A comparison of two podiatric protocols for metatarsalgia in patients with rheumatoid arthritis and osteoarthritis

S. Maddali Bongi[1], A. Del Rosso[1], S. Mikhaylova[1], G. Landi[1], B. Ferretti[1], E. Cavigli[1], M. Baccini[2], M. Matucci-Cerinic[1]

[1]Department of Experimental and Clinical Medicine, Division of Rheumatology, University of Florence; [2]Motion Analysis Laboratory, Piero Palagi Hospital, Azienda Sanitaria 10 di Firenze, Florence, Italy.

Abstract

Objective

In rheumatoid arthritis (RA) and osteoarthritis (OA) forefoot involvement causes disability and metatarsalgia. Our objective was to evaluate, in RA and OA patients, the efficacy of two protocols combining insoles in polypropylene terephtalate (PPT) and custom silicone orthoses for toes on disability and metatarsalgia.

Methods

Twenty-four women (13 with OA, 11 with RA) with metatarsalgia were treated with two protocols: group A (protocol A) wore PPT insoles (T1) for 30 days and for another 30 days silicone orthosis for toes were added (T2). Group B (protocol B) wore PPT insoles and silicone orthosis (T1) for 30 days and in the following 30 days only insoles (T2). At T0, T1 and T2, pain, disability and function (Foot Function Index – FFI), pressure (KPA) and plantar contact areas (cm2) (baropodometer), and gait spatial-temporal parameters (GAITRite®) were assessed.

Results

At T0 versus T2, both protocols reduced FFI-pain, -disability and -functional limitation ($p<0.05$), with better results of protocol A than protocol B ($p<0.05$) for FFI-pain and -disability. Both protocols reduced baropodometer foot plantar pressures ($p<0.001$), with better results for protocol A for right foot pressures ($p<0.05$) and increased foot contact areas ($p<0.05$), with no difference between them (p=NS). Gait parameters were not significantly changed by both protocols (p=NS).

Conclusion

In patients with RA and OA with metatarsalgia, the synergic action of silicone toe orthosis and PPT insoles improves FFI, reduces foot plantar pressures and increases foot plantar contact areas. Protocol A, using firstly insoles and then adding silicone toe orthoses, is the more efficacious.

Key words

rheumatoid arthritis, osteoarthritis, foot, foot function index , forefoot, pain, metatarsalgia, foot pressures, foot contact areas, baropodometer, GAITRite® System, podiatrist

*Susanna Maddali Bongi, MD**
*Angela Del Rosso, MD, PhD**
Svetlana Mikhaylova, MD
Giovanna Landi
Elisa Cavigli
Barbara Ferretti
Marco Baccini
Marco Matucci-Cerinic, MD, PhD

**These authors contributed equally to this work.*

Please address correspondence to:
Angela Del Rosso, MD, PhD,
Division of Rheumatology,
Department of Clinical and Experimental Medicine,
University of Florence,
viale Pieraccini 18,
50139, Firenze, Italy.
E-mail: angela.delrosso@fastwebnet.it

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Introduction

In patients with rheumatoid arthritis (RA) and osteoarthritis (OA), foot involvement is a frequent event.

The foot is the initial site of involvement in 16–36% of early RA patients (1) and it is clinically involved in more than 85% of patients with established RA (2).

Painful feet or ankles are referred by over 85% of RA patients during the course of the disease and by 57% of them within the first year of diagnosis (3). The structural and functional changes in RA feet often affect gait and mobility (4), impacting negatively on Quality of Life (QoL) (5), sometimes favouring foot ulcer development (6).

Foot OA, with respect to knee, hip and hand OA, has been relatively neglected. However, the first metatarsophalangeal joint (MTPJ) is among the joints most frequently affected by OA, which is diagnosed in 35% to 60% of adults aged over 65 years (7).

Furthermore, in OA, foot pain contributes significantly to locomotor disability (8), leading to postural instability and, potentially, to difficulties in walking, in daily activities, and to QoL impairment.

Moreover, in both diseases, the altered dynamics of gait cycle, due to the anatomic changes of the foot, lead to secondary changes of the other joints, in particular of lower limbs, such as ankles, knees and hips.

Although the whole foot may be involved both in RA and in OA, forefoot deformities are the most frequent and disabling. In RA, forefoot deformity, represented by hallux valgus, subluxation, dislocation and erosion of MTPJ, as well as hammer toe, or claw toe in the lesser toes, are secondary to hindfoot instability, or to inflammation of joints, tendons and ligaments (9, 10). Both hindfoot and forefoot adaptations lead to altered foot and ankle motion, higher forefoot plantar pressure loading, and increased pain during weight-bearing and locomotor activities (11-13).

OA of the first MTPJ is most often due to repetitive loading injury. Resultant painful limitation of motion is referred to as hallux rigidus. OA of the hallucal sesamoid joints is also common. A hallux valgus deformity may precipitate degenerative changes in the first ray (14). In individuals with first MTPJ OA, severity of foot pain is associated with osteophytes (15) and higher body mass index (16).

A merely pharmacologic approach is often not sufficient in dealing with foot problems of RA and OA patients. Thus, the collaboration of a rheumatologist, podiatrist and physiotherapist is needed for an efficacious treatment.

In patients with rheumatic diseases, the professional skills of podiatrists, other than in assessing and treating hard skin, callus and corns, eventual wounds and ulcers, are needed also in prescribing and providing bespoke or pre-fabricated foot orthoses and insoles, in advising about appropriate footwear and footwear adaptations, sometimes in association with orthotists (17).

In the clinical guidelines for RA of the French Society of Rheumatology, the referral to podologist for hygiene, treatment of nail anomalies and hyperkeratoses on the feet is advised, and the wearing of customised insoles, toe splints, and adapted or therapeutic shoes, is recommended when the feet are deformed and painful (18).

According to the guidelines for RA treatment drawn by UK National Institute for Health and Care Excellence (NICE), foot involvement is regarded as an issue needing multidisciplinary treatment and, also, as an area in which patients need an improvement of care (19). Notably, patients with rheumatic diseases, despite the high frequency of foot symptoms and structural and functional changes due to their underlying diseases, rarely access podiatric services (20, 21) or access them through non-specialist routes (22).

Correcting plantar loading and stabilising the foot and ankle may reduce the likelihood of foot deformities and walking disability for RA patients (23). Moreover, a correct alignment of the foot may reduce foot pain, prevent and treat OA of hip (related to high-arched foot) and knee (related to flat foot) (24).

A recent systematic review indicates that custom foot orthoses should be used judiciously in the treatment of foot pain. Moreover, custom-made foot or-

thoses were effective for painful pes cavus and rearfoot pain in RA but not for forefoot pain and metatarsalgia (25).

Despite the high frequency of the structural and functional changes of forefoot in rheumatic diseases, only few studies and guidelines about podiatric treatment of RA forefoot are published (26-28), while only scant and anecdotal data are available for OA.

Our aim is to evaluate, in patients with RA and OA, the efficacy of two podiatric treatments of the forefoot combining the use of insoles in polypropylene terephtalate (PPT) and custom silicone orthoses for toes, in terms of effects on metatarsalgia, foot disability, plantar pressures and contact areas and spatial-temporal gait parameters.

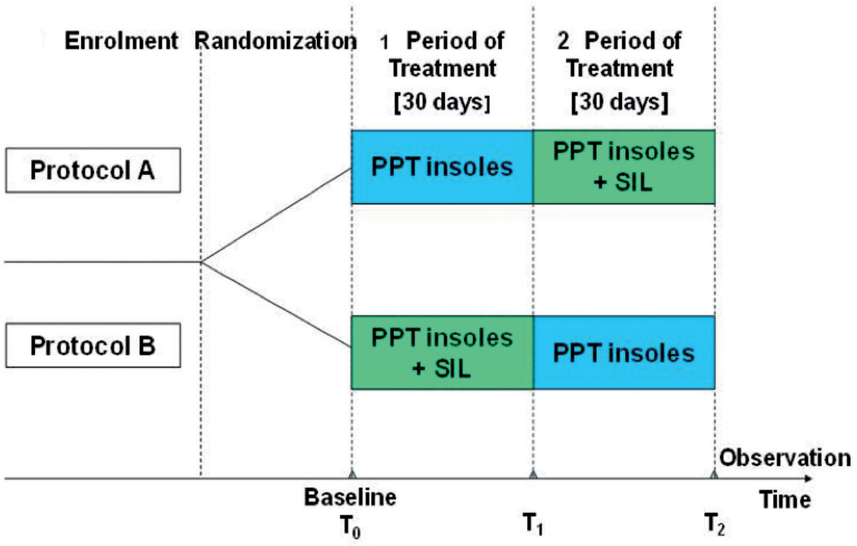

Fig. 1. Study design.
PPT: polypropylene terephtalate insoles; SIL: toe silicone orthoses.

Patients and methods

Patients

Participation in the study was proposed to 40 female patients (23 diagnosed with RA and 17 with OA), attending the outpatient clinic of our Department, living in the metropolitan Florence area. Seven of them refused to participate when contacted and 3 did not present at the first evaluation. Six out of the 30 patients who accepted did not begin the treatment after the first evaluation and randomisation.

Twenty-four patients, 13 affected with RA (age: 69.06±4.02 and disease duration: 9.20±8.60 years, respectively) and 11 with OA (age: 72.0±2.03 and disease duration: 11.35±6.5 years) (p=NS for both comparisons) participated to the study. Foot pain was present since the first phases both in RA (8.6±7.04 years) and in OA (10.2±9.31 years) (p=NS).

All the patients were adequately informed about the study details by a leaflet describing the project (aim, procedures, probable results) and agreed by a written informed consent. The study was approved by the local ethics committee and conducted in accordance with the principles of the declaration of Helsinki.

The patients were enrolled from September to November 2012 and the study lasted till May 2013. Inclusion criteria were adult age (between 20 and 75 years), diagnosis of RA (29) or OA (30), confirmed by x-rays, with metatarsalgia, no use of foot orthoses in the 30 days previous to enrolment. All the patients continued to assume their usual drug therapy for RA and OA.

Exclusion criteria were skin lesions (ulcers, dermatitis), previous surgery at feet, neurological or muscular diseases, diabetes mellitus, infiltrative intra-articular treatment with glucocorticoids or hyaluronic acid at feet in the previous 3 months and presence of tarsal tunnel syndrome.

Study design

The study has a cross-over research design, with a duration of 60 days (Fig. 1). After the enrolment, participants were randomly divided into 2 groups: Group A (12 patients, 6 affected by RA and 6 by OA) and Group B (12 patients, 7 affected by RA and 5 by OA). Randomisation was made by a random number sequence prepared by a person not involved in the study, who also gave sequentially numbered and sealed envelopes. Patients were assessed at baseline (T0), after 30 days (T1) and at the end of the whole treatment period, after 60 days (T2).

At baseline, none of the assessed items were different between RA and OA patients (data not shown)

Patients of group A (protocol A) wore insoles without silicone orthoses in the first 30-day period and PPT insoles with silicone orthoses in the following 30 days. Patients of group B (protocol B), conversely, wore silicone orthoses insoles in the first period and only insoles in the second one.

Orthoses and insoles

– Insoles

The insoles used were built in breathable polypropylene terephtalate (PPT), a shock-absorbing material with return memory that increases the area of distribution of plantar pressures and redistributes the load on non painful and/or non hyper-loaded surfaces. The insoles are 5 mm high and double-layer, with an upper smooth low density (180 kg/m^3) layer and a lower high density (360 kg/m^3) layer. The combination of the two layers allows the insole to be effective in shock-absorbing and in protecting foot tissues from stresses. For each participant, two insoles were built, one for each foot (Fig. 2).

– Custom silicone orthoses for toes

We used a paste of a smooth monocomponent silicone (2 shores) to build thin orthoses, that could be easily worn in the shoes over the PPT insoles. The orthoses were custom made directly on the patient's foot by using a silicone past and a solidifying catalyst, as follows:

- the needed quantity of silicone was taken and amalgamated;
- the catalyst was added to the silicon and the components were mixed;

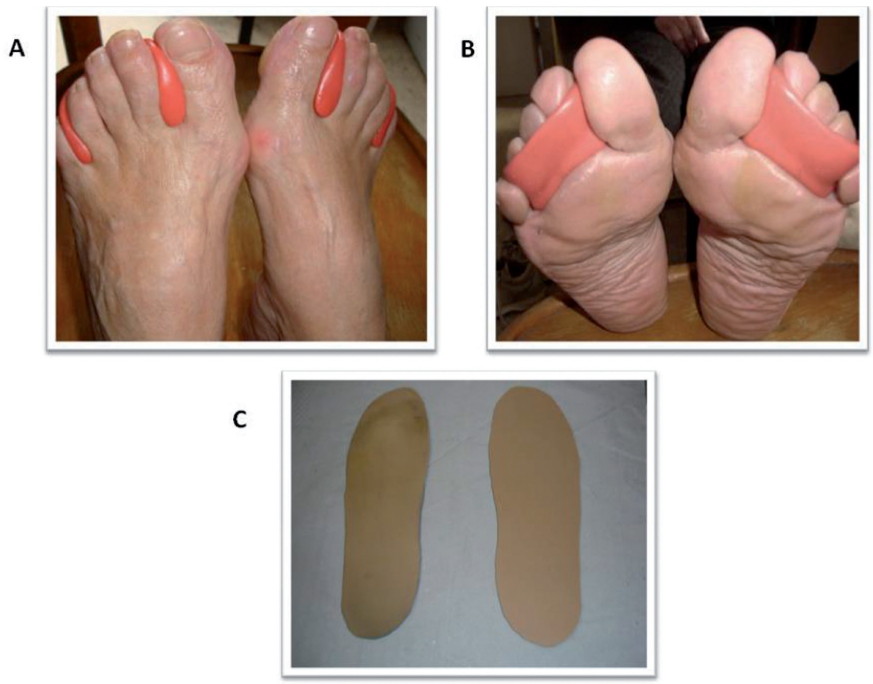

Fig. 2. Toe silicone orthoses and polypropylene terephtalate (PPT) insoles.
2A: Toe silicone orthoses, view from foot dorsum; **2B**: Toe silicone orthoses, view from foot plant; **2C**: PPT insoles.

Table I. Basal values (T0) of Foot Function Index, baropodometric and gait parameters in Group A and B.

	Group A	Group B	*p*-value
FFI-pain	5.57 ± 1.60	5.83 ± 2.2	NS
FFI-disability	5.53 ± 2.01	5.89 ± 2.31	NS
FFI-functional limitation	2.72 ± 2.52	2.37 ± 1.92	NS
Right foot pressure (Kpa)	116.55 ± 48.56	102.32 ± 46.19	NS
Left foot pressure (Kpa)	111.19 ± 52.32	99.25 ± 45.57	NS
Right foot surface (cm^2)	75.42 ± 27.43	87.92 ± 40.51	NS
Left foot surface (cm^2)	80.42 ± 29.84	85.00 ± 43.34	NS
Gait speed	106.02 ± 34.12	100.21 ± 24.08	NS
Cadence	103.78 ± 23.91	108.12 ± 9.81	NS
Right step time	0.56 ± 0.10	0.56 ± 0.05	NS
Left step time	0.71 ± 0.40	0.57 ± 0.06	NS
Right step length	59.98 ± 7.94	55.27 ± 9.57	NS
Left step length	60.86 ± 6.96	54.66 ± 9.15	NS
Right DS time (% gait cycle)	26.83 ± 4.76	29.33 ± 4.97	NS
Left DS time (% gait cycle)	26.49 ± 4.23	29.34 ± 4.63	NS
Right SW time (% gait cycle)	36.30 ± 3.16	35.40 ± 2.85	NS
Left SW time (% gait cycle)	38.13 ± 1.73	36.07 ± 2.70	NS
Right ST time (% gait cycle)	63.70 ± 3.16	64.60 ± 2.87	NS
Left ST time (% gait cycle)	61.87 ± 1.74	63.93 ± 2.70	NS
Right toeing out angle	8.52 ± 2.80	9.35 ± 5.60	NS
Left toeing out angle	6.55 ± 5.31	4.86 ± 3.83	NS
Base of support	6.77 ± 2.43	8.05 ± 3.52	NS
FAP	85.33 ± 18.32	92.07 ± 8.47	NS

DS: double stance period; SW: swing phase; ST: stance phase; FAP: Functional Ambulation Performance score.

- the orthoses were moulded over the foot, checking the homogeneity of the material and the appropriateness of silicone and design; the modelled silicone was posed under the plantar aspect of the 2nd, 3rd and 4th; then, its verges were whirled and placed between the 2nd and the 4th toes, in order to sustain and separate them from the 1st and the 5th toes and to increase their plantar support surfaces.
- a sufficient time elapsed before removing the orthoses to let the compound acquire the adequate consistency.

Afterwards, the orthoses were consigned to the patient, who was told to wear them since the following day, when catalysation would have been completed (Fig. 2).

Patients were taught to use the insoles and the silicone orthoses for brief periods (3–5 hours/day) for the first 3 days at the beginning of the 30-day period and, afterwards, to use them for most of the day (12 hours maximum) inside their usual shoes.

For the purpose of our study, two custom digital orthoses, one for each foot, tailored according to the patient needs, were built.

Outcome measures

The following outcome measures were used at each time point (T0, T1, T2):

- Pain, disability and functional limitation, assessed by Foot Function Index;
- Plantar contact areas and pressures in upright stance, measured by a baropodometer
- Spatial and temporal gait parameters, assessed by GAITRite® System.

Foot Function Index (FFI)

FFI is a widely used self-administered questionnaire evaluating problems related to foot involvement. It is composed by 23 questions rated with a 0-10 Verbal Numeric Scale (VNS), where 0=the best possible condition and 10=the worst possible condition) and organised in 3 sections: pain (9 questions), disability (9 questions) and functional limitation (5 questions). The patients are asked to score all the questions on the basis of their condition in the preceding 7 days. For each section, the mean scores are calculated in order to obtain a pain score (FFI-pain), a disability score (FFI-disability) and a functional limitation score (FFI- functional limitation) (31).

Baropodometeric measures

Baropodometeric measures were assessed by Ecowalk baropodometer, Ecosanit®). The baropodometer is

formed by a 5 mm platform (50x70 cm; weight: 7 kg; thickness: 5 mm), with 2304 sensors of resistive type, linked to a processing software, analysing and measuring plantar pressures and load distribution on foot plants and plantar support surfaces.

The measurements obtained by baropodometer are not invasive, accurate, immediate and repeatable. They provide orthostatic evaluations of the patient and allow to compare surfaces and pressures of right and left foot.

Plantar pressures are measured in kilopascal (KPA) and are displayed in different colours, from blue (minor pressures) to red (higher pressures) color, and plantar pressure areas are measured in cm^2.

For the purpose of our study, feet pressures and areas were assessed in static upright position.

Gait parameters

Gait performance was recorded using the GAITRite® System, a portable electronic walkway mat, whose active area (61x4.30 cm) contains 48x384 encapsulated sensors arranged in a grid-like pattern to identify footfall contacts. The system allows the recording of the spatial (step and stride length, heel to heel base of support, toeing out angle) and temporal (cadence, mean velocity, step time, duration of stance phase, swing phase and double support period) gait parameters. The system also integrates selected temporal and spatial parameters to provide a single, numerical representation of gait, *i.e.* the Functional Ambulation Performance (FAP) score.

The validity of the GAITRite system in the assessment of spatial-temporal gait parameters measurements is widely demonstrated (32, 33).

Participants were evaluated using the GAITRite system at the Motion Analysis Laboratory of Azienda Sanitaria 10 di Firenze, Florence, Italy. Before starting the test, the subject's leg length was measured as the vertical distance from the greater trochanter to the floor with the subject standing in a relaxed upright position.

Data analysis

One-way ANOVA for mean values was used to compare participants demographic characteristics and baseline assessment between the two groups.

For each outcome measure, a 3x2 ANOVA with repeated measures with 2 factors, Time (T0, T1, T2) and Group (A, B), was used to compare the effects of the two treatments.

For measures with a significant time x group interaction T0-T2 by ANOVA (to assess the differences between protocol A and B during the treatment), a further analysis was also conducted by comparing the changes at T1 *versus* T0 and at T2 *versus* T1 in the 2 groups using an independent samples *t*-test.

The level of statistical significance was set at 0.05. Data analysis was performed using the SPSS statistical package 17.0 for Windows.

Results

At enrolment (T0), patients of the two groups were not different in any of the assessed items: FFI, baropodometer parameters and spatial-temporal gait parameters (Table I).

Effects of the treatment on Foot Functional Index

In the *T0-T2* period, both protocol A and B significantly reduced FFI-pain ($p<0.001$), FFI-disability ($p<0.001$) and FFI-functional limitation ($p=0.001$) (Table II). A significant time x group interaction *T0-T2* was found for FFI-pain ($p=0.001$) and FFI-disability ($p<0.05$), with better results in protocol A than in protocol B, but not for FFI-functional limitation (Table II; Fig. 3A-B).

Table II. Effects of treatment on Foot Function Index, baropodometric and gait parameters in group A and B by ANOVA 3x2.

	Group A			Group B			Time (T)	Group(G)	T x G
	T0	T1	T2	T0	T1	T2	*p*-value	*p*-value	*p*-valu
FFI-Pain	5.7 ± 1.60	3.88 ± 2.17	2.88 ± 1.86	5.83 ± 2.20	3.43 ± 2.73	4.68 ± 2.35	<0.001	NS	0.001
FFI-Disability	5.53 ± 2.01	3.58 ± 2.29	2.72 ± 1.99	5.89 ± 2.31	3.98 ± 2.57	4.69 ± 2.52	<0.001	NS	<0.05
FFI-functional limitation	2.72 ± 2.52	1.90 ± 2.39	1.57 ± 2.21	2.37 ± 1.92	1.40 ± 1.17	2.00 ± 1.43	0.001	NS	NS
Right foot pressure (Kpa)	116.55 ± 48.56	94.93 ± 52.37	83.78 ± 53.90	102.3 ± 46.19	73.07 ± 55.43	84.27 ± 51.62	<0.001	NS	<0.05
Left foot pressure (Kpa)	111.19 ± 52.32	92.95 ± 50.12	85.57 ± 54.12	99.25 ± 45.57	74.89 ± 47.10	80.11 ± 48.32	<0.001	NS	NS
Right foot surface (cm^2)	75.42 ± 27.43	83.67 ± 28.80	90.25 ± 23.15	87.92 ± 40.51	103.25 ± 45.06	89.83 ± 24.42	<0.05	NS	NS
Left foot surface (cm^2)	80.42 ± 29.84	89.58 ± 28.63	100.25 ± 28.22	85.00 ± 43.34	102.92 ± 45.88	93.83 ± 23.22	<0.01	NS	NS
Gait speed	106.02 ± 34.12	99.99 ± 25.35	107.41 ± 22.65	100.21 ± 24.08	104.19 ± 16.99	99.44 ± 15.36	NS	NS	NS
Cadence	103.78 ± 23.91	103.77 ± 16.69	108.23 ± 16.71	108.12 ± 9.81	107.63 ± 7.34	106.27 ± 6.40	NS	NS	NS
Right step time	0.56 ± 0.10	0.59 ± 0.11	0.57 ± 0.10	0,56 ± 0.05	0.57 ± 0.06	0.56 ± 0.04	NS	NS	NS
Left step time	0.71 ± 0.40	0.60 ± 0.12	0.57 ± 0.10	0.57 ± 0.06	0.56 ± 0.05	0.57 ± 0.04	NS	NS	NS
Right step length	59.98 ± 7.94	56.90 ± 6.97	59.01 ± 5.99	55.27 ± 9.57	58.59 ± 6.86	56.56 ± 6.96	NS	NS	<0.05
Left step length	60.86 ± 6.96	57.17 ± 6.81	60.65 ± 9.01	54.66 ± 9.15	57.24 ± 7.61	55.49 ± 7.70	NS	NS	<0.05
Right DS time (% gait cycle)	26.83 ± 4.76	28.21 ± 6.02	24.96 ± 3.21	29.33 ± 4.97	29.38 ± 4.36	27.58 ± 2.97	NS	NS	NS
Left DS time (% gait cycle)	26.49 ± 4.23	27.30 ± 6.58	24.63 ± 3.21	29.34 ± 4.63	30.25 ± 6.48	27.54 ± 3.16	NS	NS	NS
Right SW time (% gait cycle)	36.30 ± 3.16	36.51 ± 2.23	37.74 ± 1.71	35.40 ± 2.85	35.77 ± 2.09	36.30 ± 2.58	NS	NS	NS
Left SW time (% gait cycle)	38.13 ± 1.73	36.53 ± 3.57	37.75 ± 1.78	36.07 ± 2.70	35.52 ± 3.95	37.17 ± 1.34	NS	NS	NS
Right ST time (% gait cycle)	63.70 ± 3.16	63.49 ± 2.22	62.28 ± 1.71	64.60 ± 2.87	64.25 ± 2.09	63.71 ± 2.58	NS	NS	NS
Left ST time (% gait cycle)	61.87 ± 1.74	63.47 ± 3.57	62.25 ± 1.78	63.93 ± 2.70	64.46 ± 3.95	62.84 ± 1.36	NS	NS	NS
Right toeing out angle	8.52 ± 2.80	8.35 ± 3.02	6.99 ± 4.57	9.35 ± 5.60	8.23 ± 5.07	8.50 ± 4.90	NS	NS	NS
Left toeing out angle	6.55 ± 5.31	6.62 ± 4.98	6.69 ± 6.41	4.86 ± 3.83	5.14 ± 3.29	5.07 ± 3.50	NS	NS	NS
Base of support	6.77 ± 2.43	7.95 ± 1.86	6.89 ± 2.63	8.05 ± 3.52	6.76 ± 3.61	8.07 ± 4.02	NS	NS	NS
FAP	85.33 ± 18.32	88.83 ± 16.97	90.25 ± 17.46	92.07 ± 8.47	95.42 ± 3.18	94.27 ± 4.04	NS	NS	NS

FFI: Foot Function Index; DS: double stance period; SW: swing phase; ST: stance phase; FAP: Functional Ambulation Performance score; T x G: time x group interaction.

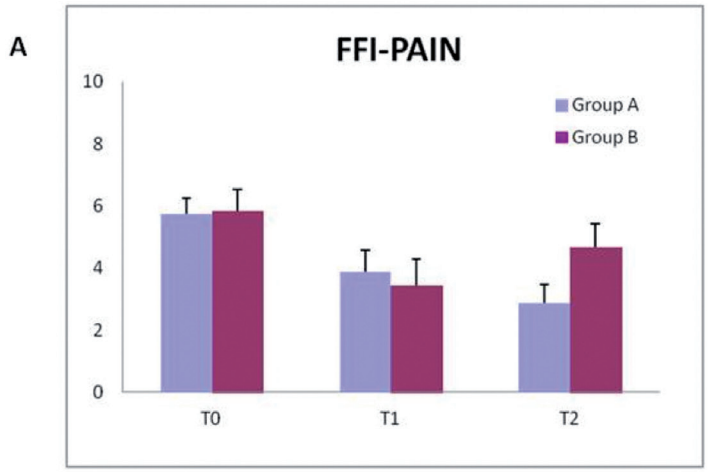

Fig. 3A. Effect of the treatment on FFI-pain in Group A and B.
FFI-pain: Foot Function Index-pain; values are represented as mean scores ± standard errors.

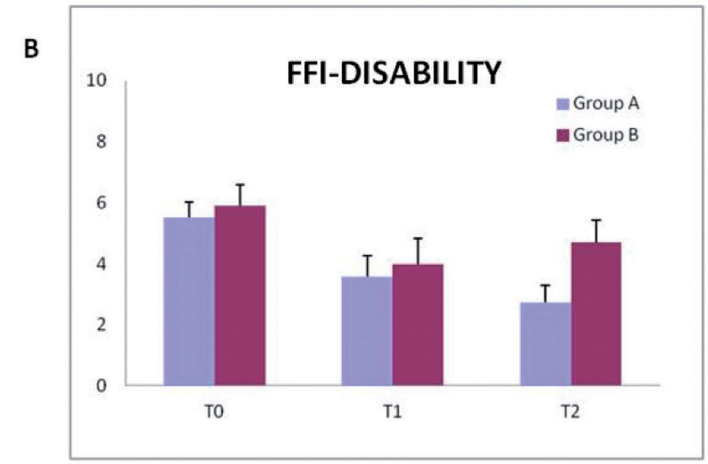

Fig. 3B. Effect of the treatment on FFI-disability in Group A and B.
FFI-disability: Foot Function Index-disability; values are represented as mean scores ± standard errors.

Accordingly, in the first period of the study (*T0-T1*), analysis by *t*-test, showed that both protocols reduced significantly FFI-pain ($p<0.001$) and FFI-disability ($p<0.001$) (Table III), without significant difference between them. However, in the second period (*T1-T2*), when silicone orthosis was added in protocol A and removed in protocol B, changes in T2 in respect to T1 were significantly different in the two groups in FFI-pain ($p<0.001$) and in FFI-disability ($p=0.001$) with better results in protocol A (Table III; Fig. 3A-B).

Effects of the treatment on plantar pressures and areas

In the *T0-T2* period, in both protocols, baropodometer measures showed a reduction in plantar pressures, both at the right and left foot ($p<0.001$). However, a significant time x group interaction *T0-T2* was found for right foot pressures alone, with better results in protocol A than in protocol B ($p<0.05$) (Table II; Fig. 4A).

By *t*-test, in the *T0-T1* period, both protocols reduced significantly plantar pressures at the right and left foot ($p<0.001$), but changes were not significantly different between the protocols. In the *T1-T2* period, changes in right and left foot pressure were significantly different between the 2 protocols ($p=0.001$ and $p<0.05$, respectively), with better results in protocol A than in protocol B (Table III; Fig. 4A).

In both protocols, during the treatment period (*T0-T2*), baropodometer measures showed a significantly increase in plantar pressure areas (right foot, $p<0.05$; left foot, $p<0.01$), but no significant time x group interaction was found.

Effects of the treatment on gait spatial-temporal parameters

In the *T0-T2* period, gait spatial-temporal parameters were not significantly changed by both protocols. Only step length showed a significant time x group interaction with better results in protocol A than in protocol B ($p<0.05$ for both right and left foot) (Table II; Fig. 4B).

By *t*-test, the 2 protocols had different effects on these parameters, since changes in step length were significantly better in protocol B than in protocol A , in the *T0-T1* period (right foot, $p=0.01$; left foot, $p<0.05$) and in protocol A, in the *T1-T2* period (right foot, $p<0.05$; left foot, $p<0.05$) (Table III; Fig. 4B).

Effects of the treatment on OA and RA

By comparing, within protocol A and protocol B, the data of patients with RA and OA at the end of the treatment (T2), we did not find any significant difference in any of the assessed items (data not shown).

Discussion

To the best of our knowledge, this is the first study assessing the utility of PPT insoles and custom made silicone orthoses for toes in relieving symptoms in RA and OA patients with metatarsalgia. In the whole, both protocols (the first, using PPT insoles further complemented with toe custom made silicone orthoses and the second, using insoles with silicone orthoses, which, further, were taken off) improved foot function, reduced significantly foot pain, disability, plantar foot pressures and increased plantar pressure areas. On the contrary, gait parameters, except for the step length, were not affected by the treatment. Thus, the protocol using PPT insoles further complemented with toe custom made silicone orthoses yielded most successful results.

Both in RA and OA, the frequent involvement of the foot causes functional damage and structural deformities, leading to pain, difficulties in deambulation, postural instability and, consequently, to local disability, impairment of daily activities and QoL.

Foot pain is present in RA in a very high percent of patients (especially at forefoot and/or ankle), and its main predictive factors are represented by long

Table III. Effects of treatment in T1 *vs*. T0 and T2 *vs*. T1 on Foot Function Index, baropodometric and gait parameters in group A and B by *t*-test.

	Group A		Group B		Within groups *p*-value	Between groups *p*-value
	T0	T1	T0	T1		
FFI-Pain	5.7 ± 1.60	3.88 ± 2.17	5.83 ± 2.20	3.43 ± 2.73	<0.001	NS
FFI-Disability	5.53 ± 2.01	3.58 ± 2.29	5.89 ± 2.31	3.98 ± 2.57	<0.001	NS
Right foot pressure (Kpa)	116.55 ± 48.56	94.93 ± 52.37	102.3 ± 46.19	73.07 ± 55.43	<0.001	NS
Left foot pressure (Kpa)	111.19 ± 52.32	92.95 ± 50.12	99.25 ± 45.57	74.89 ± 47.10	<0.001	NS
Right step length	59.98 ± 7.94	56.90 ± 6.97	55.27 ± 9.57	58.59 ± 6.86	NS	0.010
Left step length	60.86 ± 6.96	57.17 ± 6.81	54.66 ± 9.15	57.24 ± 7.61	NS	0.012
	T1	T2	T1	T2		
FFI-Pain	3.88 ± 2.17	2.88 ± 1.86	3.43 ± 2.73	4.68 ± 2.35	NS	<0.001
FFI-Disability	3.58 ± 2.29	2.72 ± 1.99	3.98 ± 2.57	4.69 ± 2.52	NS	0.001
Right foot pressure (Kpa)	94.93 ± 52.37	83.78 ± 53.90	73.07 ± 55.43	84.27 ± 51.62	NS	0.001
Left foot pressure (Kpa)	92.95 ± 50.12	85.57 ± 54.12	74.89 ± 47.10	80.11 ± 48.32	NS	<0.05
Right step length	56.90 ± 6.97	59.01 ± 5.99	58.59 ± 6.86	56.56 ± 6.96	NS	<0.05
Left step length	57.17 ± 6.81	60.65 ± 9.01	57.24 ± 7.61	55.49 ± 7.70	NS	<0.05

Analysis was performed for measures that showed a significant time x group interaction T0-T2 by ANOVA.
FFI: Foot Function Index.

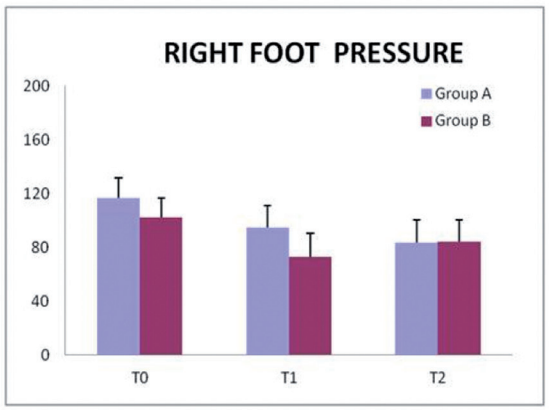

Fig. 4A. Effect of the treatment on right foot pressure in Group A and B Foot pressure is assessed in kilopascal (KPA); values are represented as mean scores ± standard errors.

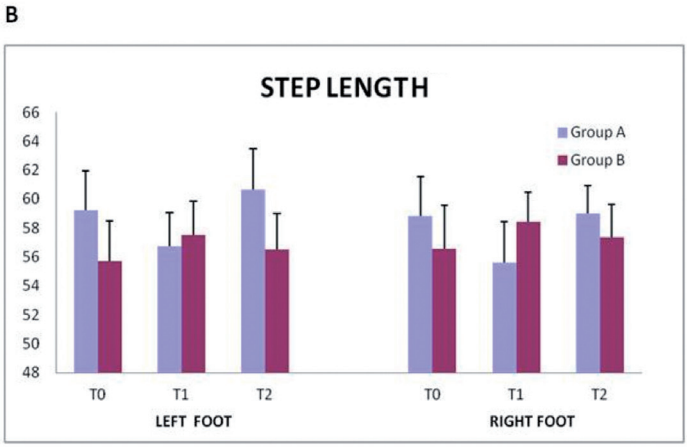

Fig. 4B. Effect of the treatment on step length in Group A and B Values are represented as mean scores ± standard errors

disease duration, high body mass index, foot stiffness and numbness (34).

Radiographic foot OA is common in older people and, although moderately associated with foot symptoms (35), in patients suffering from 1st MTPJ OA, severity of foot pain is related with the presence of osteophytes (15) and higher body mass index (16).

As foot concerns in rheumatic diseases are often not responsive to the usual drug therapy alone, a podiatrist intervention is needed. Unfortunately, in the majority of cases, patients with foot problems are referred to an orthotist and, rarely to podiatrist, as specialist podiatry services are generally only provided for diabetic patients within the hospital environment (36).

As in many areas (from Europe to New Zealand) (20-22, 37) patients with rheumatic diseases have difficulty to access to specialist podiatry services, the creation of foot clinic in rheumatology (including rheumatologist, orthotist, podiatrist and physiotherapist) is advocated.

In our study, OA and RA patients with metatarsalgia have subjective and objective benefits on foot function, foot pressures, plantar contact areas and GAITrite by podiatric treatments combining insoles and silicone orthoses. Our results are in substantial agreement with the data published in literature, although it is difficult to compare results of studies having different timing and using orthoses built with different designs and materials (38-45).

According to our data, foot function, as assessed by FFI, was improved by both podiatric protocols, with significantly better results of Protocol A at the end of the treatment on pain and disability subscales.

In Protocol A, the adding of the silicon orthoses in the second period of treatment reduced significantly pain and disability in respect to Protocol B, in which orthoses were removed, suggest-

ing that the treatment including both devices was more effective on foot function.

Our results confirm data published in literature for plantar insoles on FFI, whose improvement was reported in RA treated with supportive microrubber orthoses made with ethyl-vinyl acetate, (EVA), whose improvement at the first month was maintained throughout all the study, till sixth month (38). Amelioration in FFI was also reached by treating RA patients with custom manufactured orthoses, as described by Woodburn (39) and Van Der Leeden (40).

The reduction of pain, as assessed by FFI, is also concordant with previous results obtained by the applications of insoles in RA. Semi-rigid orthoses worn in supportive shoes improved pain due to metatarsalgia in patients with RA (41) as well as semiflexible orthotics made from Podofaam XE 1000 material (42) and custom manufactured rigid (39), semirigid (43), soft density EVA orthoses (44) and prefabricated orthoses (40).

Increased pressures and reduced plantar contact areas on metatarsal bones are usually related to metatarsalgia, thus their rebalancing by foot orthoses could help in treating foot pain.

In our study, the reduction of plantar pressures was similar at the end of the treatment for both protocols. In protocol A, plantar pressures were reduced significantly in the second period of the study, when the combined treatment with insoles and silicone orthoses was used. Differently, plantar pressure areas were similarly increased by both protocols at the end of the treatment period.

Our study confirms the results of previous studies, demonstrating the efficacy of custom made orthoses in redistributing plantar pressure, especially in metatarsal areas in RA (40, 45), while it is the first showing the efficacy on plantar pressure in OA.

In our study, among the gait spatial-temporal parameters assessed by GAITrite, better effects on step length of both right and left foot were related to the use of silicone orthoses. In fact, these parameters are significantly better in protocol B in first period and in protocol A in the second period, when combination treatment was used.

Our study is the first assessing gait spatial-temporal parameters in OA and partly confirms the results of others studies showing improvement of load pressures and step parameters during walking in patients with RA, while wearing devices (45).

To the best of our knowledge, our study firstly evaluates the effects of custom made silicone orthoses for toes in patients with RA and OA. These tools are sometimes used in patients with diabetic foot, in which they re-distribute plantar areas and pressures (46) and avoid the onset of ulcerations (47). According to our experience, they could be useful additional tools for the podiatrist in the management of foot involvement in patients with RA and OA.

Our work has some limitations, such as the small size of the study and the lacking of a follow-up period, but it is the first work describing how the synergic use of silicone orthoses and insoles could reduce pain and disability and improve function in the rheumatic foot.

According to our data, protocol A is more efficacious than protocol B. Its better results may be due to the gradual pressure re-modulation obtained by using firstly insoles, unloading pressures, and, then, by adding toe orthoses. The latter, modelled and tailored differently for each foot, further contribute to relieve pressure on metatarsal heads and to increase plantar contact areas, thus improving function and reducing disability and pain.

The data obtained, although interesting, should be substantiated on a higher number of patients with a longer follow-up to monitor the long-time outcome.

Conclusion

In patients with RA and OA, the synergic action of silicone toe orthoses and PPT insoles reduces metatarsalgia and foot disability, improves foot function, reduces foot plantar pressures and increases foot plantar contact areas. The most successful results are obtained with the protocol using with the insole alone, and then in combination with silicone toe orthoses.

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