

ORIGINAL ARTICLE

Effect of Foot Orthosis Treatment on Quality of Life in Secondary Sarcopenia Patients with Rheumatoid Arthritis-Related Foot Impairment

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Objectives: Patients with rheumatoid arthritis (RA)-related foot impairment have a high rate of sarcopenia. Treatment using a foot orthosis (FO) enables not only a reduction in pain while walking but also an increase in physical activity, helping to prevent further loss of muscle mass. However, the primary goal of treating RA is to maximize patients' long-term quality of life (QOL). We investigated whether FO treatment both increases physical activity and improves QOL. **Methods:** Among 31 patients with RA-related foot impairment, 15 with sarcopenia were treated with an FO for 6 months. Foot-specific QOL (measuring using the Self-Administered Foot Evaluation Questionnaire), foot pain, activities of daily living, and physical activity (walking-intensity activity and moderate- to vigorous-intensity activity) were compared before treatment and after 6 months of treatment. **Results:** Ten patients who completed 6 months of follow-up were analyzed. Significant QOL improvements were found in the Pain and Pain-Related category and the Physical Functioning and Daily Living category ($P = 0.02-0.04$); however, no significant changes were found in the Social Functioning, General Health and Well-Being, or Shoe-Related categories ($P = 0.09-0.21$). Foot pain and activities of daily living significantly improved ($P = 0.01-0.04$). Physical activity significantly increased for walking-intensity activity ($P = 0.04$) but did not change for moderate- to vigorous-intensity activity ($P = 1.00$). **Conclusions:** FO treatment in patients with RA-related foot impairment and sarcopenia increased light-intensity physical activity such as walking and improved physical QOL.

Key Words: foot orthosis; physical activity; quality of life; rheumatoid arthritis; sarcopenia

INTRODUCTION

Sarcopenia is a syndrome characterized by progressive and generalized loss of skeletal muscle mass and strength and is associated with an increased risk of adverse outcomes such as physical disability, poor quality of life (QOL), and death. Sarcopenia is considered to be primary when aging is recognized as the causative factor and secondary when

factors other than or in addition to aging are recognized (e.g., activity-, disease-, or nutrition-related factors). The most common diseases that cause secondary sarcopenia are associated with advanced organ failure, particularly that involving the heart, lung, liver, kidney, or brain; inflammatory disease; malignancy; and endocrine disease.^{1,2} Among inflammatory diseases, rheumatoid arthritis (RA) is a cause of secondary sarcopenia.

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Polyarthritis is a symptom of RA, which is a chronic systemic inflammatory disease. Many patients sustain damage to skeletal muscles by repeated episodes of arthritis and pain-related physical inactivity during the long disease duration, frequently resulting in sarcopenia.^{3,4} Physical inactivity caused by foot pain is particularly problematic in patients with RA-related foot impairment (e.g., deformity, limited range of motion), which is termed rheumatoid foot. Consequently, sarcopenia may be more common in patients with rheumatoid foot than in healthy people and in those with general RA.^{5–9} Physical inactivity in RA patients with sarcopenia leads not only to impairments in performing activities of daily living (ADL) but also to poor QOL. The primary goal of treating RA is to maximize patients' long-term QOL.¹⁰ Therefore, increasing physical activity through treatment of rheumatoid foot is very important because it may improve QOL.

Treatment of rheumatoid foot often involves drugs, surgery, and orthotic treatment. Among orthotic treatments, a foot orthosis (FO) has the advantage of being simple and easy to insert into the shoe; moreover, this method reportedly reduces foot pain while walking.^{11,12} We previously reported that reduction in foot pain achieved by FO treatment for 6 months increased physical activity but not muscle mass.⁹ This finding may suggest that the increase in physical activity achieved by FO treatment prevents progressive loss of muscle mass for at least 6 months in rheumatoid foot patients with sarcopenia. However, the effect of FO treatment on QOL in rheumatoid foot patients with sarcopenia is not clear. Using the same method as that applied in our previous study, the present study was performed to investigate whether FO treatment in rheumatoid foot patients with sarcopenia not only increases physical activity but also improves QOL.⁹

MATERIALS AND METHODS

Participants

Female patients with rheumatoid foot who visited our specialist outpatient orthopedic rheumatology clinic between April 2017 and March 2020 were included in this prospective cohort study. RA was diagnosed using the 2010 criteria of the American College of Rheumatology and European League Against Rheumatism.¹³ The inclusion criteria were an age of 20–90 years, foot pain, ability to walk independently, and no use of an FO immediately before enrollment. The exclusion criteria were pacemaker implantation, pregnancy, severe skin lesions, nerve disorders, dementia, and contact assistance with walking. Patients who fulfilled the inclusion

criteria were classified into two groups: those with sarcopenia and those without sarcopenia. Those with sarcopenia were treated with an FO and followed up for 6 months. All study participants provided written informed consent, and the study design was approved by the ethics review board of Kyoto Prefectural University of Medicine (approval number ERB-C-810-8).

Data Collection

The following demographic data were collected: age, height, weight, body mass index, disease duration, disease activity, Steinbrocker's stage and functional class, medication, foot deformity and function, grip strength, gait speed, and muscle mass. Disease activity was indexed using the Disease Activity Score in 28 Joints-C-reactive protein (DAS28-CRP), and participants were classified as remission (<2.3), low disease activity (≥ 2.3 to <2.7), moderate disease activity (2.7–4.1), or high disease activity (>4.1).¹⁴ Foot deformity was assessed using radiography. We examined the hallux valgus angle and M1–M5 angle in the anteroposterior weight-bearing view and the calcaneal pitch angle in the lateral weight-bearing view.^{15–17} The hallux valgus angle is an index of hallux valgus (normal range: <15°), the M1–M5 angle is an index of spread foot (normal range: <30°), and the calcaneal pitch angle is an index of flatfoot (normal range: 18–20°). Foot function was assessed using the Japanese Society for Surgery of the Foot (JSSF) RA foot–ankle scale and was used as an indicator of the severity of rheumatoid foot. JSSF RA foot–ankle scale scores indicate the presence of disorders caused by RA in the forefoot, midfoot, and ankle–hindfoot regions using five major items: pain, deformity, motion, walking ability, and ADL. Total scores range from 0 (lowest score) to 100 (highest score).¹⁸ Grip strength was measured using a hand dynamometer (TKK-5401; Takei Scientific Instruments, Niigata, Japan) with the patient in the sitting position, and the maximum value was recorded after measuring each side twice. Gait speed was defined as the normal walking speed on a 10-m walkway, measured using a stopwatch; the average value after measuring twice was recorded. Muscle mass was measured via the bioelectrical impedance analysis method using a body composition device (InBody 720; Biospace, Seoul, Korea), and the skeletal muscle mass index (SMI) was calculated by dividing the total lean mass in the arms and legs by the square of the height. Sarcopenia was diagnosed using the algorithm of the Asian Working Group for Sarcopenia 2019.¹⁹ Specifically, muscle strength (grip strength), physical performance (gait speed), and muscle mass (SMI) were selected. The cutoff

values of these items were a grip strength of <18 kg, a gait speed of <1.0 m/s, and an SMI of <5.7 kg/m². QOL, foot pain while walking, ADL disorders, and physical activity were collected as clinical variables. QOL assessment was performed using the Japanese Orthopaedic Association/JSSF Self-Administered Foot Evaluation Questionnaire (SAFE-Q). The SAFE-Q is a QOL questionnaire used in individuals with pathological conditions related to the foot and ankle as a foot-specific outcome instrument.^{20,21} This assessment tool consists of 34 questionnaire items in five subscales: Pain and Pain-Related, Physical Functioning and Daily Living, Social Functioning, Shoe-Related, and General Health and Well-Being. Each subscale is scored from 0 (least healthy) to 100 (healthiest), and all scores are significantly correlated with the JSSF RA foot–ankle scale scores. A visual analogue scale (VAS) score, ranging from 0 cm (no pain) to 10 cm (unbearable pain), was used to assess foot pain while walking. The Health Assessment Questionnaire Disability Index (HAQ-DI) is a questionnaire related to ADL disorders in patients with RA and assesses 20 items on a scale of 0 (no difficulty) to 3 (unable to perform); the highest scores in each of eight categories (dressing and grooming, rising, eating, walking, hygiene, reach, grip, and activities) are summed, and the index is then calculated by dividing this sum by eight.²² The International Physical Activity Questionnaire (IPAQ) was used to assess physical activity. The IPAQ is the most extensively used physical activity questionnaire.²³ IPAQ categories are classified as walking-intensity activity and moderate- to vigorous-intensity physical activity, which are summed by duration (in minutes) and frequency (number of days per week), and expressed as metabolic equivalent-minutes/week.

Treatment of Rheumatoid Foot

Rheumatoid foot patients with sarcopenia were treated with an FO. The FO was manufactured using the following procedure. A foam impression box was used, and the foot shape was scanned by a prosthetist and orthotist. On the basis of the foot shape, a custom-made FO was manufactured using computer technology. The shoes into which the FOs were inserted were the patients' own shoes that they wore on a regular basis and were chosen after consultation with the patients, prosthetist, orthotist, and physical therapists. Patients were instructed to use the FO during daily living for 6 months. Patients underwent no rehabilitation treatment during the follow-up period. Clinical variables were assessed before and after 6 months of FO treatment. The primary endpoint was QOL, and the secondary endpoints were foot pain,

ADL disorders, and physical activity.

Statistical Analysis

Statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).²⁴ Statistical significance was defined as $P < 0.05$. Demographic data are presented as the median (lower quartile, upper quartile) for continuous data and as the percentage (number) for categorical data. The severity of rheumatoid foot was illustrated as a histogram based on the frequency distribution of the JSSF RA foot–ankle scale score using descriptive statistics. The Wilcoxon signed-rank test was used to compare the clinical variables before and after 6 months of FO treatment. Treatment responsiveness was assessed by calculating the effect size (r) after 6 months of FO treatment. Values of >0.1, >0.3, and >0.5 were considered small, medium, and large effects, respectively. A post-hoc power analysis was performed to determine the effect of FO treatment on QOL in rheumatoid foot patients with sarcopenia.

RESULTS

Table 1 shows the demographic parameters of the 31 patients enrolled in this study. The median age, disease duration, and DAS28-CRP were 70.0 (64.5, 74.0) years, 17.0 (11.0, 25.5) years, and 2.8 (1.8, 3.1), respectively. Disease activity was remission in 32.3% (10/31) of patients, low disease activity in 16.1% (5/31) of patients, and moderate disease activity in 51.6% (16/31) of patients. Steinbrocker's stage was I in 3.2% (1/31) of patients, II in 16.1% (5/31) of patients, III in 29.0% (9/31) of patients, and IV in 51.6% (16/31) of patients. Many patients were of advanced age and had long-term disease, low to moderate disease activity, and severe joint destruction. The medications used during the follow-up period were as follows: methotrexate (MTX) alone in 9.7% (3/31) of patients, MTX + non-biological disease modifying anti-rheumatic drug (DMARD) in 29.0% (9/31) of patients, MTX + biological DMARD in 9.7% (3/31) of patients, MTX + non-biological DMARD + biological DMARD in 9.7% (3/31) of patients, biological DMARD alone in 9.7% (3/31) of patients, biological + non-biological DMARD in 12.9% (4/31) of patients, non-biological DMARD alone in 9.7% (3/31) of patients, and no anti-rheumatic drug in 9.7% (3/31) of patients. Oral corticosteroid preparations and non-steroidal anti-inflammatory drugs were administered to 38.7% (12/31) and 83.9% (26/31) of patients, respectively. These

Table 1. Demographic parameters of patients with rheumatoid foot

	All patients with rheumatoid foot (n = 31)	Rheumatoid foot patients with sarcopenia (n = 25)	Rheumatoid foot patients with sarcopenia who completed 6 months of FO treatment (n = 10)
Age, years	70.0 (64.5, 74.0)	70.0 (65.0, 74.0)	72.5 (67.0, 75.0)
Height, cm	150.8 (148.6, 158.2)	149.5 (148.0, 154.0)	148.9 (147.4, 151.0)
Weight, kg	40.9 (43.2, 57.3)	46.0 (42.1, 51.0)	48.6 (45.8, 51.0)
Body mass index, kg/m ²	21.1 (19.7, 23.6)	20.7 (18.8, 22.2)	21.9 (20.9, 23.1)
Disease duration, years	17.0 (11.0, 25.5)	18.4 (11.4, 24.0)	17.7 (9.5, 30.8)
DAS28-CRP	2.8 (1.8, 3.1)	2.8 (1.8, 3.1)	3.0 (2.6, 3.2)
Remission	32.3 (10)	28.0 (7)	20.0 (2)
Low disease activity	16.1 (5)	12.0 (3)	10.0 (1)
Moderate disease activity	51.6 (16)	60.0 (15)	70.0 (7)
Steinbrocker's stage			
I	3.2 (1)	0 (0)	0 (0)
II	16.1 (5)	12.0 (3)	20.0 (2)
III	29.0 (9)	28.0 (7)	30.0 (3)
IV	51.6 (16)	60.0 (15)	50.0 (5)
Steinbrocker's class			
II	48.4 (15)	40.0 (10)	30.0 (3)
III	51.6 (16)	60.0 (15)	70.0 (7)
Grip strength, kg	12.5 (8.9, 16.2)	11.5 (8.6, 14.8)	11.0 (9.3, 13.6)
Gait speed, m/s	0.9 (0.9, 1.1)	1.0 (0.9, 1.2)	0.9 (0.8, 0.9)
SMI, kg/m ²	5.2 (4.8, 5.6)	5.2 (4.7, 5.5)	5.2 (4.9, 5.3)

Data are presented as median (lower quartile, upper quartile) or percentage (number).

medications did not change during the follow-up period. The hallux valgus angle was 31.0° (24.0, 42.8), the M1–M5 angle was 31.5° (28.4, 37.0), and the calcaneal pitch angle was 16.0° (12.0, 18.5). In total, 96.8% (30/31) of patients had hallux valgus, 80.6% (25/31) of patients had spread foot, and 96.8% (30/31) of patients had flatfoot, with overlapping foot deformities. **Figure 1** shows a histogram of the severity of rheumatoid foot, and the median JSSF RA foot–ankle scale score was 67.0 (61.5, 78.0). The prevalence of sarcopenia was 80.6% (25/31), and the majority of patients were considered to have secondary sarcopenia because of the recognition of various risk factors, including aging, disease, and rheumatoid foot-related physical inactivity. After excluding 10 patients who underwent foot surgery and other treatments, 15 patients with sarcopenia were treated with an FO. However, muscle mass data for five patients after 6 months of FO treatment were missing, leaving 10 patients in the final analysis. Demographic parameters of rheumatoid foot patients with sarcopenia who completed 6 months of FO treatment are shown in **Table 1**. **Figure 2** shows the SAFE-Q scores

before and after 6 months of FO treatment. QOL, characterized using The Pain and Pain-Related items and the Physical Functioning and Daily Living items, significantly improved from 44.2 (31.6, 73.7) to 70.4 (53.6, 77.3) and from 45.5 (30.1, 59.6) to 68.2 (57.4, 81.3), respectively ($P = 0.02–0.04$, $r = 0.47–0.53$). However, no significant changes in QOL were noted for the Social Functioning items, Shoe-Related items, or General Health and Well-Being items ($P = 0.08–0.21$). **Table 2** shows the respective median values for foot pain, ADL, and physical activity before and after 6 months of FO treatment. The VAS score ($P = 0.01$, $r = 0.57$), the HAQ-DI score ($P = 0.04$, $r = 0.46$), and walking activity ($P = 0.04$, $r = 0.46$) all showed significant improvement, whereas moderate- to vigorous-intensity physical activity ($P = 1.00$) did not. A post-hoc power analysis showed that the powers of the tests ranged from 40.7% to 43.2%.

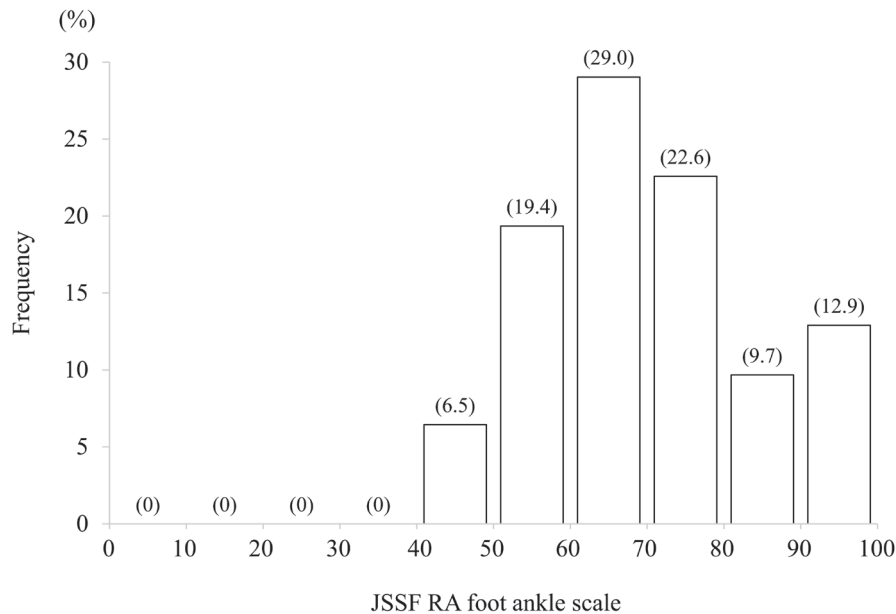


Fig. 1. Histogram of severity of rheumatoid foot. The severity of rheumatoid foot was assessed using the Japanese Society for Surgery of the Foot rheumatoid arthritis (JSSF RA) foot-ankle scale score. The frequency of each severity is presented as a percentage.

DISCUSSION

The present study was performed to investigate the effect of FO treatment on QOL in rheumatoid foot patients with sarcopenia. The majority of the participants in this study had secondary sarcopenia. FO treatment not only increased physical activity but also improved various aspects of foot-specific QOL.

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) is the gold standard tool for assessing QOL; however, it contains few items related to feet and walking.^{25,26)} In contrast, the Arthritis Impact Measurement Scales 2 (AIMS2) and Rheumatoid Arthritis Quality of Life Questionnaire (RAQoL) are frequently used to assess QOL in patients with RA.^{27,28)} The AIMS2 and RAQoL utilize disease-specific scales; however, like the SF-36, they contain few items related to feet and walking. Consequently, because the SF-36, AIMS2, and RAQoL are more whole-body oriented, they would be expected to be less responsive in the context of treatment for rheumatoid foot. In the present study, SAFE-Q was used instead of these QOL assessment tools. Because it is a foot-specific assessment tool, SAFE-Q has often been used for comparing QOL before and after foot surgery in patients with RA.^{29,30)} Moreover, because the participants in the present study had rheumatoid foot, the

use of SAFE-Q may have helped to detect changes over time caused by FO treatment.

FO treatment improved patients' QOL (as indicated by the Pain and Pain-Related items and the Physical Functioning and Daily Living items of SAFE-Q) as well as physical activity. Reduction in foot pain achieved by FO treatment reportedly leads to increased physical activity.⁹⁾ Among physical activities, walking is classified as a light-intensity physical activity³¹⁾ and is reportedly correlated with HAQ-DI as an indicator of ADL disorder caused by RA.³²⁾ The current results revealed that the reduction in foot pain achieved by FO treatment not only improved light-intensity physical activity but also improved HAQ-DI. This result is similar to that obtained in our previous study.⁹⁾ Therefore, because reduction in foot pain and improvement of ADL are directly related, the increase in light-intensity physical activity achieved by FO treatment in this study may have led to improvements in physical QOL (such as the Pain and Pain-Related items and Physical Functioning and Daily Living items of SAFE-Q) in rheumatoid foot patients with sarcopenia. However, our data showed no associations between light-intensity physical activity and physical QOL because our sample size was small. Therefore, although FO treatment improved both physical activity and physical QOL, this does not necessarily indicate the presence of a causal relationship.

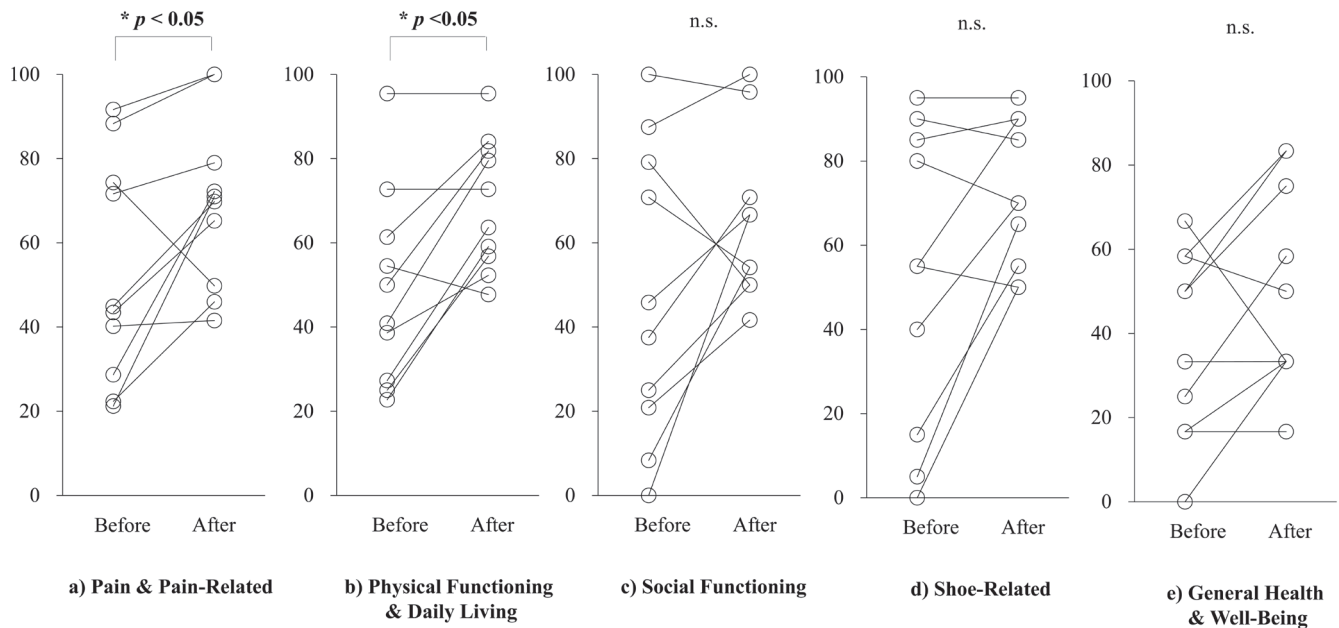


Fig. 2. Scores of the five subscales of the Self-Administered Foot Evaluation Questionnaire (SAFE-Q) before and after 6 months of foot orthosis (FO) treatment. (a) Pain and Pain-Related, (b) Physical Functioning and Daily Living, (c) Social Functioning, (d) Shoe-Related, and (e) General Health and Well-Being. The circles represent the data for rheumatoid foot patients with sarcopenia. The vertical axis shows the scores of the five subscales, ranging from zero (least healthy) to 100 (healthiest) for all subscales. Before, before FO treatment; After, after 6 months of FO treatment; n.s., not significant. $*P < 0.05$, Wilcoxon signed-rank test.

FO treatment did not change the QOL items in the Social Functioning, Shoe-Related, and General Health and Well-Being categories of SAFE-Q. Moderate-intensity physical activity for >150 min/week is generally recommended³³ because it promotes health. In one study, patients with inflammatory arthritis who met this recommendation of above moderate-intensity physical activity reported improvements in both physical QOL and mental QOL compared with patients who did not meet the recommendation.³⁴ In the present study, none of the patients performed any moderate-intensity physical activity before FO treatment, and this had not changed after 6 months of FO treatment. Exercise is recommended to increase physical activity in patients with inflammatory diseases, including RA.³⁵ Previous studies of the effects of resistance or aerobic exercise in patients with inflammatory arthritis have shown improved QOL in all aspects (i.e., physical, mental, and social).^{36,37} Our patients did not undergo rehabilitation treatment during the follow-up period. Therefore, to improve mental and social QOL (such as the items in the Social Functioning category and General Health and Well-Being category) in rheumatoid foot patients with sarcopenia, it may be necessary to increase physical

activity not only by FO treatment but also in combination with another treatment, such as therapeutic exercise. However, exercise for patients with very low exercise capacity, such as our rheumatoid foot patients with sarcopenia, may exacerbate pain and the progression of joint destruction. Future research should examine this issue. Shoe selection is also a common problem in patients with rheumatoid foot because FO treatment does not improve the shape of the foot. For patients with rheumatoid foot, shoes, in combination with the FO, should reduce plantar pressure and stress while stabilizing the foot and ankle. To increase foot and ankle stabilization, extra-depth orthopedic shoes may be effective, especially when aligned with an FO.³⁸ Patients tend to exhibit resistance to wearing these types of shoes because the size, aesthetics, design, weight, and comfort of the shoes are often unacceptable for patients with rheumatoid foot.^{39,40} Therefore, shoes were chosen in this study on the basis of patient acceptability and adherence. However, we previously reported that it was difficult to select shoes that fit the shape of the patient's own foot because of deformity and a limited range of motion caused by the disease process of rheumatoid foot.⁴¹ Many of our patients had deformity caused by severe

Table 2. Comparison of clinical variables of the ten patients who completed 6 months of FO treatment

	Before	After	P-value
Foot pain			
VAS score, cm	4.4 (3.0, 7.1)	2.7 (1.2, 4.5)	< 0.05
ADL			
HAQ-DI	1.5 (1.2, 2.2)	1.0 (0.6, 1.5)	< 0.05
Physical activity			
IPAQ			
Walking activity, MET-minutes/week	264.0 (66.0, 594.0)	990.0 (396.0, 2673.0)	< 0.05
MVPA, MET-minutes/week	0 (0, 0)	0 (0, 0)	n.s.

Data are presented as median (lower quartile, upper quartile).

Before, before FO treatment; After, after 6 months of FO treatment; MVPA, moderate- to vigorous-intensity physical activity; MET, metabolic equivalent; n.s., not significant.

joint destruction, which had already occurred during the development of rheumatoid foot. Consequently, early joint protection, orthotic treatment, and exercise therapy to prevent deformity or the need for surgery to improve the shape of the foot may be effective options for improving QOL items such as those in the Shoe-Related category.

The present study has several limitations. Major limitations included two issues that should be considered regarding the effectiveness of FO treatment on foot-specific QOL found in the present study. First, the participants in the present study comprised a group of patients with rheumatoid foot and a very high rate of sarcopenia, which may not be representative of patients with general RA. Our patients had complex and potentially confounding risk factors regarding the onset of sarcopenia, including age, disease, and rheumatoid foot-related physical inactivity, and the majority of patients were classified as having secondary sarcopenia. However, it was not possible to clarify which factors were related to the onset of sarcopenia. We hypothesized that patients with rheumatoid foot would exhibit less physical activity than patients with general RA because the condition limits mobility, such as walking. We believe that this hypothesis is supported by the high prevalence of sarcopenia observed in the present study. Second, our results were not compared with a control group (e.g., non-rheumatoid foot patients with sarcopenia). We believe that FO treatment for patients with rheumatoid foot is effective even in those without sarcopenia, but is more effective in sarcopenia patients with severe physical inactivity. These issues should be clarified in future research. There are several minor limitations to the current study. First, all the patients were women, because RA has a very high female:male ratio.⁴²⁾ Second, the study had a small sample size and low statistical power. Therefore, the magnitude of the observed effects may have been overestimated to some

extent. Third, subjective self-reported questionnaires were used to assess physical activity. Such questionnaires involve limitations such as recollection bias, potentially leading to overestimation of physical activity.^{43,44)} Fourth, although instructions were given about the use of FO in daily living at baseline, the actual frequency of use during 6 months could not be confirmed. Finally, a standard therapeutic shoe type was not used for FO treatment because the shoes were chosen on the basis of patient acceptability and adherence. However, shoe choice is an essential component of treatment success.

In conclusion, the present study showed that FO treatment not only increased light-intensity physical activity but also improved QOL items in the Pain and Pain-Related category and the Physical Functioning and Daily Living category of SAFE-Q. However, the QOL items in the Social Functioning, General Health and Well-Being, and Shoe-Related categories did not change because the increase in moderate- to vigorous-intensity physical activity and/or prevention of a decline in foot function may have been insufficient. To improve these QOL items, not only FO treatment but also additional treatment and/or early treatment should be provided. More research is needed to establish treatments that improve the QOL of rheumatoid foot patients with secondary sarcopenia.

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CONFLICTS OF INTEREST

The authors have no financial or other competing interests to declare.

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