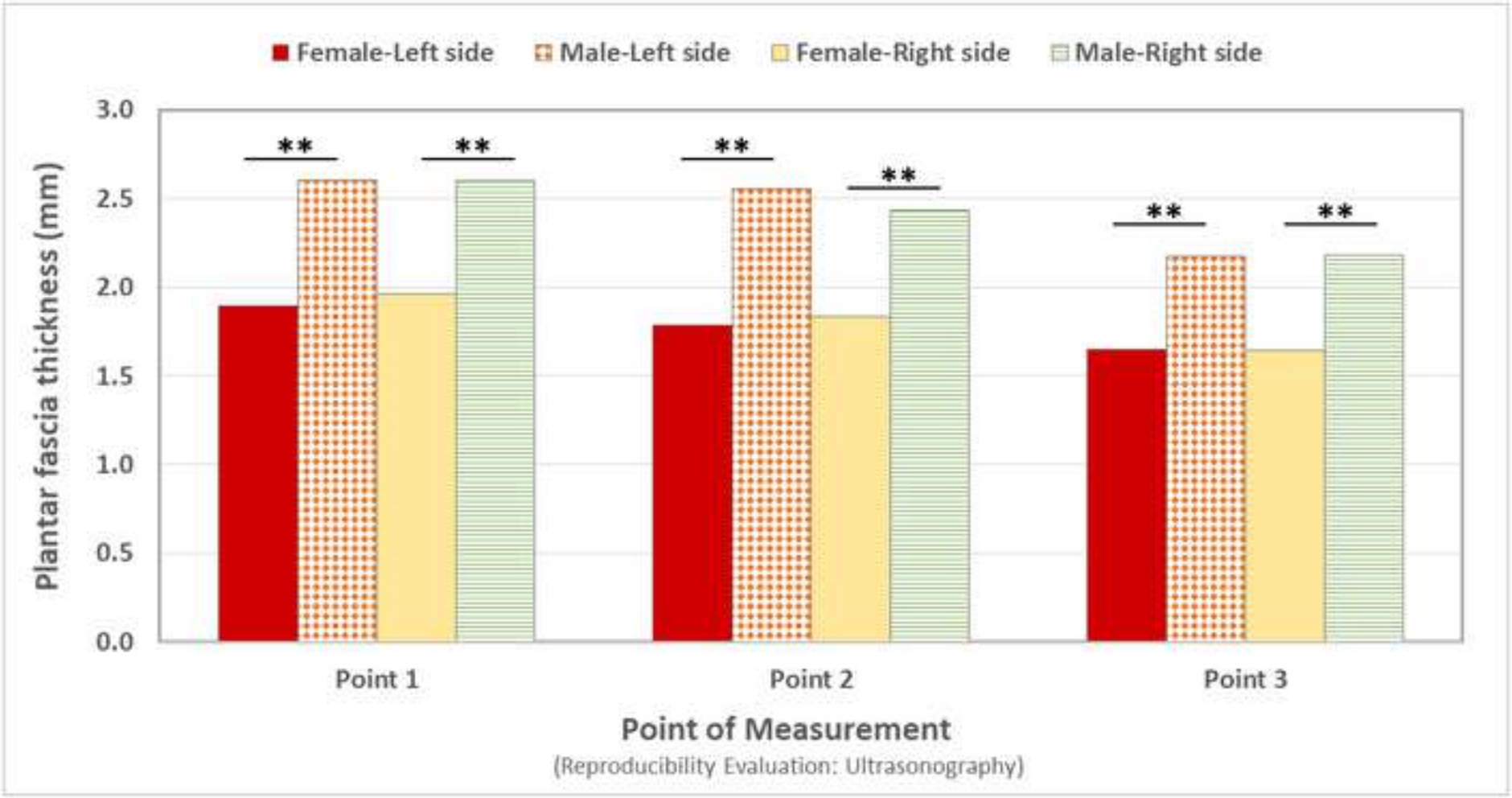

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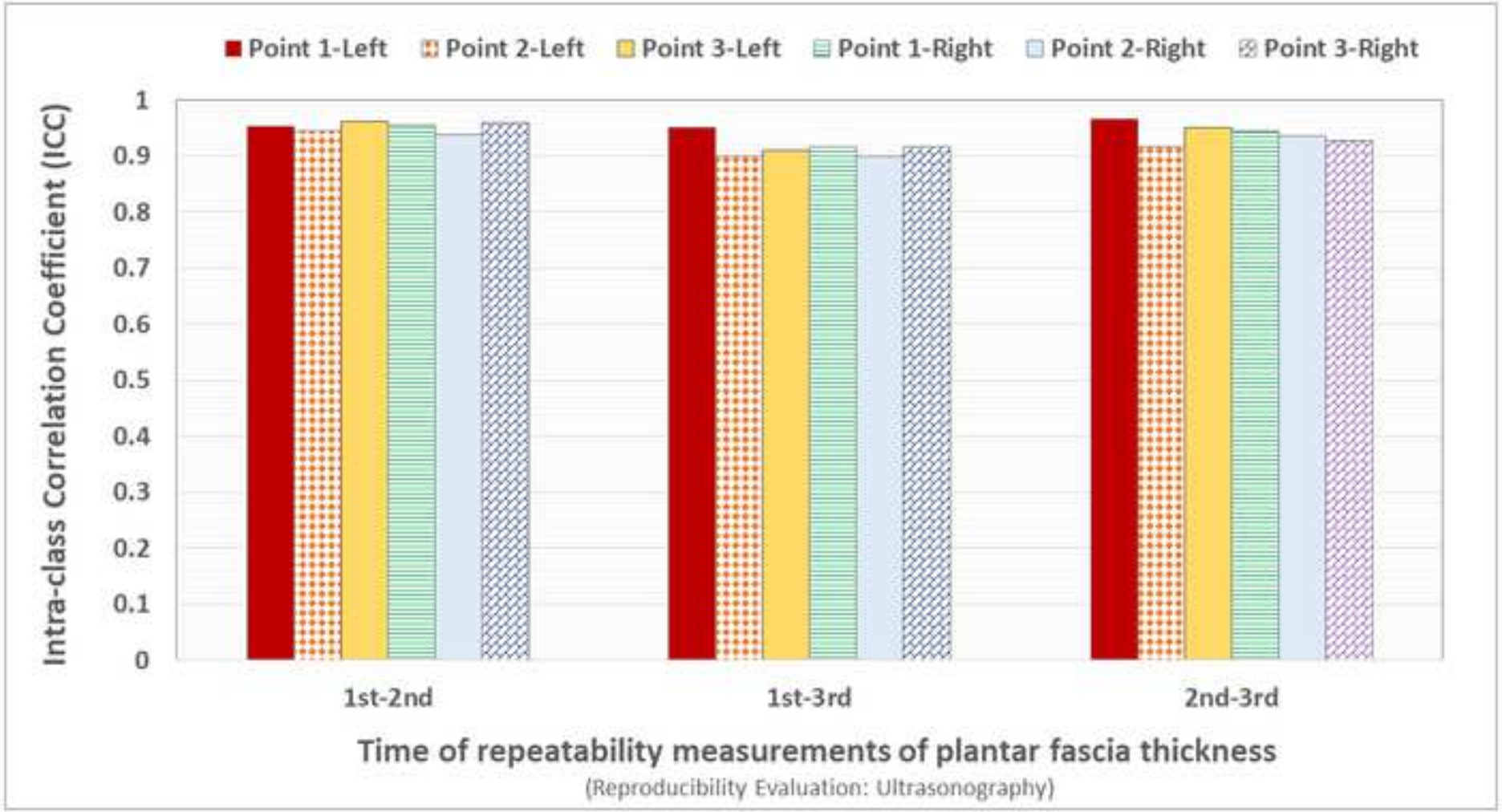

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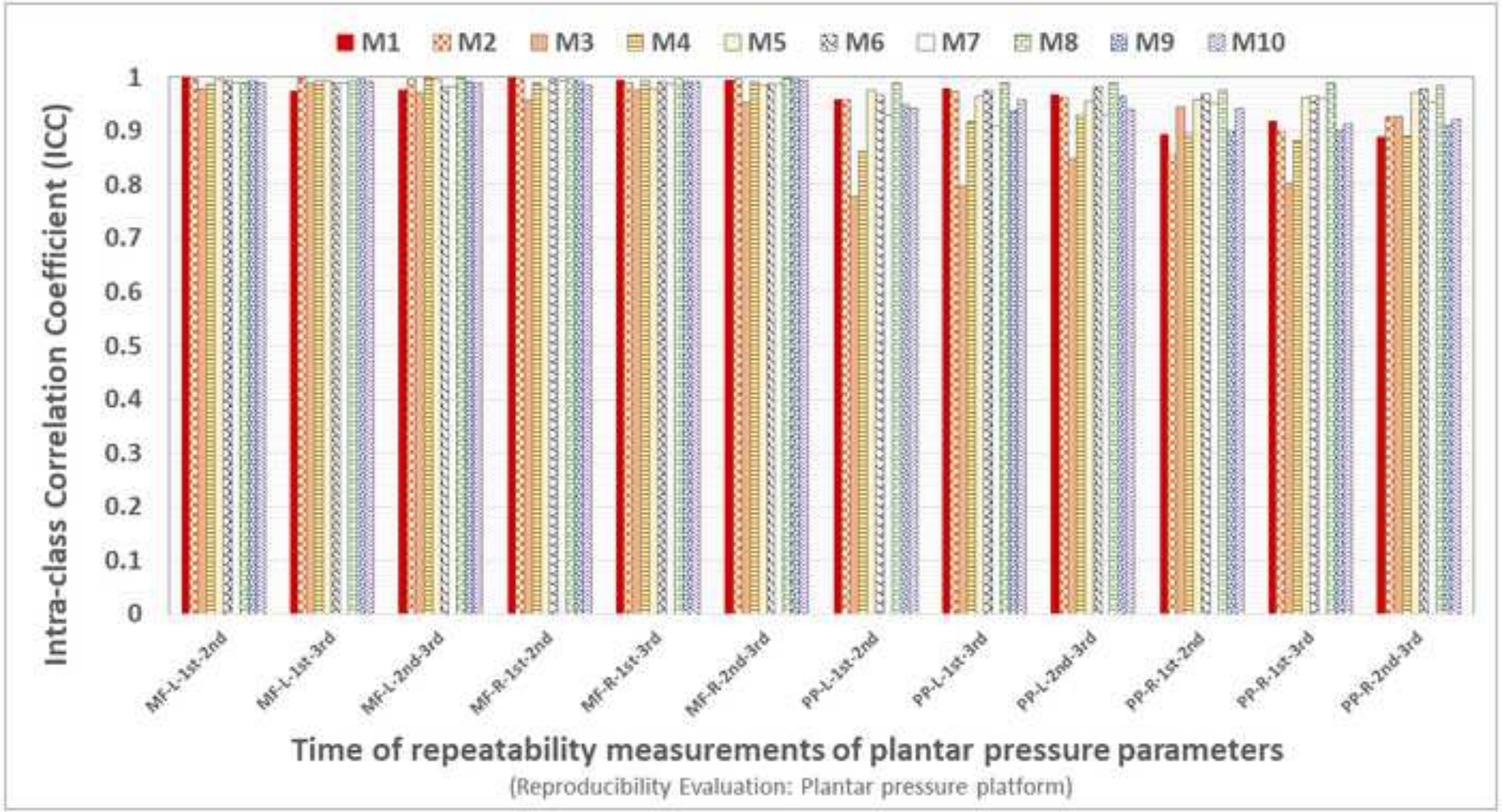

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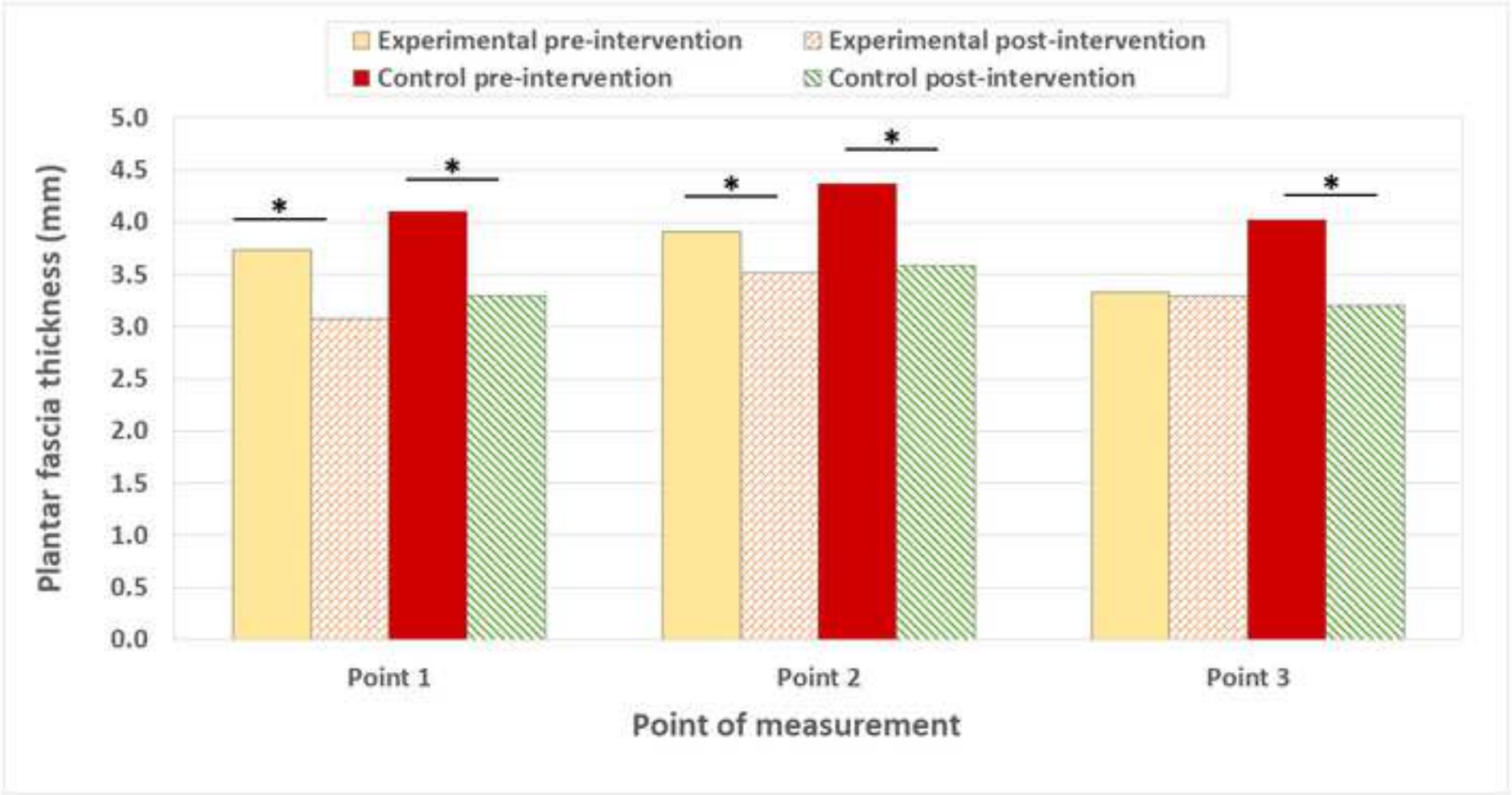

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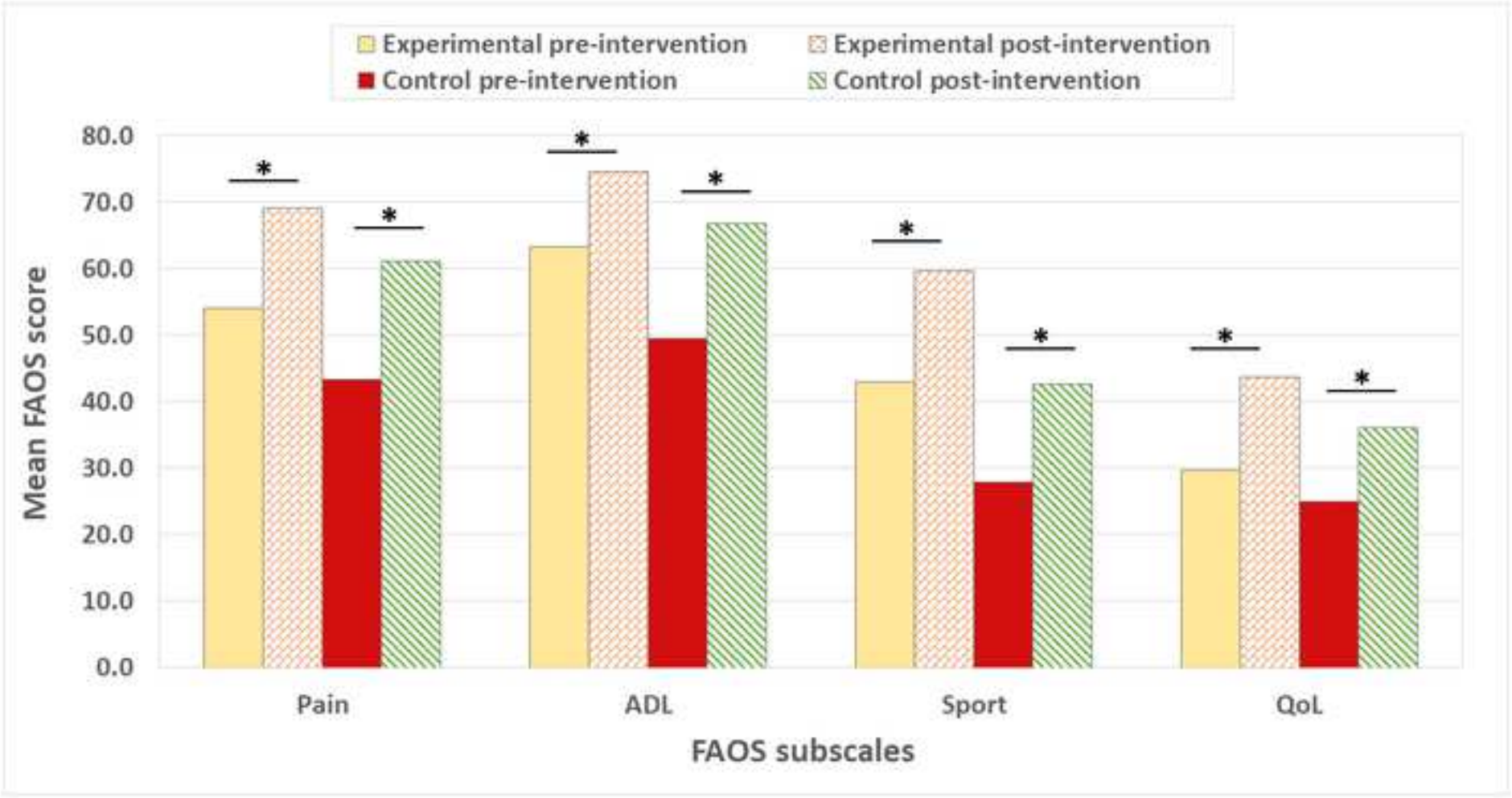

Figure 8A

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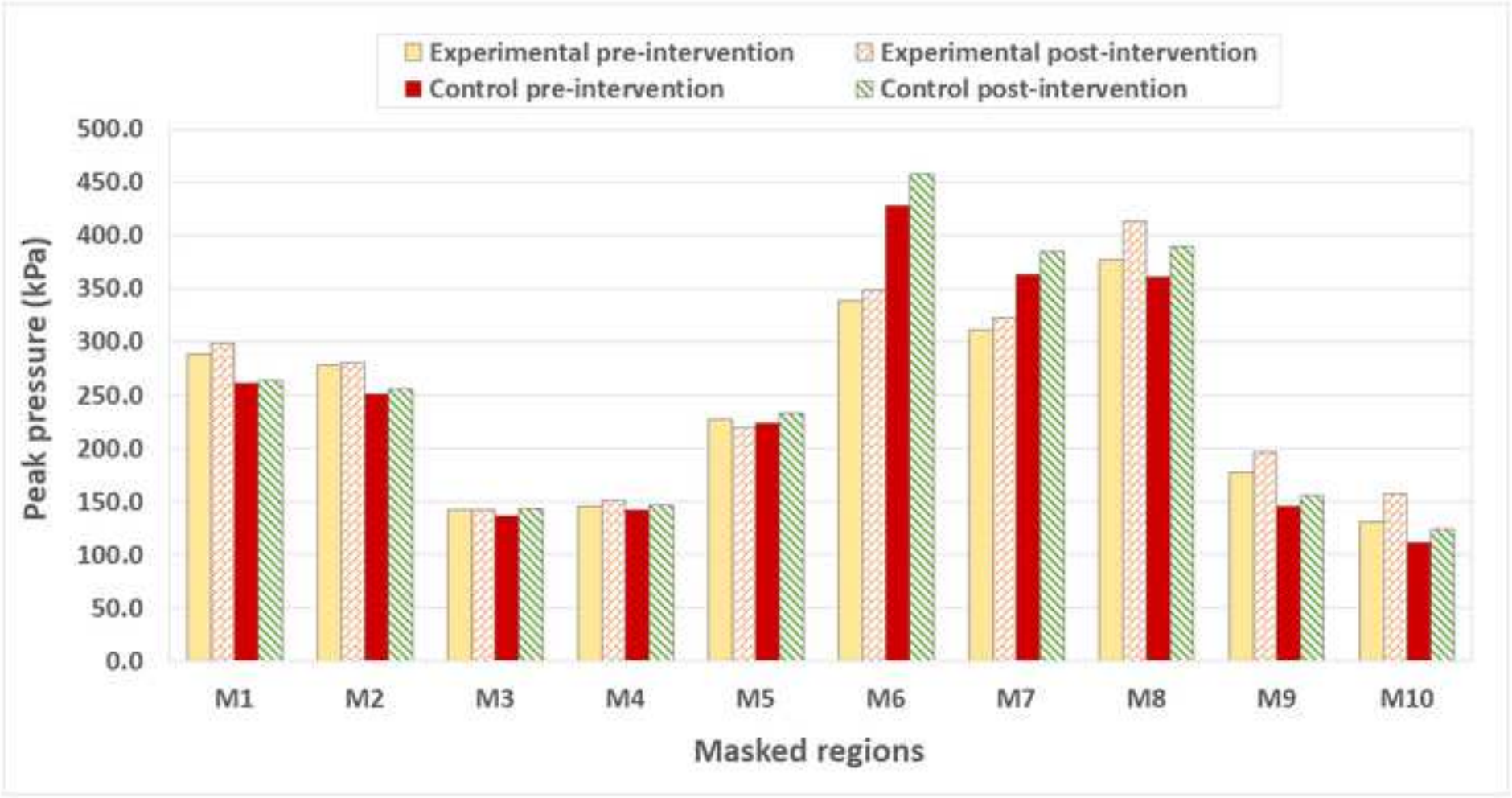

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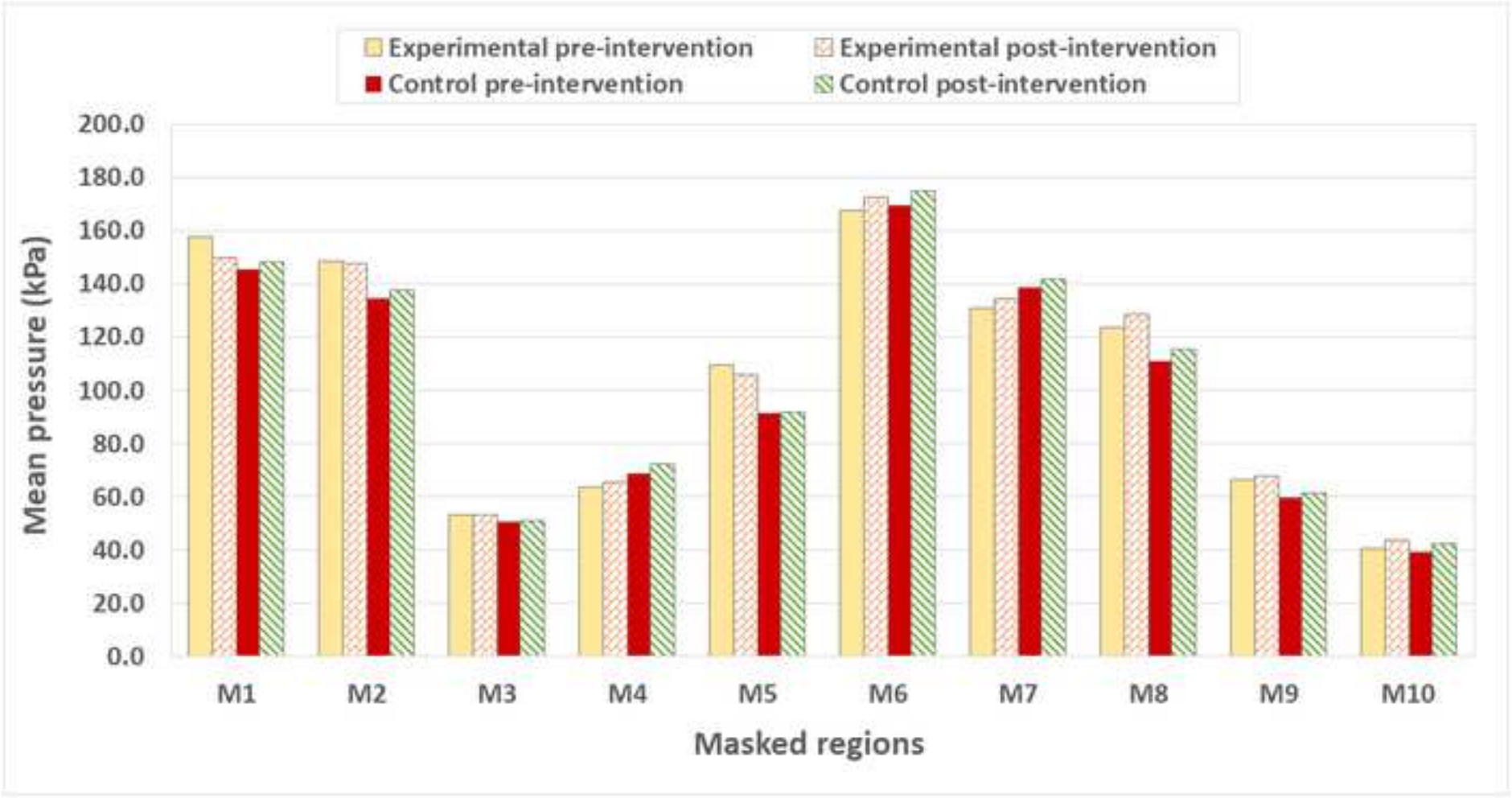

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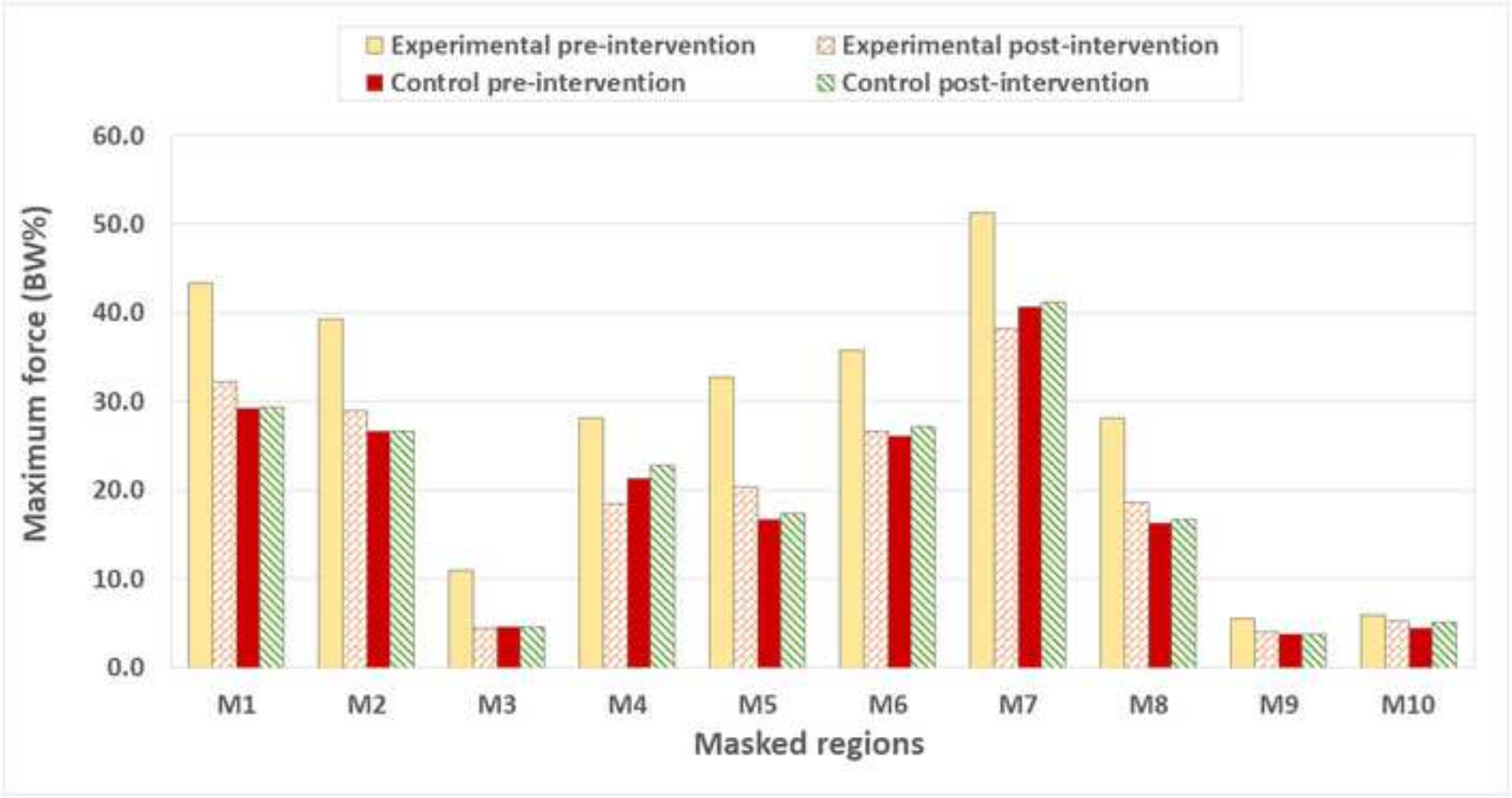

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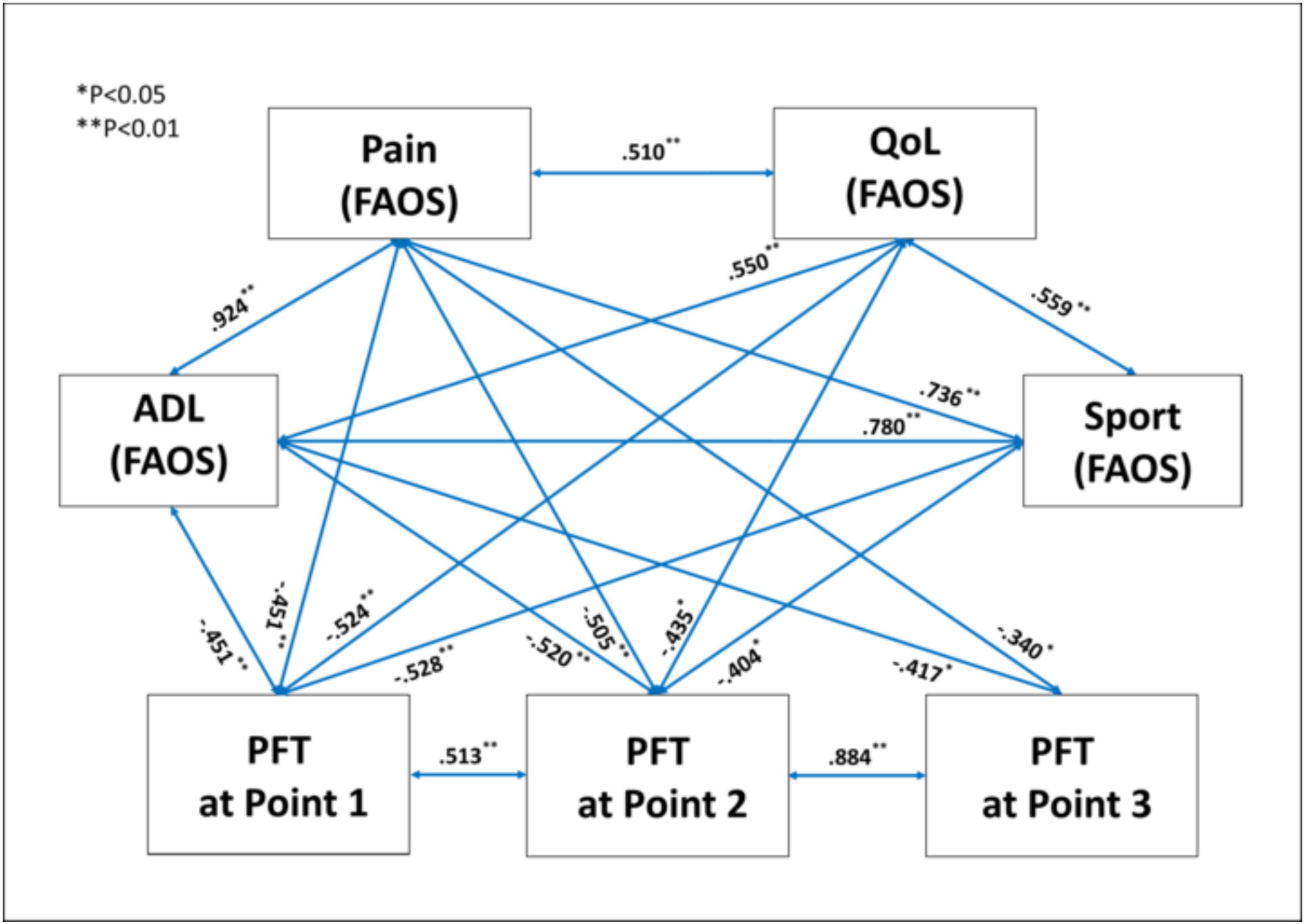

Table 1. Demographic Data of the Reproducibility Evaluation of Ultrasonography Subjects.[a]

	Female (n = 10)	Male (n = 10)
Age, y	28.5 ± 6.17 (18-35)	27.2 ± 4.80 (21-35)
Weight, Kg	54.80 ± 3.99 (50-62)	75.48 ± 7.40 (64 -85.8)
Height, m	1.63 ± 0.05 (1.52-1.70)	1.78 ± 0.03 (1.73-1.86)
BMI, Kg/m^2	20.70 ± 1.91 (17.94-22.30)	23.77 ± 1.97 (20.99-26.23)

BMI: body mass index

[a]Values are presented as mean ± SD (range) unless otherwise noted.

Table 2. Regression Analysis Using Linear Mixed Model ANOVA

	variable	level	Mean	SE	*P* value
PFT	Time	First	2.098	.060	.830
		Second	2.118	.060	
		Third	2.106	.060	
	Side	Left	2.108	.059	.983
		Right	2.107	.059	
	Sex	Female	1.792	.081	.000**
		Male	2.423	.081	

PFT: plantar fascia thickness, SE: standard error, (**: P < .01)

Table 3. Demographic Data of the Reproducibility Evaluation of Plantar Pressure Platform.[a]

	Female (n=10)	Male (n=10)
Age, y	28.85 ± 4.08 (23-34)	27.4 ± 4.95 (22-35)
Weight, Kg	52.22 ± 3.74 (45-58)	75.93 ± 10.73 (62.5 -95)
Height, m	1.61 ± 0.06 (1.52-1.68)	1.78 ± 0.04 (1.73-1.86)
BMI, Kg/m^2	20.22 ± 1.78 (89-22.94.17)	23.94 ± 2.29 (20.88-28.37)

BMI: body mass index, SD: standard deviation

[a]Values are presented as mean ± SD (range) unless otherwise noted.

Table 4. Demographic Data of the randomized controlled trial study subjects by intervention groups[a]

	Experimental	Control	*P* value
Sex (Female/Male)	14/3	15/2	
Age, y	43.41 ± 9.37	47.00 ± 7.41	.309
Weight, Kg	77.06 ± 14.79	76.00 ± 11.59	.300
Height, m	1.64 ± 0.09	1.65 ± 0.07	.259
BMI, Kg/m^2	28.78 ± 5.42	27.83 ± 3.35	.078
Duration of symptoms, d	258.82 ± 222.62	195.88 ± 175.93	.166
Standing time in a day, hr	5.85 ± 2.51	6.15 ± 2.50	.990

BMI: body mass index

[a]Values are presented as mean ± SD (range) unless otherwise noted.

Table 5: Comparison of the evaluated variables between groups after one month intervention

Table 5: Comparison of the evaluated variables between groups after one month intervention

Variable		Experimental	Control	P-value
PFT (mm)	Point 1	-0.661 ± 0.725	-0.806 ± 1.053	.643
	Point 2	-0.398 ± 0.505	-0.782 ± 0.865	.126
	Point 3	-0.041 ± 0.682	-0.816 ± 0.788	.004**
FAOS	Pain	15.033 ± 17.181	17.811 ± 16.697	.636
	QoL	13.971 ± 14.240	11.029 ± 19.457	.618
	ADL	11.159 ± 21.005	17.128 ± 17.007	.369
	Sport	16.765 ± 27.268	14.706 ± 24.397	.818
PP (kPa)	M1	10.294 ± 67.696	2.353 ± 37.505	.675
	M2	1.471 ± 40.841	4.118 ± 35.277	.841
	M3	-0.294 ± 21.467	7.353 ± 21.442	.307

	M4	6.177 ± 22.117	4.118 ± 17.251	.764
	M5	-8.530 ± 44.362	8.530 ± 59.022	.348
	M6	10.882 ± 37.593	29.412 ± 66.752	.328
	M7	11.177 ± 40.021	21.765 ± 58.5219	.542
	M8	36.177 ± 120.941	28.529 ± 186.763	.888
	M9	18.824 ± 41.327	9.412 ± 44.084	.525
	M10	-0.738 ± 5.645	0.659 ± 2.160	.348
	M1	-11.169 ± 48.542	0.048 ± 3.282	.349
	M2	-10.310 ± 41.824	0.033 ± 3.087	.317
MF (%BW)	M3	-6.415 ± 26.326	-0.088 ± 3.392	.333
	M4	-9.716 ± 42.166	1.420 ± 4.071	.287
	M5	-12.381 ± 47.908	0.683 ± 4.897	.272

	M6	-9.053 ± 39.438	1.070 ± 5.099	.302
	M7	-13.098 ± 60.933	0.628 ± 7.287	.363
	M8	-9.572 ± 43.790	0.407 ± 4.731	.357
	M9	-1.452 ± 6.643	-0.014 ± 1.403	.389
	M10	-0.738 ±5.645	0.659 ± 2.160	.348
	M1	-7.871 ± 30.242	2.612 ± 17.045	.222
	M2	-0.812 ± 20.256	3.265 ± 19.596	.555
	M3	0.318 ± 7.668	0.559 ± 9.566	.936
MP (kPa)	M4	2.129 ± 7.284	3.641 ± 9.478	.606
	M5	-3.394 ± 21.608	0.418 ± 15.462	.558
	M6	4.741 ± 14.727	5.518 ± 21.754	.904
	M7	3.847 ± 22.983	3.071 ± 21.721	.920

M8	5.053 ± 23.731	4.653 ± 30.887	.966
M9	1.112 ± 10.082	1.865 ± 13.440	.855
M10	3.041 ± 7.582	2.959 ± 12.201	.981

PP: peak pressure, MF: maximum force, L: left, R: right, M1: medial hindfoot, M2: lateral hindfoot, M3: medial midfoot, M4: lateral midfoot, M5: first metatarsal, M6: second metatarsal, M7: third to fifth metatarsal, M8: hallux, M9: second toe, M10: third to fifth toes