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AN ANALYSIS OF ORTHOTIC FUNCTION USING THE FOOTMAXX GAIT ANALYSIS AND ORTHOTIC MANUFACTURING SYSTEM

A 12 MONTH RETROSPECTIVE REPORT

Edward English, B.A., M.D., F.R.C.S
Jeffrey Cowen, B.A., D.CH.
Alan Lustig, B.A., D.P.M.

Abstract

Research in the field of gait analysis and orthotic function has become an area of great interest as computer generated gait analysis systems like the F-Scan and the E.D.G. become more clinically acceptable. The need to assess the validity and reliability of these systems is an essential task. Peter Cavanagh, PhD and other prominent practitioners who study human biomechanics and gait have stressed how computers have revolutionized gait analysis.(1) Traditional hands on plaster casted non-weight bearing molds have given way to computer assisted gait force plate technology in many clinical settings. The speed and accuracy of these computers is based on their analog to digital conversions, or in simple terms their ability to convert electronic signals into numbers and therefore quantitatively measure biomechanical phenomena dynamically. The Footmaxx system is a dynamic weight bearing system with an advanced sensory force plate, high quality graphics and proprietary software which translates gait force plate data into specifications for functional orthotic devices and gait analysis.

Two hundred and fifty patients participated in this randomized controlled 12 month clinical study. Mean age was 54.8 years. The ratio of female to male patients was 2.4:1. All patients were diagnosed as to their lower extremity condition and then made a pair of functional orthotics. Follow-up was done via a questionnaire by telephone 8-10 weeks after the patient started wearing the orthotics. Overall improvement in condition and patient satisfaction with the orthotics were measured.

The results show an average improvement in condition of 75.27% for all of the diagnostic categories combined, and an overall patient satisfaction of 80.23% for all of the categories combined. This research demonstrates the efficacy of the Footmaxx gait

analysis and orthotic system in a clinical situation, based upon subjective patient information.

Introduction

The purpose of this 12 month retrospective study is to assess orthotic function on various biomechanical and lower leg conditions using the dynamic weight bearing Footmaxx system in a real life busy orthopaedic and foot care centre. Practical issues relevant to a practice of this type were focused on. These included overall patient satisfaction, how comfortable and easy to wear the orthotics were, and the patients perceived improvement in their condition. Patients were charged our clinic's normal orthotics case fee. As is our usual policy, patients understood that a full refund would be available if they felt the orthotics were of little or no help to them. Our subjects did not know that they were part of a clinical trial. They understood that our frequent inquiries as to their progress were simply part of our clinic's normal tracking of a new orthotics system. The study began 5 January, 1996 and was completed on 18 December, 1996. In total 250 subjects were tracked and analyzed.

Design, Materials and Method

All 250 subjects were randomly selected from a busy orthopaedic and foot care practice over a 12 month period. Protocol for subject entry into this study was based upon the subject being diagnosed with one of several lower extremity biomechanical conditions, including lower back pain and hip pain. The subjects were randomly chosen as those requiring orthotic treatment. Some subjects were new patients and some subjects were return patients, but all subjects were assessed and diagnosed by two Podiatric Specialists. The diagnosis were divided into 11 of the most common biomechanical lower leg and foot conditions including lower back pain and hip pain. The diagnoses were based upon chief complaints. Each subject was then made a pair of prescription custom orthotic devices using the Footmaxx system. The Footmaxx system consists of a force plate which the patient walks across connected to a Pentium laptop which runs the Footmaxx software. The patients were fitted with their orthotics and then monitored by a research staff person-not the diagnosing Specialist. The follow-up was done via a telephone questionnaire at an 8-10 week interval after the subject started wearing the orthotics. The 8-10 week follow-up allowed the subject the normal 'break-in' period after a patient starts to wear their orthotics. Some subjects were made dress type orthotics and some were made sports orthotics depending on their condition and footwear design. Some subjects were seen back after 4 weeks for minor adjustments and/or modifications to their orthotic devices. The questionnaires were completed by one of two research assistants during clinic hours. All questionnaires were then reviewed by both Podiatric Specialists and the questions were tabulated into results and subsequent statistics. All questionnaires were completed at an 8-10 week interval following the dispensing of the orthotic device. This variance of two weeks allowed the research staff time to contact by telephone those patients that were difficult to reach. The questionnaire was designed to assess two critical variables; the first is the subjects' overall perceived improvement in their condition and the second is the subjects' overall satisfaction level in regards to wearing the orthotic

devices. These two variables are important on a practical basis in a real life practice in terms of determining the efficacy of orthotic design and function. Many studies regarding plantar pressure measurement and orthotics use have been done but few have focused on the subjects' tolerance to the orthotics and the subjective improvement in condition. The outcome analysis of this questionnaire give a clear indication as to both of these variables.

The questionnaire was designed using rating scales of 0% to 100% to assess patients' subjective information based on two variables: The first being the patients' improvement in condition, and the second being the patients' overall satisfaction level. These two variables were measured by questions #5 and #6 on the questionnaire. After all of the questionnaires were collected, the percentages for each of these questions were averaged for each condition. In defining terms, the 'improvement in condition' refers to how much the patient believes or feels that he/she has improved physically since treatment began (when they first started wearing the orthotics). For example, a 77% 'improvement in condition' in the 'knee pain' category means that the patient is reporting a 77% improvement in the physical discomfort regarding the diagnosed knee pain since the time they started wearing their orthotics (in this case the subject answered question #5 with a 77% on the 0%-100% scale). The 'overall patient satisfaction' category refers to how happy or pleased the patient is with their orthotics in general. This category accounts for all factors associated with wearing orthotics, such as shoe fit, ease of break-in period, feel of wearing the orthotic, etc.

Results

Of the 250 subjects, 177 were female (70.8%) and 73 were male (29.2%). The mean age was 54.8 years. The largest grouping in a single diagnostic category was Plantar Fasciitis, followed by Pes Planus. As these are common biomechanical anomalies the large number of these diagnoses was expected. The smallest group was 'hip pain'. Of the entire 250 subject pool, 4 subjects (1.6%) rejected their orthotics because they could not accustom themselves to wearing them.

Discussion

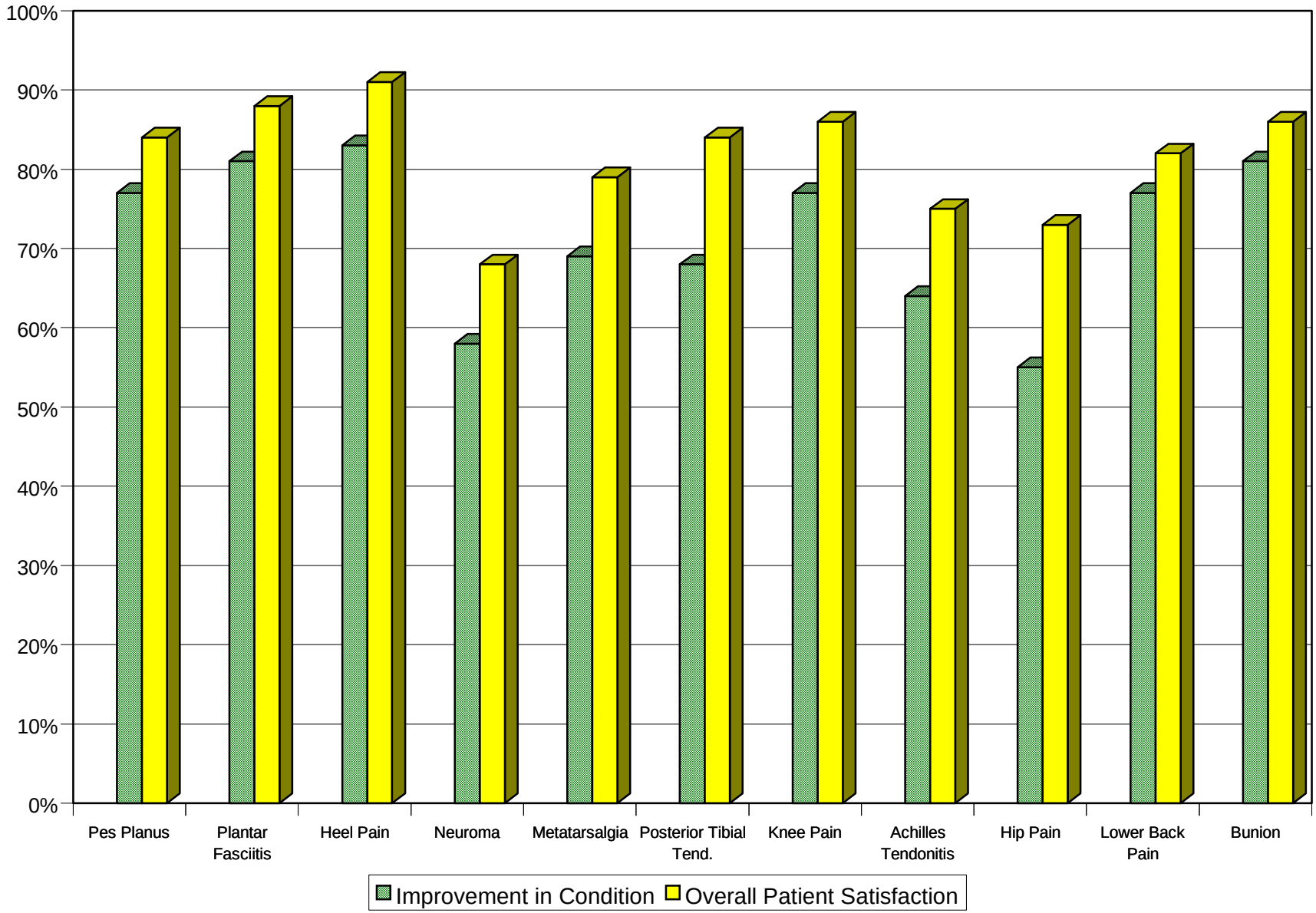
This research study was designed to determine the efficacy of Footmaxx technology and custom orthotic devices in a real life busy podiatric and orthopaedic practice. One significant finding and a commonality for all diagnostic categories is that the average percentage in overall satisfaction was consistently higher than the average percentage in overall subjective improvement in condition. One hypothesis is that the Footmaxx orthotics are quite easily tolerated by the subjects and are more comfortable to break in and wear. One reason for this may be the low profile design of Footmaxx orthotic devices themselves, which is due to the intrinsic forefoot posting and thin heel design. Patients seemed to break in these new orthotics quickly and easily, particularly the womens' dress orthotics, which traditionally have been difficult to successfully implement into a woman's dress shoe. Problems associated with the orthotics were not specific to any particular diagnostic category or orthotic design, but were general with regards to wear

time and the break in period. These problems included odour problems, topcovers coming off, and slippage. There were no concerns regarding difficulty in shoe fit due to increase bulk in the footgear while wearing the orthotic. Traditionally, orthotics and specifically sports orthotics are often felt by patients to be bulky and difficult to fit into a generic shoe. There were no problems associated with the functional integrity of the orthotic devices themselves. Overall, it appears that the Footmaxx orthotics do provide good to excellent biomechanical control with a significant reduction in symptoms for many of the diagnostic categories. The orthotics were most successful in treating heel conditions, knee pain, lower back pain and bunions. They were least effective in treating neuroma and hip pain conditions, but even in these latter two categories patient satisfaction was averaging 70%.

The diagnostic categories for ‘hip pain’, ‘knee pain’ and ‘lower back pain’ were streamlined into general chief complaints, and not specific knee or hip conditions. In this way, any patient complaining of knee pain, for example, as their chief complaint was put into the ‘knee pain’ category regardless of which specific type of knee condition they suffered from.

DATA FOR 250 SUBJECTS
BREAKDOWN OF DIAGNOSTIC CODES WITH AVERAGES

DIAGNOSTIC CODE	SUBJECTS	IMPROVEMENT IN CONDITION	OVERALL PATIENT SATISFACTION	PERCENTAGE OF TOTAL
Pes Planus	**36**	**77%**	**84%**	**14.4%**
Plantar Fasciitis	**54**	**81%**	**88%**	**21.6%**
Heel Pain	**7**	**83%**	**91%**	**2.8%**
Neuroma	**14**	**58%**	**68%**	**5.6%**
Metatarsalgia	**22**	**69%**	**79%**	**8.8%**
Posterior Tibial Tend.	**10**	**68%**	**84%**	**4%**
Knee Pain	**28**	**77%**	**86%**	**11.2%**
Achilles Tendonitis	**11**	**64%**	**75%**	**4.4%**
Hip Pain	**6**	**55%**	**73%**	**2.4%**
Lower Back Pain	**33**	**77%**	**82%**	**13.2%**
Bunion	**29**	**81%**	**86%**	**11.6%**
TOTAL	**250**	**75.27%**	**80.23%**	**100%**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Pes Planus
Plantar Fasciitis
Heel Pain
Neuroma
Metatarsalgia
Posterior Tibial Tend.
Knee Pain
Achilles Tendonitis
Hip Pain
Lower Back Pain
Bunion
Improvement in Condition
Overall Patient Satisfaction