Original Article

The Use of Total Contact Orthoses in Patients with Foot Problems in Foot Clinic, Siriraj Hospital

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Objective: To study the use rate, outcome, and concomitant factors of the use of the total contact orthoses (TCO) in the Foot Clinic, Siriraj Hospital

Materials and Methods: The present study was a cross-sectional descriptive study collecting data from patient medical records and questionnaires. Patients who had foot problems without impairment of foot sensation and received the TCO from the Foot Clinic between July 2015 and April 2016 were interviewed before and after using the latest TCO for one month.

Results: One hundred seven participants were recruited. Most were female (84.1%) with a median age of 59.3 years. The majority had chronic plantar fasciitis (26.2%), posterior tibial tendon dysfunction (PTTD) (25.2%), hallux valgus (21.5%), or metatarsalgia (21.5%). The TCO user was defined as a participant who had to use the TCO for more than three days per week and for more or equal to 50% of daily walking and standing duration. The use rate was 67.3%. The TCO provides standing and walking stability (p=0.008). For patients with metatarsalgia, using the TCO could significantly reduce pain (p=0.002). Using univariate analysis, many factors were found to be associated with the use of the TCO including having level of convenience of putting on or taking off shoes with TCO at 9 or more (odds ratio 2.66, 95% CI 1.16 to 6.12), having difficulty to find proper shoes that fit with the TCO (odds ratio 0.36, 95% CI 0.15 to 0.89), receiving more than one pair of TCO (odds ratio 4.09, 95% CI 1.51 to 11.05), and having level of comfort satisfaction during the TCO use at 9 or more (odds ratio 3.61, 95% CI 1.55 to 8.40). The latter two factors were found to be associated with the use of the TCO from stepwise logistic regression analysis (adjusted odds ratio 3.39, 95% CI 1.18 to 9.71 and 3.02, 95% CI 1.07 to 8.47, respectively).

Conclusion: The use of the TCO in the Foot Clinic, Siriraj Hospital was 67.3%. Using the TCO could promote walking stability. Factors affecting the use of the TCO included receiving more than the first pair of TCO and having comfort satisfaction level of 9 or more.

Keywords: Use, Total contact orthoses, Total contact insole, Foot problems

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Foot problems are common complaints that bring patients to the rehabilitation medicine department. The common complaints including pain, walking instability, a decrease in walking distance, or even concerns of developing further deformities that may restrict ambulation, limit activities, and influence participation in activities[1,2]. Frequently diagnosed diseases are metatarsalgia, chronic plantar fasciitis, posterior tibial tendon dysfunction (PTTD), hallux valgus, non PTTD flat feet (pes planus), high arch feet (pes cavus), and osteoarthritis of the foot joints. Deformities such as hammer toe, mallet toe, and overriding toe are also seen[3,4]. Foot orthosis is one effective treatment for these problems[5-12]. Insoles are often used to promote cushion as well as support and redistribute weight. However, prefabricated insoles sometimes cannot provide appropriate size and contour to approximate the plantar surface of the foot to all patients with various structural or functional deficits. Generally, custom-made insoles can provide better intimate fit, longevity, and adjustability[5]. Therefore, customized total contact orthoses or insoles (TCO) are regularly prescribed.

Orthoses usually provide therapeutic effect

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when they are worn, therefore, compliance is one important determinant. Previous studies reported that compliance of custom-made orthoses for foot pain in plantar fasciitis, rheumatoid arthritis (RA), painful pes cavus, and hallux valgus were generally good[6,7,11]. The least compliant one was foot pain from RA. Thirty-one percent of the subjects did not use the orthoses in the previous 30 days while owning one for 36 months[13]. However, each study defined compliance differently.

Around 200 pairs of TCO were prescribed annually for various conditions in Foot Clinic, Siriraj Hospital. Manufacturing required skilled professionals and multiple time-consuming processes. Each pair costs up to 80 USD. An earlier study conducted in the Foot Clinic about the use rate of custom-made shoes in non-diabetic foot patients showed the use being as low as 47.8%[14]. The present study aimed to identify the use rate of patients who received a TCO from the Foot Clinic, Siriraj Hospital, which has never been established before. The result and concomitant factors with the use were also studied to improve the service quality and lean process.

Objective

The main purpose was to explore the use rate and result of the use of a TCO in the Foot Clinic, Siriraj Hospital, including the factors associated with the use of a TCO.

Materials and Methods

Patients who had foot problems and received a TCO from the Foot Clinic, Siriraj Hospital between July 2015 and April 2016 were recruited into the study by referrals from non-investigator physiatrists.

The inclusion criteria were being older than 18 years old, having foot pain, or having walking instability. Patients who could not report symptoms due to having foot numbness (impaired 5.07 Semmes-Weinstein test) or being unable to communicate were excluded.

The present study was a cross sectional descriptive study. Based on the previous study, the use of custom-made shoes in patients with foot deformities in the Foot Clinic, Siriraj Hospital was 47.8%[14]. The sample size calculation was determined by using n Query Advisor 5.0 program. Type 1 error and type 2 error were set at 5% and 10%, respectively. Ninety-six patients were statistically required.

Participants were interviewed using questionnaires that contained three parts. The first part was background information including age, gender, body weight, height, payment methods, diagnosis (each patient could have more than one diagnoses), whether they obtained physician's explanation regarding benefits from using a TCO, and participation in the TCO selection. The second part was set to retrieve reported information about the patients' perceived pain and stability level during barefoot walking (before receiving the latest pair of TCO), average daily standing and walking time, TCO prescription with any modification, and the number of TCO the patients had received. These parts were collected from the medical records and patients themselves in the visit that they received the new pair of orthoses. The last part was interviewed at one month follow-up, about the routine, consisting of average wearing time in daily percentage and day(s) per week, difficulty in finding shoes that fit properly with the TCO, pain and stability level while using the TCO, complications from wearing the TCO (callus or skin thickening and wound), perceived level of convenience of putting on and taking off shoes with the TCO. Satisfactions in five aspects including comfort, perspiration, cosmetic appearance, ease of maintenance, and overall were also assessed. Level of foot pain was defined by using numeric rating scale scoring from 0 (no pain at all) to 10 (worst pain). Walking stability was also rated from 0 (worst stability) to 10 (best stability) by the participants following the method done in previous studies conducted in the Foot clinic, Siriraj Hospital[14,15]. For the level of satisfaction and convenience of putting on and taking off shoes with the TCO, the score ranges from 0 (no convenience at all or not satisfying at all) to 10 (most convenient or most satisfying).

The use rate was the primary outcome. The present study defined the user as a patient who used a TCO more than three days per week and more or equal to 50% of daily walking and standing duration. The patients who were non-users were requested to give the reason, why they rejected the orthoses. Lastly, all patients were asked if there was any suggestion for improvement.

The data were collected from the latest pair of TCO that patients received from the Foot Clinic. Patients who could not come for a 1-month routine follow-up were interviewed via phone by a researcher. The interviews were performed by the researchers who were not the patients' treating physicians.

The present study protocol was approved by the Siriraj Institutional Review Board (SI430/2015) and supported by Siriraj Research Development Fund.

Statistical analysis

Statistical analysis was done using PASW Statistics (SPSS), version 18.0 (SPSS Inc., Chicago, IL, USA). The data including gender, health benefits, diagnoses, TCO modifications, number of TCO received, obtaining physician's explanation regarding benefits from using TCO, participation in TCO selection, complications from using TCO, and number of patients who defined as the user and non-user were reported in both number and percentage. Continuous variables such as body mass index (BMI) was calculated in mean and standard deviation. Levels of foot pain and walking stability both before and after using TCO were reported in median (range).

Mann-Whitney U test was used to differentiate pain and stability level between the user and non-user groups. Chi-square test was applied to explore the difference of gender, diagnoses except the diagnosis of high arch foot, obtaining physician's explanation regarding the benefits from using a TCO, having participated in TCO selection, receiving TCO modification, receiving more than one pair of TCO, having difficulty in finding proper shoes to fit with the TCO, convenience of putting on or taking off shoes with the TCO, and satisfaction with the TCO between user and non-user groups. For the smaller calculating number, Fisher's exact test was used. Finally, Stepwise Logistic Regression Analysis was used to explore the factors associated with the use of TCO. A p-value of less than 0.05 was considered statistically significant.

Results

One hundred seven patients were recruited. All of them met the eligibility criteria and completed the three parts of the questionnaires. Data from all the participants were analyzed. There were 17 males and 90 females with a mean age of 59.3 years old. The average BMI was 24.5 kg/m^2. Only 14 patients (13.1%) paid by themselves, the rest of the patients had various kinds of health benefits covering their expenses. Most of the cases were chronic plantar fasciitis (26.2%), PTTD (25.2%), which more than half of them were in stage 2 and if a patient had different stage of PTTD of each side, we would account that patient's severity by the worse side, hallux valgus (21.5%), and metatarsalgia (21.5%). Almost all patients obtained an explanation on the benefit of using TCO (98.1%), and most of the patients participated in the TCO selection (84.1%). The average standing and walking time of all patients was five hours per day. The levels of foot pain and stability on barefoot walking (before receiving the TCO) were generally high (median 7, range 0 to 10). Some patients had more than one pair of TCO, ranged from two to ten, but more than half of them just received their first pair. Twenty-nine pairs of TCOs were modified (27.1%), and the component frequently added was medial arch support (44.8%). The rest were metatarsal cushion (10.3%), heel cushion (10.3%), pressure relief (10.3%), medial wedge (10.3%), lateral wedge (10.3%), toe filler (3.4%), and insole lift (3.4%).

According to the definition of user, which are the one using the TCO more than three days per week and more than or equal to 50% of the daily walking and standing duration, there were 72 patients (67.3%) classified as user. The level of foot pain in all diagnoses did not decrease significantly between the user and non-user groups. Subgroup analysis by each diagnosis was done in four most common conditions. Metatarsalgia was the only condition that had statistical significance between the user and non-user groups in pain level before receiving the TCO and pain level difference (calculated by numeric rating scale [NRS] before receiving the TCO minus NRS after receiving the TCO, positive value means decreased pain) ($p=0.002$) (Table 1). The median (P25, P75) level of stability during walking with the TCO recorded by NRS in the user group was 9 (8, 10), which was statistically significant higher compared to 8 (7, 10) in the non-user group ($p=0.006$). The stability difference (calculated by NRS after receiving the TCO for one month minus NRS before receiving the TCO, a positive value means increased stability) compared in user and non-user group was also statistically significant ($p=0.008$) (Table 2).

Many factors were found to be associated with the use of a TCO when using univariate analyses. Those were receiving more than one pair of TCO, having difficulty in finding proper shoes to fit with the TCO, the high level of convenience of putting on or taking off shoes with a TCO, and the high level of comfort satisfaction ($p<0.05$) (Table 3). The stepwise logistic regression analysis revealed that having received more than the first pair of TCO and high level of comfort satisfaction were statistically related to the use of TCO. Patients who had received more than one pair of TCO were likely to use their TCO more frequently than those who had just received their first pairs (adjusted odds ratio 3.39, 95% CI 1.18 to 9.71). Additionally, patients who reported comfort satisfaction level of 9 or more had a higher chance to use TCO than those who rated lower than 9 (adjusted odds ratio 3.02, 95% CI 1.07 to 8.47).

Table 1. Levels of foot pain before receiving TCO and after receiving TCO in all diagnoses and in 4 frequent diagnoses

Levels of foot pain	User (n=72) Median (P25, P75)	Non-user (n=35) Median (P25, P75)	p-value[b]
Levels of foot pain in all diagnoses			
Before receiving TCO	7 (5, 8)	6 (3, 8)	0.116
After receiving TCO	1 (0, 2.75)	1 (0, 3)	0.919
Differences of pain levels[a]	5 (3, 7)	4 (2, 7)	0.210
Levels of foot pain in each frequent diagnosis			
Chronic plantar fasciitis			
• Before receiving TCO	7.5 (4.75, 8)	7.5 (6.25, 10)	0.601
• After receiving TCO	1.5 (0, 2)	1 (0, 3)	0.980
• Differences of pain levels[a]	5.5 (2.5, 7)	6.5 (4.25, 7.75)	0.469
Posterior tibial tendon dysfunction (PTTD)			
• Before receiving TCO	6 (5, 8)	7 (4.25, 8)	0.775
• After receiving TCO	2 (1, 4)	1 (0, 4.25)	0.449
• Differences of pain levels[a]	3 (2, 5)	5.5 (1, 7)	0.307
Metatarsalgia			
• Before receiving TCO	7 (5.5, 9)	4.5 (1.75, 7)	0.036
• After receiving TCO	0 (0, 2)	1 (0, 5.75)	0.516
• Differences of pain levels[a]	6 (4, 7.5)	2 (0.5, 2.75)	0.002*
Hallux valgus			
• Before receiving TCO	7.5 (6, 8.75)	7 (5, 8)	0.379
• After receiving TCO	0 (0, 2.75)	0 (0, 3)	0.928
• Differences of pain levels[a]	6 (2.75, 7.75)	5 (2, 7)	0.487

TCO=total contact orthoses

Levels of foot pain and walking stability were recorded by numeric rating scale

[a] Calculated by score before receiving TCO minus score after receiving TCO (positive value means the patients had less pain after receiving TCO), [b] Using Mann-Whitney U test, * p<0.05 is statistical significance

Table 2. Levels of standing and walking stability before receiving TCO and after receiving TCO in all diagnoses, levels of convenience of putting on/taking off shoes with TCO and satisfaction levels with TCO

	User (n=72) Median (P25, P75)	Non-user (n=35) Median (P25, P75)	p-value[b]
Levels of standing and walking stability			
Before receiving TCO	7 (4, 8)	7 (5, 10)	0.355
After receiving TCO	9 (8, 10)	8 (7, 10)	0.006*
Differences of stability levels[a]	2 (0, 5)	1 (0, 3)	0.008*
Levels of convenience of putting on/taking off shoes with TCO	9.5 (8, 10)	8 (5, 10)	0.003*
Satisfaction levels with TCO			
Comfort	9.5 (8, 10)	8 (7, 10)	0.003*
Perspiration	9 (7.25, 10)	9 (7, 10)	0.880
Cosmetic appearance	9 (8, 10)	9 (8, 10)	0.778
Ease of maintenance	9 (8, 10)	9 (8, 10)	0.480
Overall	9 (8, 10)	9 (8, 10)	0.088

TCO=total contact orthoses

a Calculated by score after receiving TCO minus score before receiving TCO (positive value means the patients had higher stability level after receiving TCO), b Using Mann-Whitney U test, * p<0.05 is statistical significance

Table 3. Univariate Analysis of demographic data, convenience of putting on/taking off TCO and satisfaction with TCO

	User [n=72 (67.3)] n (%)	Non-user [n=35 (32.7)] n (%)	p-value
Sex			
Male	9 (12.5)	8 (22.9)	0.169[a]
Female	63 (87.5)	27 (77.1)	
Health benefits			
Not own expenses	63 (87.5)	30 (85.7)	0.769[b]
Own expenses	9 (12.5)	5 (14.3)	
Diagnoses			
Chronic plantar fasciitis	20 (27.8)	8 (22.9)	0.587[a]
Posterior tibial tendon dysfunction	19 (26.4)	8 (22.9)	0.693[a]
Hallux valgus	17 (23.6)	6 (17.1)	0.445[a]
Metatarsalgia	12 (16.7)	11 (37.4)	0.081[a]
Non-PTTD flat feet	10 (13.9)	6 (17.1)	0.658[a]
High arch foot	6 (8.3)	6 (17.1)	0.201[b]
Others	17 (23.6)	6 (17.1)	0.445[a]
Obtaining physician's explanation regarding benefits from using TCO	71 (98.6)	34 (97.1)	0.549[b]
Having participated in TCO selection	60 (83.3)	30 (85.7)	0.752[a]
Receiving TCO modification	16 (22.2)	13 (37.1)	0.103[a]
Number of TCO received			
First pair	39 (54.2)	29 (82.9)	0.004[a]
More than first pair	33 (45.8)	6 (17.1)	
Having difficulty in finding proper shoes to fit with TCO	14 (19.4)	14 (40.0)	0.023[a]
Convenience of putting on/taking off shoes with TCO			0.020[a]
<9	28 (38.9)	22 (62.9)	
≥9	44 (61.1)	13 (37.1)	
Satisfaction with TCO			
Comfort			0.002[a]
• <9	23 (31.9)	22 (62.9)	
• ≥9	49 (68.1)	13 (37.1)	
Perspiration			0.883[a]
• <9	34 (47.2)	16 (45.7)	
• ≥9	38 (52.8)	19 (54.3)	
Cosmetic appearance			0.671[a]
• <9	34 (47.2)	15 (42.9)	
• ≥9	38 (52.8)	20 (57.1)	
Ease of maintenance			0.595[a]
• <9	25 (34.7)	14 (40.0)	
• ≥9	47 (65.3)	21 (60.0)	
Overall			0.091[a]
• <9	21 (29.2)	16 (45.7)	
• ≥9	51(70.8)	19 (54.3)	

TCO=total contact orthoses; PTTD=posterior tibial tendon dysfunction

Using [a] chi-square test and [b] Fisher's exact test

Callus or skin thickening, and wound were the main concern and complications from using a TCO. Only three patients in the user group reported an increase of callus, while there was no patient in non-user group that had this problem. No single patient reported having wound caused by using a TCO nor bleeding.

The reasons for not using the TCO reported by the patients in the non-user group could be divided into four categories, using only outdoor or for long distance walking (54.3%), improper fit of the TCO to feet or to shoes (20.0%), using only in sport activity (14.3%), and spontaneous pain resolution without having to use the orthoses (0.03%). The most frequent suggestions from the patients were about the TCO material such as durability and inflexibility of TCO surface (28% with 27% for the user group and 1% for the non-user group) and the bulky appearance of the TCO (12% with 10% for the user group and 2% for the non-user group).

Discussion

TCO has been prescribed for a great variety of foot problems both diabetic and non-diabetic and has proven to be effective[7]. The present study aimed to investigate patients with foot problems who had intact feet sensation because these patients did not need to use TCO at all time, unlike patients with diabetic feet who must use TCO whenever their feet bear weight to prevent or treat ulcers. Since pain in this population is commonly related to the length of time they are standing and walking, a TCO can help redistribute the weight and relieve excessive pressure from sensitive and painful areas[7]. Evaluation in almost every aspect would be different between these two groups of patients. Therefore, only patients who have had foot problems without numbness were selected in the present study.

Definition of the use of TCO has not been established yet. While there were studies about TCO for many conditions, almost all were randomized controlled trials focusing on evaluating the effectiveness. Each study defined compliance differently. No specific amount of suitable duration and frequency of using time is identified yet. There were only studies of Jannink et al[16] about the use of orthopedic shoes in patients with degenerative disorders of foot, Paechareon and Chadchavalpanichaya[14] about the use of custom-made shoes in patients with foot deformities at the Foot Clinic, Siriraj Hospital, and Dacharux and Chadchavalpanichaya[15] about the use of University of California Berkeley Laboratories Shoe Insert (UCBL) orthosis in patients with flat foot in the Foot Clinic, Siriraj Hospital, that defined the use similarly as using at least 50% of daily standing and walking for more than three days a week. The authors expected that this would be the proper time for outdoor activities requiring longer standing and walking period, which can cause a more continuous weight loading to feet.

The present study revealed that 67.3% of patients used their TCO regularly at one month after delivery. Use rate varied from one randomized controlled trial to another as all of them measured compliance as the secondary outcome at different point of time[6,10-13]. The highest compliance was as high as 96%[11]. On the other hand, the lowest defined as non-use was 31%[13]. However, the present study's result might not be able to compare to those previous studies since those were randomized controlled trials (RCTs) with TCO as intervention and patients were requested to use TCO as scheduled. When compared to the use rate of other orthoses manufactured from the Foot Clinic, Siriraj Hospital, custom-made shoes (47.8%)[14] and UCBL orthoses (63%)[15] with the same definition of use and similar population, TCO use rate is relatively higher. Two main reasons might explain this issue. First, TCO must be inserted into the shoes. Therefore, outer appearance is not the main concern unlike custom made shoes[14]. The other reason could be that TCO is made from more flexible material than UCBL orthoses. It provides more comfort and offers less restriction to the motion.

For stability result after using TCO, it showed that patients who used the TCO regularly had better stability compared to patients who did not regularly wear. This result is consistent with a previous study that indicated that TCO could control, stabilize, and support foot deformities through total contact concept[5], especially in patients with abnormal arches of the foot[6,17]. The present study also reveals that there is no significant pain relief from using a TCO in almost all diagnoses except metatarsalgia. It was found that patients with metatarsalgia in the user group have higher pain level initially and gain more pain reduction after using a TCO compared to the non-user group. It is possible that a TCO provide cushion and relieve pressure from high plantar loading areas by evenly redistributing weight-bearing pressures covering the entire plantar surface[6]. In other diagnoses such as chronic plantar fasciitis, other treatments are also required. A TCO is usually prescribed for prevention of recurrence in chronic plantar fasciitis. This result could be the guidance on

TCO prescription in the future. However, this study was not designed to investigate the effectiveness of TCO.

Many factors were found to be associated with the use of a TCO. However, only two factors were found to be related when using Stepwise Logistic Regression Analysis. These factors were receiving more than the first pair of TCO and a comfort satisfaction level of 9 or greater. It can be implied that their previous pair(s) of TCO could help with their problems. For patients who reported a comfort satisfaction level of 9 or more, they would use a TCO approximately three times more than the ones who reported a comfort satisfaction level lower than 9. Therefore, processes that related to providing TCO comforts such as material selection, contour adjustment, and pressure relief are crucial elements to the use of TCO.

Callus or skin thickening was the only adverse effect of using a TCO, which was also reported in other studies[6,11]. Most TCOs manufactured from the Foot Clinic were made with EVA (Ethylene-Vinyl-Acetate) foam, which could cause some friction. Adjusting for more intimate fit or adding less friction material could be useful.

However, the present study had some limitations. First, it was not designed to evaluate patients who use TCO only in a sports activity or for long distance or outdoor walking. These patients accounted for more than half of the patients who were classified as non-user. A further study aimed at these patients could provide more information. The other limitation was that the stability levels were collected by patients' ratings. No standardized stability measurement tool was applied. An application of good stability measurement in further studies might provide more information about the stability provided by a TCO.

Conclusion

The use of a TCO in the Foot Clinic, Siriraj Hospital was 67.3%. Factors associated with the use were receiving more than the first pair of TCO and high comfort satisfaction.

What is already known on this topic?

TCO is one effective treatment for various foot conditions and often prescribed. The use rate of TCO is generally high, but it varies in each diagnosis. Measurements to determine the use were also diverse and inconclusive.

What this study adds?

The use of a TCO in the Foot Clinic, Siriraj Hospital was 67.3%. Using TCO could decrease pain in patients with metatarsalgia. High comfort satisfaction with a TCO resulted in good compliance.

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Conflicts of interest

The authors declare no conflict of interest.

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