

1 **Abstract**

2 *Background*

3 Arthroplasty of the first metatarsophalangeal joint is an alternative treatment option
4 for end-stage hallux rigidus to the current gold standard of arthrodesis. The aim of this study
5 was to investigate the mid-term functional outcome of an anatomically shaped prosthesis for
6 the first metatarsophalangeal joint using pedobarography

7 *Methods*

8 Ten patients (12 affected feet; age at surgery: 62.1 (SD: 7.2) years) were investigated
9 preoperatively and 52 (SD: 3) months postoperatively using pedobarography (EMED, novel
10 GmbH, Munich, Germany). Two patients were excluded at follow-up because their prosthesis
11 was converted to an arthrodesis. Peak force and plantar pressure under the five metatarsal
12 heads and the hallux were analyzed and correlated with the clinical outcome (pain, American
13 Orthopaedic Foot and Ankle Society forefoot score and radiographic maximum first
14 metatarsophalangeal dorsiflexion). Differences between pre- and postoperative data were
15 analyzed using paired t tests ($\alpha = .05$).

16 *Findings*

17 Postoperatively, forefoot peak forces under the fourth (+40.9%; $P = .018$) and fifth
18 metatarsal (+54.9%; $P = .037$) and plantar pressures under the fifth metatarsal (+38.7%;
19 $P = .027$) increased significantly, while peak plantar pressures and forces under the hindfoot,
20 medial forefoot and hallux did not change. While maximum passive dorsiflexion was not
21 significantly greater at the 4-year follow-up compared to preoperatively, overall greater
22 passive dorsiflexion was associated with higher first metatarsal peak pressure.

23 *Interpretation*

24 Despite of patients reporting less pain, our functional results indicate an altered and
25 potentially non-physiological postoperative gait pattern with a lateralization of the load during
26 walking, especially in patients with limited passive dorsiflexion.

1 **Highlights:**

- 2 • Evaluation of the functional outcome of a first metatarsophalangeal joint prosthesis
- 3 • Peak plantar pressure increased in the fifth metatarsal region
- 4 • Peak force increased in the fourth and fifth metatarsal region
- 5 • Higher passive dorsiflexion was associated with higher first metatarsal pressure

1 **1. Introduction**

2 Hallux rigidus is associated with decreased mobility of the first metatarsophalangeal
3 (MTP-I) joint, especially in dorsiflexion. Dorsiflexion in the metatarsophalangeal joints is
4 important for propulsion in walking because it provides stability during toe-off [1] and
5 facilitates the windlass effect that tightens the plantar aponeurosis [2]. Moreover, the highest
6 pressures during the physiological push-off phase of walking occur in the hallux, the first and
7 the second metatarsal regions [3]. In patients with hallux rigidus, this normal function of the
8 MTP-I joint during walking is impaired and their gait patterns are altered. Besides a smaller
9 MTP-I plantarflexion/dorsiflexion range of motion (RoM) [4, 5], a smaller forefoot
10 pronation/supination RoM was observed in patients during walking [5]. Patients with
11 radiological MTP-I osteoarthritis without pain had higher peak force and peak plantar
12 pressure in the hallux area than healthy people [6]. However, the study investigated only pain
13 free subjects, and it remains unclear whether similar results would be observed in patients
14 with symptomatic MTP-I osteoarthritis.

15 Arthrodesis is the standard surgical treatment for end-stage osteoarthritis of the MTP-I
16 joint [7-9]. While clinical studies showed pain relief and improved function [10, 11],
17 pedobarographic studies reported no changes in the peak plantar pressure in the forefoot [10,
18 11] and increased peak pressure and peak force in the hallux segment after arthrodesis [11].
19 Moreover, gait analysis studies reported, for instance, that ankle power generation from the
20 plantarflexors during push-off remained altered with lower postoperative ankle power on the
21 operated than on the healthy side [11], and increased ankle power compared to preoperative
22 values [12]. Among other factors, these remaining differences in postoperative gait patterns
23 contributed to the development of MTP-I prostheses. Recent clinical results showed improved
24 pain and functional scores after surgery for some prosthesis designs [10, 13, 14]. However,
25 compared to arthrodesis, more complications and only limited RoM gain have been reported

1 [10]. While some clinical data on the outcome of MTP-I prosthesis are available, little is
2 known on the function of MTP-I replacements during walking. Gibson et al. compared peak
3 plantar pressures in the first and fifth metatarsal between MTP-I arthrodesis and arthroplasty
4 in a randomized controlled trial and found indications for an increased lateral load 2 years
5 after MTP-I arthroplasty [10]. However, another study with a different prosthesis design
6 reported a postoperative decrease of the lateral peak force and no changes on the medial side
7 [14].

8 To date, data on the functional outcomes such as the dynamic plantar pressure
9 distribution is limited and dependent on the MTP-I prosthesis. The purpose of this prospective
10 study was to test the hypotheses that an anatomically shaped MTP-I prosthesis improves both
11 the clinical and functional mid-term outcome. Specifically, we hypothesized that the peak
12 plantar pressure and peak force in the forefoot increase, especially in the medial forefoot and
13 hallux. The second aim of this study was to test the hypothesis that patients with better
14 clinical results have higher peak pressure and force in the forefoot.

15

16 **2. Methods**

17 ***2.1. Patients and procedures***

18 Ten patients (7 males, 3 females; 12 affected feet; age at surgery: 62.1 (SD: 7.2 years))
19 were included in this prospective pedobarographic study. All patients suffered from end-stage
20 hallux rigidus and had undergone MTP-I arthroplasty. These patients were all part of a larger
21 cohort where the clinical outcome of MTP-I arthroplasty with the same anatomically designed
22 3-component MTP-I prosthesis (Metis, Newdeal SA, Integra Life Science ILS, New Jersey,
23 USA) was studied [15] and some of the patients had undergone pedobarography
24 preoperatively. Postoperatively, the patients wore a stiff hallux shoe for 6 weeks and were

1 allowed full weight bearing if tolerated. All patients received physiotherapy during the first 6
2 to 12 weeks after surgery, where active and passive motion and lymphatic drainage were
3 performed to support soft tissue healing and to regain MTP-I mobility [15]. At the
4 pedobarographic follow up measurement (52 (SD: 3) months after surgery), two patients were
5 excluded because their MTP-I arthroplasty had been converted to an MTP-I arthrodesis.
6 Therefore, pre- and postoperative clinical and pedobarographic data were available for eight
7 patients (6 males, 2 females; 10 affected feet; age at follow up: 65.7 (SD: 7.1) years). The
8 study was approved by the local ethics committee and conducted in accordance with the
9 Declaration of Helsinki.

10 Plantar pressure distribution parameters were assessed pre- and postoperatively using
11 dynamic pedobarography (EMED, Novel GmbH, Munich, Germany, 4 sensors/cm²) during
12 walking at self-selected speed. For each patient five dynamic trials of the left and right foot
13 were recorded facilitating a sufficient reliability [16].

14 The clinical assessment included pre- and postoperative radiological measurements of
15 passive MTP-I RoM using fluoroscopy. For both maximal plantarflexion and dorsiflexion, the
16 angle between the long axis of the first metatarsal and the proximal phalanx was measured
17 (Figure 1). Furthermore, the pain level was assessed using a visual analogue scale (VAS; 0 –
18 no pain to 10 – worst pain) and the clinical functional outcome using the American
19 Orthopaedic Foot and Ankle Society (AOFAS) forefoot score [17].

20 **2.2. Data analysis**

21 The EMED software (novel GmbH, Munich, Germany) divides the foot into ten
22 regions according to the manufacturer's software – hindfoot, midfoot, first to fifth metatarsal,
23 hallux, second toe, lesser toes – and provides peak pressure, peak force, contact time and
24 contact area for each of these segments. To assess the load distribution between the medial

1 and lateral aspect of the foot, we defined a mediolateral forefoot index for both peak pressure
2 and peak force:

$$\text{mediolateral forefoot index} = \frac{\max(\text{first metatarsal}, \text{second metatarsal}, \text{hallux})}{\max(\text{third metatarsal}, \text{fourth metatarsal}, \text{fifth metatarsal})}$$

3 A mediolateral forefoot index greater than 1, indicates that the highest forefoot pressure or
4 force occurs on the medial side and an index smaller than 1, indicates that the highest forefoot
5 pressure or force occurs on the lateral side.

6 **2.3. Statistics**

7 Only the affected feet were included in the analysis. Pre- and postoperative group
8 means and standard deviations of all pedobarographic parameters were calculated from the
9 averages of five steps of the respective measurement. Differences between the two
10 measurements were analyzed with paired t tests. Effect sizes for the differences were
11 calculated using Cohen's $d = (\text{mean, post} - \text{mean, pre}) / \text{pooled standard deviation}$ [18]. To
12 assess the relationship between clinical and pedobarographic results, the Pearson product
13 moment correlation coefficient was calculated. All statistical analyses were performed using
14 MATLAB (MathWorks, Natick, MA, USA) and the significance level was set a priori to
15 $\alpha = .05$. A post-hoc power and sensitivity analysis for the correlation coefficients showed
16 that for 80% power the absolute values of the correlation coefficient needed to be greater than
17 0.53 [19]. This value was subsequently used as a threshold for relevant correlations.

18

1 **3. Results**

2 **3.1. Clinical results**

3 Compared to the preoperative measurement patients had significantly less pain and
4 higher AOFAS forefoot scores at follow-up. Postoperatively, the MTP-I passive RoM was on
5 average smaller than preoperatively but the difference was not statistically significant.
6 Specifically, patients had significantly less MTP-I plantarflexion after surgery, while the
7 amount of MTP-I dorsiflexion tended to be higher (Table 1).

8 **3.2. Pedobarography**

9 The peak plantar pressure at follow-up was on average higher in the hindfoot, all five
10 metatarsal and in the hallux regions. However, the increase was only significant in the fifth
11 metatarsal region (+38.7%; $P = .027$; $d = 0.88$; Figure 2). The peak force increased at follow-
12 up in the hindfoot, all metatarsal and the hallux regions. However, this increase was only
13 significant in the fourth (+40.9%; $P = .018$; $d = 0.60$) and fifth metatarsal region (+54.9%; $P =$
14 $.037$; $d = 0.78$; Figure 2). The mediolateral forefoot index for peak plantar pressure remained
15 unchanged and the mediolateral forefoot index for peak force decreased significantly from 1.1
16 (SD: 0.2) to 0.8 (SD: 0.3) ($P = 0.014$; $d = -0.85$; Figure 2).

17 **3.3. Correlation between clinical results and pedobarography**

18 Pain level did not correlate with peak forces or peak plantar pressures. AOFAS score
19 positively correlated with peak plantar pressures in the hindfoot, third and fourth metatarsals
20 but not with peak forces. Maximum passive MTP-I dorsiflexion positively correlated with
21 peak plantar pressure in the first metatarsal, and mediolateral forefoot index for peak pressure
22 (Figure 3).

1

2 **4. Discussion**

3 The aim of this prospective study was to investigate whether an anatomically shaped
4 MTP-I prosthesis improves the clinical and functional outcome and whether a better clinical
5 outcome (higher AOFAS score, lower pain score) is associated with higher peak plantar
6 pressures and forces in the forefoot. Although patients had less pain and a higher clinical
7 functional AOFAS score 4 years after MTP-I arthroplasty, their MTP-I RoM did not improve.
8 Furthermore, peak plantar pressure and force increased significantly under the lateral but not
9 in the medial forefoot. While higher AOFAS scores positively correlated with peak plantar
10 pressures under the hindfoot, the third and fourth metatarsal and the amount of dorsiflexion
11 positively correlated with peak plantar pressure under the first metatarsal, there were no
12 significant correlations between pain and peak pressure and force. Hence, these results only
13 partially support our hypotheses.

14 The clinical results are in agreement with previous studies that reported reduced pain
15 levels [10, 13, 14, 20] and functional improvements using scores such as the AOFAS score
16 [13, 20]. However, results in the literature concerning MTP-I RoM vary greatly. While
17 Gibson et al. [10] also reported no increase in RoM 2 years after MTP-I arthroplasty, more
18 recent studies with different types of MTP-I prostheses and average follow-up times of 18 to
19 30 months reported significant increases [21, 22]. Nevertheless, retaining and even improving
20 MTP-I RoM is one of the main theoretical advantages of MTP-I arthroplasty compared to
21 arthrodesis, which was not the case in the patients included in this study. The average
22 postoperative plantarflexion angle of -15° indicates a dorsiflexion contracture with no
23 plantarflexion relative to the first metatarsal. In standing radiographs, an anatomical
24 declination angle of on average 23° was measured for the first metatarsal [15], hence patients
25 with dorsiflexion contracture should still be able to touch the floor with their hallux during

1 standing. Moreover, measurements of hallux kinematics during walking indicate no
2 plantarflexion between hallux and forefoot segments [5, 23]. Therefore the measured
3 dorsiflexion contracture might not be limiting during walking.

4 This study hypothesized that the load bearing function of the MTP-I joint would
5 improve postoperatively and that this would lead to increased peak pressure and force
6 especially in the medial forefoot. However, the results did not confirm this hypothesis.
7 Although average peak plantar pressure and force increased in all forefoot regions, this
8 increase was only significant for lateral forefoot peak plantar pressure (fifth metatarsal) and
9 force (fourth and fifth metatarsal). Furthermore, the postoperative mediolateral forefoot index
10 of the peak force significantly decreased to values below 1 indicating that the highest forces
11 occurred postoperatively in the lateral instead of the medial forefoot which is opposite of what
12 would be expected in a healthy foot [3]. Therefore, the results suggest that despite having less
13 pain and a better AOFAS score than preoperatively, patients postoperatively did not increase
14 medial load bearing but rather increased the load on the lateral aspect of the forefoot. These
15 results are in line with a previous study from a clinical trial with a 2-year follow-up after
16 MTP-I arthroplasty [10]. In contrast, a recent study found decreased peak forces in the lateral
17 forefoot with a mean follow-up of 3 years (range 1.0 to 7.2 years) [14]. Hence, it is possible
18 that different prosthesis designs have different effects on the postoperative plantar pressure
19 distribution. As known, both MTP-I flexion and extension are greater in passive than in active
20 measurements. For instance, average maximum MTP-I dorsiflexion during gait is around 42°
21 and passive dorsiflexion around 59° in healthy persons [24]. In this study, an average passive
22 dorsiflexion of 24° and 44° was reported pre- and postoperatively, respectively, suggesting
23 reduced active RoM in these patients compared to healthy subjects even with the
24 postoperative improvement.

1 A positive correlation was reported between MTP-I dorsiflexion and peak pressure
2 and force in the first metatarsal. This is in agreement with a study on MTP-I arthrodesis where
3 patients with higher dorsiflexion angles (position of the fused joint) also had higher plantar
4 pressures in the first metatarsal [26]. While patients with lower MTP-I dorsiflexion angles
5 after MTP-I arthrodesis had higher plantar pressures in the hallux [26], this study did not
6 observe a similar relationship in patients after MTP-I prosthesis. Moreover, peak pressure in
7 the hallux increased after arthrodesis compared to preoperatively [11]. Hence, it is possible
8 that the higher maximum passive dorsiflexion angle in the patients after MTP-I prosthesis
9 allowed sufficient flexibility in the joint during walking that it did not influence peak pressure
10 in the hallux.

11 This prospective study only included eight patients (10 feet) representing a small
12 sample size hence limiting the generalizability of the results. Nevertheless, the follow-up
13 ranged from 48 to 55 months which is longer and more homogeneous than that in previous
14 studies using pedobarography as outcome measure for MTP-I arthroplasty [10, 14].
15 Furthermore, both unilateral and bilateral cases were included in the analysis. It is possible
16 that patients who received bilateral MTP-I prostheses adapt their gait patterns differently than
17 patients with unilateral prostheses. However, the main interest of this study was to assess
18 changes in plantar pressure distribution after MTP-I prosthesis and hence all operated feet
19 were included in the analysis. Contrary to other studies, the contralateral side was not used for
20 comparison because it is possible that its plantar pressure distribution is also affected by
21 adaptation processes. The clinical measurement set up utilized in this study did not allow
22 measurements of spatiotemporal gait parameters or three-dimensional joint kinematics during
23 walking. Investigating additional functional data may help to understand the foot
24 biomechanics and especially the forefoot kinematics in patients with MTP-I osteoarthritis and
25 after MTP-I prosthesis.

1 In conclusion, this study showed that on average 4 years after MTP-I prosthesis
2 patients had higher lateral peak pressure and force than preoperatively despite reporting less
3 pain. This indicates a lateralization of the load bearing which is contrary to what would be
4 expected in a healthy foot. Medial load bearing through the first metatarsal head was
5 influenced by the amount of passive dorsiflexion were greater passive dorsiflexion was
6 associated with higher peak pressures and forces. Therefore, passive MTP-I dorsiflexion
7 might be important for the distribution of peak pressure and force in the forefoot.

8

9 **References**

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25 metatarsophalangeal joint. *Foot & Ankle International*. 2013;34:504-11.

1 Table 1: Preoperative and postoperative clinical results

	Preoperative (<i>n</i> = 10 feet) Mean (SD)	Postoperative (<i>n</i> = 10 feet) Mean (SD)	<i>P</i> value	Effect size d
Body mass index (kg/m ²)	27.0 (4.6)	25.4 (3.6)	.151	-0.37
Body mass (kg)	77.1 (17.8)	73.4 (16.2)	.219	-0.22
Pain level (VAS)	5.2 (1.9)	1.5 (1.8)	<.001*	-2.03
AOFAS forefoot score [17]	58 (13)	84 (12)	.001*	2.10
Passive range of motion (°)	42 (11)	30 (9)	.075	-1.21
Passive MTP-I dorsiflexion (°)	24 (15)	44 (23)	.059	1.03
Passive MTP-I plantarflexion (°)	17 (9)	-15 (23)	.003*	-1.81

2 *: indicates significant differences between pre- and postoperative measurements (*P*<.05)

3 SD: standard deviation

4 VAS: visual analogue scale from 0 (no pain) to 10 (worst pain)

5 AOFAS: American Orthopaedic Foot and Ankle Society

6 MTP-I: first metatarsophalangeal joint

1 **Figure captions**

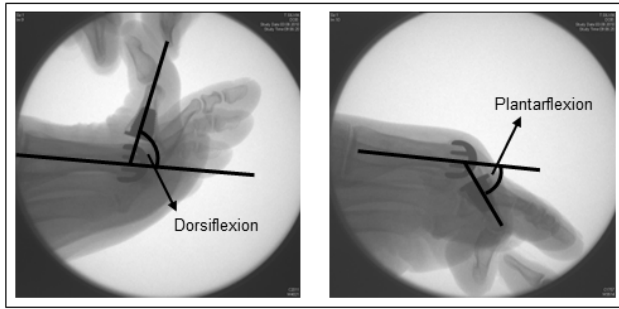
2 Figure 1: Measurement of the maximal first metatarsophalangeal joint dorsiflexion (left) and
3 plantarflexion (right) angle using fluoroscopy.

4 Figure 2: Peak plantar pressures (upper row) and forces (bottom row) in the hindfoot,
5 midfoot, forefoot and toe regions including the mediolateral (ML) forefoot index.

6 Preoperative data are depicted in light grey and postoperative data in dark grey. Significant
7 differences between the two measurements are indicated with asterisks.

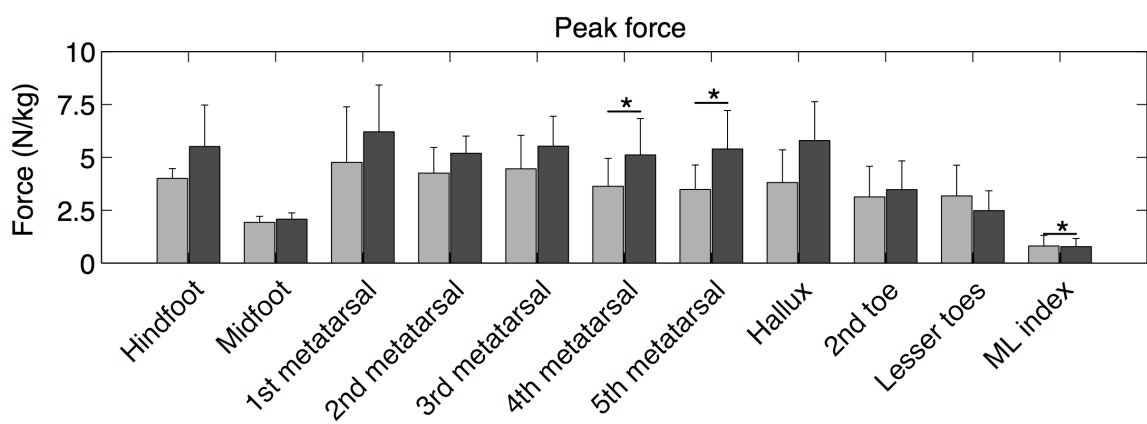
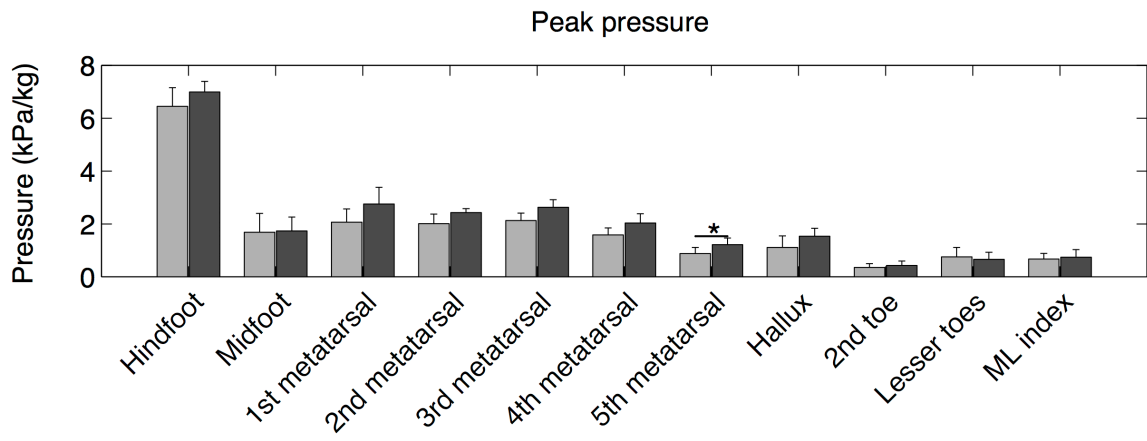
8 Figure 3: Significant ($P < .05$) and relevant (power $> 80\%$) relationships between clinical
9 results on passive dorsiflexion motion (upper row) and AOFAS score (lower row) and peak
10 plantar pressure and forces in different foot segments. Preoperative data sets are depicted as
11 points and postoperative data sets as crosses.

12



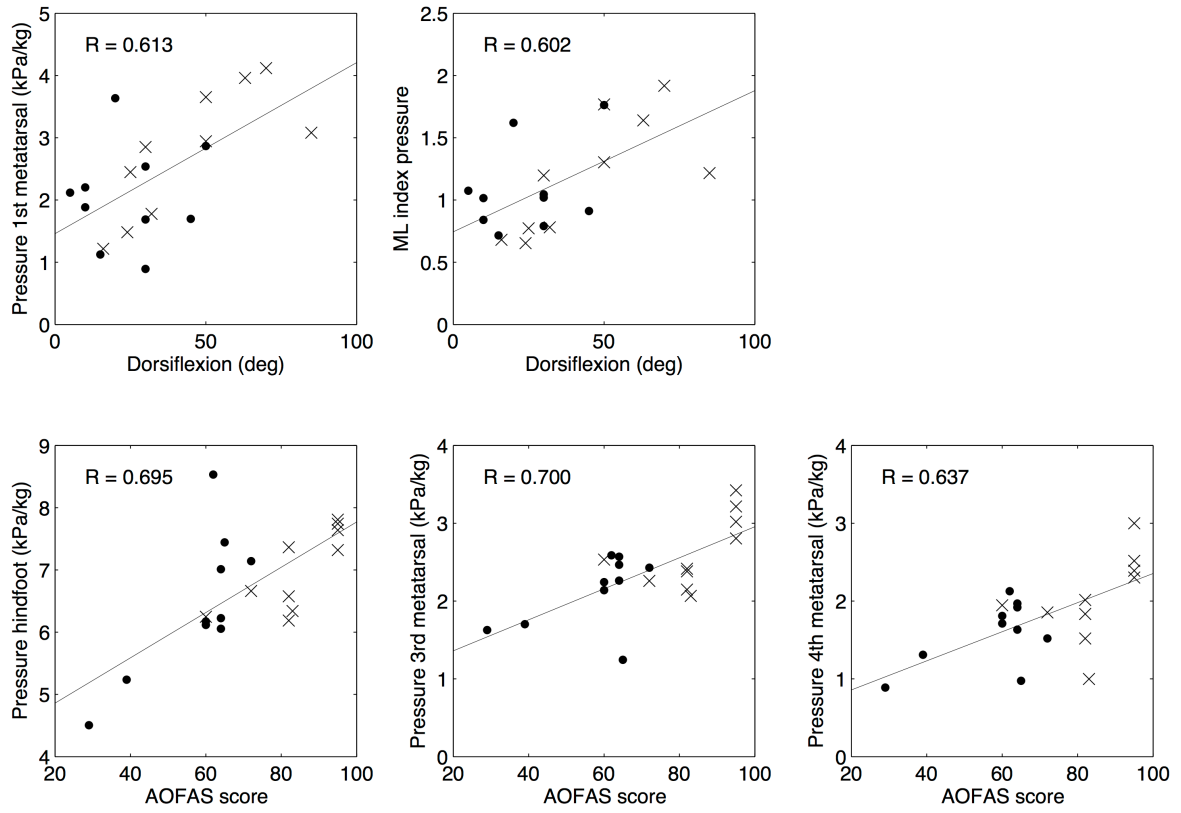
1

2 Figure 1



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2 Figure 2



1

2 Figure 4