Corrective Shoes and Inserts as Treatment for Flexible Flatfoot in Infants and Children*

BY DENNIS R. WENGER, M.D.†, SAN DIEGO, DONALD MAULDIN, M.D.‡, GAIL SPECK, M.D.¶, DEAN MORGAN, C.PED.‡, DALLAS, TEXAS, AND RICHARD L. LIEBER, PH.D.†, SAN DIEGO, CALIFORNIA

From the Texas Scottish Rite Hospital, Dallas, and the Division of Orthopedics, University of California at San Diego, San Diego

ABSTRACT: We performed a prospective study to determine whether flexible flatfoot in children can be influenced by treatment. One hundred and twenty-nine children who had been referred by pediatricians, and for whom the radiographic findings met the criteria for flatfoot, were randomly assigned to one of four groups: Group I, controls; Group II, treatment with corrective orthopaedic shoes; Group III, treatment with a Helfet heel-cup; or Group IV, treatment with a custom-molded plastic insert. All of the patients in Groups II, III, and IV had a minimum of three years of treatment, and ninety-eight patients whose compliance with the protocol was documented completed the study. Analysis of radiographs before treatment and at the most recent follow-up demonstrated a significant improvement in all groups (p < 0.01), including the controls, and no significant difference between the controls and the treated patients (p > 0.4).

We concluded that wearing corrective shoes or inserts for three years does not influence the course of flexible flatfoot in children.

Flexible flatfoot is so common a disorder in children that it has been thought by some to be an anatomical variant, related to ligamentous laxity, that may not need treatment7-10,11,15. Others have believed that flatfoot is a precursor to a painful problem with the foot in adulthood and that the condition should be vigorously treated during early childhood4-7.

Flat feet are often detected by a child’s parents, who may be concerned because they know of adults for whom the condition is painful. The concern is a common reason for orthopaedic consultation. Many parents request treatment because the concept of corrective shoes has been firmly established in our culture. Many of the parents wore corrective shoes in childhood, and they may assume that the shoes were responsible for any improvement that they may have noted.

Despite concerted attention to the subject, no scientific study has established whether corrective shoes or inserts in shoes affect the course of flexible flat feet. Previous studies either have been retrospective or, when described as prospective, have not included randomization of patients to treatment and control groups or the use of matched controls23.

In 1977, we conducted a prospective study to determine whether treatment with corrective shoes and inserts changes the course of flexible flatfoot in children. We enrolled forty patients, but we were forced to abandon the trial because the parents of the patients, who had been selected from a clinical population, had a poor understanding of the study, and the compliance with treatment was unsatisfactory. We were also criticized by the Prescription Footwear Association because the shoes were not fitted by certified pedorthists.

In 1978, we redesigned the study, incorporating the expertise of the Prescription Footwear Association for fitting the shoes. To minimize problems with compliance, we recruited only children who had typical flat feet and who were referred by private pediatricians.

This prospective randomized trial was designed to determine whether corrective shoes or inserts affect the course of flexible flatfoot in children.

Materials and Methods

Eligibility for the Study

One to six-year-old children who had flexible flat feet, as diagnosed by their pediatricians, were referred to the Texas Scottish Rite Hospital Flatfoot Clinic, Dallas, which was organized for the sole purpose of conducting this study. One hundred and twenty-nine children met the criteria for entry and were enrolled in the study. The children had to be less than six years old at the time of enrollment (Fig. 1), but if they passed their sixth birthday during the period of follow-up they still remained in the study.

Enrollment began late in 1978 and was completed late in 1980, when enough children had been enrolled to ensure a large enough sample for each group. To allow a minimum three-year follow-up for all patients, the study continued until early 1984. A move by the senior one of us (D. R.
The private pediatricians in our community were informed about our prospective randomized trial and were asked to refer children who had flexible flat feet. Because these patients were referred for the specific problem that was of concern to the parents, the families were very receptive in terms of following the specific treatment that we assigned, and, early in the study, the follow-up schedule was rarely disregarded. However, during the six-year study period thirty-one patients had to be dropped from the study, most because of non-compliance and a few because their families moved from the state.

Initially, 131 children were examined to confirm that they had flexible flat feet. The diagnosis was based on a valgus position of the heel and poor formation of the arch, as observed by the referring physician and by us. The patient was first observed from the rear while weight-bearing, to confirm that the heel was in a valgus position. Then the child was asked to stand on tiptoe, and in every patient the heel shifted into a varus position, confirming flexibility of the subtalar joint.
Tightness of the heel cord was documented by measuring the degree of passive dorsiflexion of the ankle with the talonavicular joint locked in inversion. Laxity was scored using a scale of 1 to 5, based on the criteria of Wynne-Davies (Fig. 2). In addition, several subjective factors were documented, including the parental reports of pain in the calf or foot. Also, when the patients were entered into the study, we measured the foot-progression angle (to document the degree of toeing-in or toeing-out) and the degree of genu varum or genu valgum.

The foot-progression angle is defined as follows. For a person walking in a straight line, the angle of each foot in relation to that line is measured in degrees. If the person is toeing-in, the value in degrees is stated as a negative (for example, $-25$ degrees). If the person is toeing-out, the value is stated as a positive (for example, $+25$ degrees).
Any child who had, or proved to have, a neurological condition (cerebral palsy or muscular disease) or a syndrome that was known to be associated with excessive laxity of the joints (Down or Ehlers-Danlos syndrome), or who had had prior treatment with corrective footwear or inserts, was excluded from the study. One hundred and twenty-nine of the 131 patients who were referred to us met the criteria for entry into the study.

Special Studies at the Time of Entry

Anteroposterior and lateral radiographs of the feet were made with the child standing. Every child met one of two criteria:

1. An angle between the talus and the sole of the foot (Fig. 3-A) of more than 35 degrees. (This angle has also been described as the plantar flexion angle of the talus and as the talohorizontal angle.) The normal value in children is 26.5 ± 5.3 degrees.

2. An angle between the talus and the first metatarsal (Fig. 3-A) of more than 10 degrees. In a normal foot, this angle is 0 degrees or slightly negative. A cavus foot has a markedly negative value. A flatfoot that is associated with a sag at the talonavicular or naviculocuneiform joint has a positive angle.

The conventional talocalcaneal angle (Fig. 3-B) was also recorded initially, but it was not used as a criterion at the time of interim follow-up because of difficulty in interpreting and measuring anteroposterior radiographs that are made while a child is wearing a corrective shoe that has a steel shank.

The subjects were photographed while standing on a custom-designed mirror-table, to allow simultaneous assessment of the front, top, side, and rear views of the foot during weight-bearing. This allowed a clear view of the plantar surface of the foot and provided data for subsequent comparison of the foot before and after treatment.

Assignment to Groups

According to a protocol that had been approved by the hospital's institutional review board, the patients were assigned to treatment groups (I, II, III, and IV) by a nurse who picked numbers randomly. Of the 129 patients who were initially enrolled in the study, thirty-one were assigned to the control group; thirty-two were treated with corrective shoes; thirty-five, with Helfet heel-cups; and thirty-one, with University of California Biomechanics Laboratory inserts. Thirty-one patients were later dropped from the study due to poor compliance (twenty-five patients), relocation out of the state (five patients), or development of a neurological disorder (one patient). Thus, ninety-eight patients met the strict standards for compliance and were followed for three years or more (Table I). In sixteen patients, only one foot met the radiographic criteria for entry into the study, so the number of feet that were included in the analysis was not always double the number of patients.

In Group I, twenty-one controls (thirty-nine feet) wore standard-last leather shoes — that is, so-called orthopaedic shoes — that had no corrective features built in. The shoes were normal in contour (not straight-last) and had a steel shank.

The patients in the other three groups wore identical shoes, with the following exceptions. The twenty-eight patients (fifty-four feet) in Group II wore shoes that had a Thomas heel, a long medial counter, and a navicular pad. The twenty-seven patients (forty-nine feet) in Group III wore a Helfet heel-cup in shoes that had a Thomas heel and a long medial counter. The twenty-two patients (thirty-eight feet) in Group IV wore shoes that had a University of California Biomechanics Laboratory custom-molded plastic insert.

Follow-up

Interim

All patients were re-examined at three-month intervals in the Flatfoot Clinic by the study team, which included a research nurse, an orthopaedic surgeon, and a certified pedorthist. Through arrangement with the Prescription Footwear Association, the pedorthist was present for all visits to ensure that all of the corrective shoes were fitted according to the standards and specifications of that association.
Great care was taken to maintain a proper fit of the shoes, since one of the criticisms of the earlier, failed trial had been that the fit of the shoes might not have been correct or might not have been maintained satisfactorily, or both. The fit of the shoes and of the corrective inserts was confirmed at each visit. If it was not correct, new shoes or inserts, or both, were provided. Compliance was documented by observing the wear of the shoes. Non-compliant patients were dropped from the study.

To allow efficient, correct shoe-fitting, an inventory of 500 pairs of shoes was kept on portable carts in the central storage area of the hospital and was brought for each follow-up visit. All of the shoes were provided by the Prescription Footwear Association. Data on growth of the feet and the frequency that the shoe size changed because of the growth were recorded.

Every six months, repeat anteroposterior and lateral radiographs of the feet were made for each patient while the child stood barefoot and also while the child stood wearing the corrective shoes (Fig. 4). The photographic study was also repeated at six-month intervals.

To ensure unbiased scoring, all records, photographs, and radiographs were stored in a confidential file by the research nurse. At the time of the three-year follow-up, clinical, radiographic, and photographic analyses were completed with the examiners in ignorance of the child's treatment group.

Most Recent

To assess the clinical improvement in the appearance of the foot, the orthopaedic surgeons and certified pedorthist compared the clinical photographs that had been made at the beginning of the study with those that were made at the most recent follow-up. This was done in a blinded manner — that is, without knowledge of the patient's name or treatment group. The paired sets of photographs (initial and most recent) were graded on a scale of 1 to 4, with 1 meaning greatly improved; 2, improved; 3, no change; and 4, worse. This was done to determine if there was a correlation between clinical impressions and the radiographic parameters.

Statistical Analysis

The data from the radiographic measurements were transcribed from standardized forms onto a PDP-11/73 computer (Digital Equipment, Maynard, Massachusetts) for analysis using the BMDP statistical package. Assumptions of the parametric statistical methods that were used (as will be described) were tested explicitly by testing for equality of variance between groups using BMDP program P7D. The log of the mean was plotted against the log of the standard deviation for the four experimental groups. On the basis of this analysis, it was determined that none of the data sets required transformation for variance stabilization. In addition, the distribution of all data sets was tested for normality and symmetry by calculating skew $g_1$ and kurtosis $g_2$ for each experimental group. As a result, all radiographic variables were log-transformed, which resulted in a normally distributed, symmetrical data set and satisfied the assumptions of the parametric tests.

In order to test the null hypothesis that the various types of treatment had no effect on the change in the radiographic angles, a one-way analysis of covariance was used, specifying the initial radiographic angle as the covariant (BMDP program P2V). This parameter was implemented as a covariant on the basis of the observation that the initial radiographic angle differed significantly between groups ($p < 0.01$). Assumptions of the analysis of covariance (equality of slopes between groups and equality of variances between groups) were explicitly tested and shown to be satisfied.

Two separate models for analysis of covariance were used because, in a few patients (sixteen of ninety-eight), only one foot was measured. The first model was used when both feet were evaluated (eighty-two of ninety-eight children). In this model, the data were grouped by treatment, the foot (left or right) was used as the within factor, and the initial radiographic angle was used as the covariant. In the second model, the data were grouped by treatment.
(Groups I to IV), there was no within factor, and the initial radiographic angle was again used as the covariant. The two methods yielded identical results. Thus, for simplicity, the significance levels that were obtained using the first two methods yielded identical results. Thus, for simplicity, the significance levels that were obtained using the first model are discussed in the text.

To determine whether the clinical impression, as determined from photographs, was related to the radiographic variable, multivariate discriminant analysis was performed between the four experimental groups, using F-to-enter = 3.000 and F-to-remove = 2.995. Finally, in order to understand the course of the flatfoot better, stepwise linear regression was used to determine which of the numerous measured variables contributed most to the change in a particular radiographic angle. Results were considered significant at $p < 0.05$.

To protect against Type-II error (accepting a false null hypothesis), a priori statistical power analysis was performed to select the size of the sample that was needed for the experimental design. With standard equations, size of the sample was calculated using four treatment groups, a population standard deviation of 5 degrees, a desired difference to detect of 5 degrees, a significance level of 0.05, and a power of 0.9. Under these conditions, twenty samples were needed for each group. Expecting that some children would not complete the study because of failure to cooperate, we planned to enroll at least thirty children in each group, hoping that approximately twenty in each group would complete the study. In this way, if we accepted the null hypothesis when $p > 0.05$, we would be 90 per cent sure that we were not committing a Type-II error.

**Results**

Data were collected on all 129 patients over the six-year period of study. Thirty-one patients who did not return for all of the follow-up visits, did not wear the shoes regularly, or moved from the state were dropped from the study. The remaining ninety-eight patients had a minimum follow-up of three years and complete clinical, radiographic, and photographic records (Table II).

The radiographic severity of the flatfoot in each treatment group at the time of entry into the study and the most recent follow-up is documented in Figures 5, 6, and 7.

An analysis of covariance between the four groups, using the initial radiographic angle as the covariant, revealed no significant difference between groups for change in the angle between the talus and the sole of the foot ($p > 0.4$), in the angle between the talus and the first metatarsal ($p > 0.5$), or in the talocalcaneal angle ($p > 0.5$). (Figs. 8, 9, and 10). For all radiographic parameters, there was a positive correlation between the initial angle and the change in radiographic angle ($p < 0.001$), demonstrating that the patients who had a large initial angle had the most change, independent of the method of treatment. Discriminant analysis between experimental groups, based on the impression derived from the photographs, resulted in a relatively poor discriminating function. Only two variables (initial talocalcaneal angle and change in the angle between the talus and the sole of the foot) were entered into the discriminating equation. Most radiographic angles had a great deal of covariance. The ability of the discriminating equation to classify various classes into the correct group retrospectively ranged from a high of 60 per cent (for the group that was clinically described as worse) to a low of 12 per cent (for the group that was classified as having no change).

Stepwise linear regression again revealed that the greatest contributor to change in the radiographic angle was the initial radiographic angle. Interestingly, initial laxity also contributed to change in the radiographic angle, with the patients who had the greatest initial laxity having the most improvement. Serial correlation coefficients for the three variables ranged from 0.33 (change in the angle between the talus and the first metatarsal) to 0.47 (change in the talocalcaneal angle), indicating that these correlations with laxity were relatively weak.
FIG. 5
Bar graphs documenting the severity of flatfoot in each group, as measured by the lateral angle between the talus and the sole of the foot, at the time of both entry into the study and the most recent follow-up. UCBL = University of California Biomechanics Laboratory.

FIG. 6
Bar graphs documenting the severity of flatfoot in each group, as measured by the lateral angle between the talus and the first metatarsal, at the time of both entry into the study and the most recent follow-up. UCBL = University of California Biomechanics Laboratory.
CORRECTIVE SHOES AND INSERTS AS TREATMENT FOR FLEXIBLE FLATFOOT

807

VOL. 71-A, NO. 6. JULY 1989

Subjective Impressions

Some parents reported that the children — even those in the control group — had less pain in the feet, fewer aches in the calves, and better gait after they began wearing the shoes. The reports were difficult to validate and often seemed related to parental personality. Cheerful, cooperative parents were more likely to report relief of pain. Also, the recipient of the data seemed to affect the report. The research nurse often received a somewhat different report than did the orthopaedic surgeon or the pedorthist.

Because we were unable to accurately quantify the reported improvement in gait or decrease in aching, these factors were not analyzed further.

Discussion

A recent study demonstrated that normal preschool children commonly have poor formation of the longitudinal arch and that the arch gradually improves with growth. Whether children who have marked flatfoot also have spontaneous improvement with growth, and whether the degree of improvement can be affected by treatment, have not been previously determined, to our knowledge.

Bleck and Berzins reported the results of treatment with University of California Biomechanics Laboratory inserts and Helfet heel-cups in 122 children, but they did not randomly assign the patients to the two methods of treatment or include matched controls. Bordelon treated fifty children with custom-molded inserts and reported improvement in the talometatarsal angle, as measured on lateral radiographs. However, only twenty-two patients completed the study and no controls were included.

The results of the present study demonstrated that flexible flatfoot in children, quantitated by measurement of the angles between the talus and the sole of the foot, the talus and the first metatarsal, and the talus and the calcaneus, naturally improves over a three-year period. In our series, the degree of improvement was not affected by wearing a corrective shoe or a shoe with an insert.

Because flatfoot is thought to reflect ligamentous laxity, we analyzed the relationship between laxity and improvement of flatfoot. Interestingly, our data suggested that children who had greater laxity, as measured using the Wynne-Davies scale when they entered the study, had somewhat greater improvement than did children who had less laxity. This somewhat surprising correlation was only weakly supported by statistical analysis. Also, the radiographic angles improved more with time for the patients who had more severe flatfoot initially than for the children who had lower values. Thus, a child who had greater laxity...
and more severe flatfoot was likely to have more improvement. However, the serial correlation coefficients demonstrated that the initial radiographic angles, which reflected severity, were far more significant than laxity in predicting radiographic improvement.

In this study, the age range (one to six years) was selected because the clinical problem and parental concern peak at this time. The age for entry into the study was lowered to one year at the urging of pedorthists, who emphasized that treatment must be started early, before the deformity becomes "irreversible". We did not want to study only older children who had extremely severe pronation of the feet. Also, these younger children account for a large percentage of the flat feet that are encountered in clinical practice. We chose an upper age-limit of six years old because after that age peer pressure to wear sneakers or other fashionable footwear makes treatment with shoes or inserts impractical.

Although we considered three years to be adequate for initial assessment, we thought that we might subsequently extend the period of treatment to five or six years. However, the number of patients who returned for the most recent...
follow-up confirmed that children can be persuaded to wear corrective shoes for only a few years. Although generally the families were stable and the parents were responsible and well adjusted, some parents were unable to convince the children to wear the corrective footwear, and these children were dropped from the study. The compliance of the ninety-eight children who completed the study was documented; however, almost none wanted to continue wearing the shoes after the completion of the three-year trial.

For these reasons, we doubt that a carefully controlled study requiring diligent wear of the corrective shoes could be easily prolonged for more than three years. In a longer study, the rate of non-compliance would probably become so high as to negate the validity of the results. Similarly, even if a stoical group of children could be coerced into participating in a five or ten-year treatment plan and the outcome suggested that the inserts were effective, the information would be of little practical value. Average North American children cannot be persuaded to wear corrective shoes beyond the age of entry into school.

We do not recommend corrective shoes or inserts for children who have typical flexible flatfoot. Instead, we advise that the child wear either no shoes or soft, flexible shoes to protect the soles of the feet. Sneakers (rubber-soled tennis shoes) seem to be satisfactory for most children. However, on carpeted or other abrasive surfaces, a toddler may walk better wearing lightweight, soft leather shoes that have a smooth, flexible sole.

We still occasionally advise that a child wear supportive shoes or inserts if he or she has severely symptomatic flatfoot, whether the symptoms are in the foot or in the calf. This is done only after known causes of painful flatfoot (tarsal coalition or subtalar rheumatoid arthritis) have been ruled out. Since we could not document any long-term structural benefit to the foot (that is, improvement in radiographic angles), we suggest that children wear corrective shoes only if the parents note a functional benefit. For the rare older child (five to fifteen years old) who has flatfoot and aching in the foot or calf, widely available high-top, lightweight athletic shoes generally provide adequate support to relieve symptoms and are better accepted than traditional orthopaedic footwear.

Parental perceptions of flexible flatfoot as a serious disorder that must be treated remain a major roadblock to application of our recommendations. Frequently, the parents themselves had flat feet as children, wore corrective footwear, and are convinced that the footwear was responsible for any improvement that occurred. A physician's attempt to dissuade the parents from buying corrective footwear is often met with serious skepticism. Unfortunately, often the shortest and easiest escape for the physician is to write a prescription for corrective shoes or inserts. When possible, we avoid this by carefully examining the child and the feet, ruling out abnormalities, and emphasizing to the parents that the flatfoot is a normal variation that will improve over time. We state that it is unlikely that the child will have symptoms in adult life. When one or both parents have severe, symptomatic flat feet, we clarify that the child may indeed have a similar condition when he or she is fully grown, but that it can be treated with a supportive insert at that time. We also give the parents an illustrated booklet explaining current opinion about the nature of flexible flatfoot and its treatment.

In conclusion, the results of this study confirmed that flexible flatfoot in young children slowly improves with growth and that intensive treatment with corrective shoes or inserts for a three-year period does not alter the natural history.

\[\text{Key} \quad \begin{array}{cc}
\text{Initial} & \text{Final} \\
\end{array} \]

\begin{figure}
\centering
\includegraphics[width=\textwidth]{fig10}
\caption{Comparison of the initial and the most recent lateral angles between the talus and the first metatarsal. There is no significant difference between the four groups (p > 0.5). UCBL = University of California Biomechanics Laboratory.}
\end{figure}

\textbf{NOTE:} The authors thank the clinical research nurses for their help in enrolling and maintaining the patients in the study and Judy Leach, R.P.T., for her help in preparing the paper.
References