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Biomechanical Effects of Custom-made Foot Orthoses for the Treatment of Patellofemoral Pain Syndrome

by

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "Biomechanical Effects of Custom-made Foot Orthoses for The Treatment of Patellofemoral Pain Syndrome" submitted by Yukiko Toyoda in partial fulfilment of the requirements of the degree of Master of Science.

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Abstract

Foot orthoses are commonly used in runners for treatment of overuse injuries. In spite of the number of success, the mechanisms of how foot orthoses reduce overuse pain are not well understood. Thus, the purposes of this thesis were to investigate the effects of foot orthoses on lower extremity kinematics, kinetics and muscle activity and to understand why foot orthoses reduce pain related to overuse injuries in runners.

The results showed that the custom-made foot orthoses significantly reduce pain for patellofemoral pain syndrome runners. Such foot orthoses had systematically changed internal knee rotation and EMG intensity ratio between the VMO and VL in all subjects. The amount of pain reduction was related to the amount of increase of EMG intensity for the VMO. This information suggests importance of neuromuscular effects of foot orthoses and helps to understand the mechanisms of foot orthoses in treatment of patellofemoral pain syndrome.

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Dedication

To my parents, Masao and Mutsuyo Toyoda,

and to my family

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1 INTRODUCTION

Foot orthoses and shoe inserts are commonly used by people of various age and lifestyle. Many types of foot orthoses and shoe inserts are available commercially and prescribed at podiatric offices or medical clinics. People use these foot orthoses and shoe inserts for different reasons including increase of comfort, prevention of injury, and probably most commonly, reduction of pain. Foot orthoses are claimed to reduce musculoskeletal pain and discomfort. However, little is known about how the body responds to foot orthotic interventions, and whether and/or why foot orthoses reduce musculoskeletal pain and discomfort.

This thesis is focused on the use of foot orthoses for runners with patellofemoral pain syndrome. Running is one of the most popular leisure sport activities and the basis for many other sports activities. However, running injuries are common and often lead to a reduction or cessation of training (van Mechelen, 1992). Running injuries also produce discomfort in daily life. Therefore it is important to prevent such injuries or to rehabilitate from overuse running injuries as quickly as possible.

Running injuries occur most frequently in the knee joint. Patellofemoral pain syndrome is the most common diagnosis among all running injuries (James et al. 1978, Clement et al. 1981, Matheson et al. 1989, Taunton et al. 2002). The best predictor of running injuries is the running distance (Powell et al., 1986). Biomechanical factors such as impact force and loading rate (Hreljac et al., 2003), foot eversion (Messier and Pittala, 1988), tibial rotation (James et al., 1978) and varus foot deformity (Clement et al., 1981) have been speculated to be associated with the development of running injuries. Additionally, large knee joint moments and muscle imbalances were proposed to be related to patellofemoral pain syndrome.

Foot orthoses have been used by runners for treatment of various overuse injuries including patellofemoral pain syndrome. In retrospective studies, success rates for foot orthotic treatment of lower extremity musculoskeletal pain have been reported between 70 and 90% (James et al. 1978; Donatelli et al. 1988; Gross et al., 1991; Saxena and Haddad, 1998). Some of the randomized control studies also reported positive results for foot orthoses in the treatment of patellofemoral pain syndrome (Eng and Pierrynowski, 1993; Way, 1999). Therefore, it is speculated that using foot orthoses may be a proper treatment for patellofemoral pain syndrome.

Traditionally, it was proposed that foot orthoses may align the skeleton and control rearfoot movement during the stance phase of gait (Subotnick, 1975; James et al. 1978). Varus deformities, which are compensated by pronating the subtalar joint, were frequently observed in runners with overuse musculoskeletal problems (James et al, 1978, Clement et al. 1981). Such pronated feet were described to introduce abnormal movement of the lower leg, i.e. excessive and/or prolonged foot eversion coupled by excessive internal tibial rotation during the stance phase, resulting in overuse injuries. Therefore, the concept that foot orthoses would correct malalignment of the lower extremities and change the lower extremities to normal movement seems intuitively to make sense. However, there is little agreement on the effects of foot orthoses on aligning the skeleton (Smith et al., 1986; Novic and Kelly, 1990; Eng and Pierrynowski, 1994; Nawoczenski et al., 1995; Mündermann et al., 2003; Stacoff et al., 2000). The inconsistencies in the results of previous studies may be attributed to differences in the type of orthoses, the material used, speed/cadence of locomotion and/or the method of measurement between studies (Razeghi and Batt, 2000). Nonetheless, the effects of foot orthoses on foot eversion and internal rotation of the tibia seems to be, if any, very small. Therefore, it is speculated that the main effects of foot orthoses may not be reducing foot eversion and tibial internal rotation as traditionally proposed.

In addition, most of the former investigations for the effects of foot orthoses on kinematics were limited to the ankle joint. Therefore, the changes in the knee joint due to orthotic intervention were not well studied. It is difficult to accurately measure the skeletal motion at the knee joint with currently available non-invasive technique such as skin markers (Cappozzo et al., 1996; Reinschmidt et al., 1997b). However, the knee joint is the most common site of running injuries. Therefore, if foot orthoses reduces knee pain, one may speculate that there may be substantial changes in knee joint kinematics. However, to date, only a limited number of studies are available and the results are inconclusive.

A new paradigm was proposed describing the possible effect of foot orthoses (Nigg et al., 1999). According to this theory, the skeleton has a preferred movement path for every movement task and will attempt to maintain this movement path for a given movement task. If external interventions try to change this movement path (e.g. an orthotic that should align the skeleton) the muscles of the lower extremities will be activated to avoid such changes. Only in extreme situations, when the muscles can not compensate anymore, the movement pattern will be changed. Based on this new paradigm one should expect that changes in kinematics due to orthotic interventions may be small. One should also expect that foot orthoses reduce muscle activity if they support the preferred movement path of the skeleton (Nigg et al. 1999). Until recently, the effects of foot orthoses on muscle activity were not the scope of inquiry. Systematic changes in EMG intensity (Nawoczenski and Ludewig, 1995; Mündermann, 2003) and the onset of muscle activity (Bird et al., 2003) have been reported for some muscles, while subject specific changes were observed for the rest of the muscles investigated. Patellofemoral pain syndrome has often been associated with muscle imbalances between the vastus lateralis and vastus medialis oblique (Paulos, et al., 1980; Souza and Gross, 1991; Powers wt al., 1996; McConnell, 1996; Gilleard et al., 1998; Klarenaar, 1999; Cowan et al., 1999 and 2001; Powers, 2000; Witvrouw et al., 2000; Tang et al., 2001; Malone et al., 2002). Quadriceps muscle strengthening exercises, which may change muscle activity patterns, have been successfully used for treatment of patellofemoral pain syndrome (Shelton and Thigpen, 1991; Doucette and Goble, 1992; Natri et al., 1998; Thomeé, 1999). Therefore, one may hypothesize that foot orthoses alter muscle activity patterns. Further investigations are needed.

Other proposed effects of foot orthoses are changing the ground reaction forces (Lockard, 1988) and joint loading (Arendse, 2004). When the foot contacts the ground during running, the impact forces acting on the human body are approximately 2-3 times body weight. Ground reaction forces produce moments with respect to the joints in the lower extremities, which correspond to loading of bone, cartilage, ligament and muscles. Lateral wedged orthoses were successfully used to reduce pain in medial knee osteoarthritis patients (Marks and Penton, 2004). These orthoses reduced the knee abduction moments and medial knee joint loads (Crenshaw et al., 1999). Running overuse injury such as tibial stress fracture was related to impact forces (Grimston et al., 1991) and patellofemoral pain syndrome was related to large knee joint moments (Stefanyshyn et al., 1999). Therefore, positive outcome from the use of foot orthoses in runners for treatment of overuses injuries may be because foot orthoses alter ground reaction forces and joint loading.

All the proposed effects of foot orthoses, however, are reflections based on the etiology of running injuries. To the author's knowledge, there is no study that investigated biomechanical effects of foot orthoses concurrently with the effects on pain. Therefore, the relevance of the proposed effects of foot orthoses, if any, in reducing musculoskeletal pain is not yet understood thoroughly. In order to understand the relevance of each effect of foot orthoses in treatment of overuse injuries, biomechanical investigation must take place in a prospective study combined with the quantification of pain.

Therefore, the purposes of this thesis were:

1. to quantify the effects of foot orthoses on lower extremity kinematics and kinetics for runners who were diagnosed with patellofemoral pain syndrome,
2. to quantify the effects of foot orthoses on lower extremity muscle activities for runners who were diagnosed with patellofemoral pain syndrome and
3. to quantify the relationship between change in pain and changes in lower extremity kinematics, kinetics and muscle activity pattern due to foot orthotic intervention.

Chapter 3 discusses the first purpose and the third purpose regarding to kinematics and kinetics. Chapter 4 discusses the second purpose and the third purpose in terms of muscle activity. The third purpose is discussed thoroughly in chapter 5 by combining the results for kinematics, kinetics and muscle activity. Chapter 6 provides summary of significant findings of this investigation.

2 REVIEW OF LITERATURE

The literature review provides an overview of previous work regarding to patellofemoral pain syndrome and foot orthoses. Section 2.1 describes the definition, etiology and treatment of patellofemoral pain syndrome. Section 2.2 reviews studies testing the effects of foot orthoses on musculoskeletal system and clinical effects.

2.1 Patellofemoral pain syndrome

2.1.1 Definition of patellofemoral pain syndrome

Several terms are used to describe the pain that occurs at the anterior aspect of the knee. Terms such as “anterior knee pain”, “patellofemoral pain”, “patellofemoral pain syndrome” and “chondromalacia patellae” are the most frequently used terms in the literature and sometimes they are used interchangeably. These expressions are generally umbrella words, except chondromalacia patellae, which is a pathologic description of the articular cartilage in early degenerative arthritis (Juhn, 1999). However, the term chondromalacia patellae has been used as a synonym for patellofemoral pain for half a century (Thomeé et al. 1999). The term “anterior knee pain” has the broadest meaning including any kind of pain related problems of the anterior part of the knee. The term “patellofemoral pain” is narrower in definition and includes pain around the patellofemoral joint only. By excluding pain related to bursitis and tendonitis, plica syndromes, Sinding Larsen's disease, Osgood-Schlatter's disease, intra-articular pathology and iliotibial band syndrome from "patellofemoral pain", the remaining anterior knee pain can be diagnosed as "patellofemoral pain syndrome" (Reid, 1993; Thomeé et al., 1999). Patients with patellofemoral pain syndrome have anterior knee pain that typically occurs with activity and often worsens when they are descending steps or hills, and sitting for prolonged periods of time. It is believed that pain is a result of physical and biomechanical change in the patellofemoral joint (Juhn, 1999). McClelland (1998) defined patellofemoral pain syndrome as "a syndrome with a history of retropatellar or peripatellar pain which worsens with activity and prolonged flexion, and occurs in the absence of trauma, osteoarthritis and patellar instability". It has been stated that "physical exam reveals medial facet tenderness with or without retinacular or lateral facet tenderness and absence of articular or bony deformities, or dysfunction in the connective tissue" (McClelland, 1998).

Clement et al. (1981) conducted an extensive retrospective study using their patient data base of 1650 patients with 1819 injuries which were seen at the Allan McGavin Sports Medicine Centre at the University of British Colombia from 1978 to 1980. They found that the knee joint was the most common site of injuries (41.7%) and patellofemoral pain syndrome was the most common diagnosis (25.9% of all the injuries). More recently, Taunton et al. (2002) conducted an extensive retrospective clinical study using 2002 patient charts from 1998 to 2000 at the Allan McGavin Sports Medicine Centre at the University of British Colombia. They found that the knee joint was still the most common site of running injuries (42.1 %) and patellofemoral pain syndrome was still the most common diagnosis (16.9 % of all injuries). It was also reported that females are more prone to suffer from patellofemoral pain syndrome than males (Taunton et al., 2002) and younger generations are more prone to sustain patellofemoral pain syndrome than older generations (Matheson et al., 1989).

2.1.2 Etiology of patellofemoral pain syndrome

Despite a number of studies that have investigated the etiology of patellofemoral pain syndrome, risk factors which contribute to the onset of patellofemoral pain syndrome are still unclear. Risk factors can be categorized into extrinsic factors and intrinsic factors. In this section, intrinsic risk factors of patellofemoral pain syndrome are discussed.

2.1.2.1 Malalignment and patellofemoral pain syndrome

In an extensive review of the literature (Thomeé et al., 1999) malalignment was discussed as a one of three major contributing factors which increase the risk of developing patellofemoral pain syndrome. Malalignment parameters which were proposed to be related to the development of patellofemoral pain syndrome include; excessive femoral anteversion, squinting patellae, increased Q-angle, leg length discrepancy, external tibial torsion, genu recurvatum, genu varum or valgum, patella alta, patella infra, rearfoot valgus and varus, pes plunus and cavus arch (Reid, 1993; Thomeé et al, 1999; Post et al. 2003). Among these, the Q-angle and foot malalignment have been most frequently discussed in scientific studies.

The Q-angle is defined as an angle between two lines, one connecting the anterior superior iliac spine and the centre of the patella, the other connecting the center of the patella and tibial tuberosity. These two lines are assumed to represent the direction of the two muscle-tendon forces acting on the patella, the resultant quadriceps force and the patellar tendon force. It has been proposed that the force pulling the patella laterally increases with increasing Q-angle (D'Amico and Rubin, 1986; Powers, 2003). Consequently, it was speculated that large Q-angles are associated with abnormal stress in the patellofemoral joint, contributing to the onset of patellofemoral pain syndrome (Mizuno et al., 2000). In some case studies (Reider et al., 1981; Messier et al., 1991; Moss et al., 1992) significantly greater Q-angles were found for the patellofemoral pain group compared to the asymptomatic group. However, in other case studies, no statistical differences in the Q-angles were found between healthy and anterior knee pain groups (Caylor et al., 1993; Duffey et al., 2000). Additionally, in a prospective study with 282 students taking physical education classes (Witvrouw et al., 2000) no statistical differences in the Q-angle were found between students who did and students who did not develop patellofemoral pain syndrome. Based on these results, it is speculated that a large Q-angle may in certain cases be the reason for the onset of patellofemoral pain syndrome.

However, it is only a possible and not a necessary condition for the development of patellofemoral syndrome.

Foot malalignment such as calcaneal varus and/or forefoot varus in a non-weight bearing position results in an abnormal subtalar pronation which is composed of foot eversion, abduction and dorsiflexion, when the foot is in a weight bearing position. Foot pronation may be caused by factors external to the foot (e.g. tibia varum, Root, 1994). In retrospective clinical surveys, "excessive pronation" was often reported for runners with overuse injuries (James et al., 1978; Clement et al., 1981). However, in a case controlled study, Messier et al. (1991) did not find differences in foot type using arch index between patellofemoral pain runners and healthy control. Results from prospective studies were controversial. Witvrouw et al. (2000) did not find any differences in foot alignment between subjects who developed patellofemoral pain syndrome (n=24) and who did not (n=258). Lun et al. (2004) found that there was a significant difference in forefoot varus between runners who developed patellofemoral pain syndrome (n=6) and who did not develop any injuries (n=18) over six months of training. Therefore, the association between foot malalignment and the onset of patellofemoral pain syndrome is not clear. It was reported that anatomical factors have not been well studied in the epidemiology studies (Powell et al., 1986). However, as Powell et al. (1986) stated, "it is too reasonable to deny the hypothesis that structural abnormality is a risk factor for running injuries". It is possible that foot malalignment may introduce abnormal movement pattern in the lower extremities, increasing the risk of developing patellofemoral pain syndrome. However, evidence for this association is missing.

2.1.2.2 Lower extremity movement and patellofemoral pain syndrome

Normal gait pattern of running during the stance phase is as follows. At heel strike, the foot contacts to the ground with the subtalar joint (STJ) slightly supinated and the knee joint slightly flexed. From heel strike to 30-50 % of stance phase, the STJ pronates and the knee joint flexes. After about 50 % of stance, the STJ starts supinating and the knee joint starts extending. The STJ and the knee joint continue to supinate and extend respectively, during the mid-stance and propulsive phases (Rodgers, 1988; Nigg et al. 1993; McClay and Manal 1998; Williams et al., 2003). There is a coupling mechanism between the foot and the tibia via ankle joint complex causing the tibia to rotate internally or externally as the foot pronates or supinates (James et al., 1978; Tiberio, 1987; McClay and Manal, 1998; Nigg et al., 1993). Therefore, as a general pattern, knee flexion during the stance phase is accompanied by internal tibial rotation, while knee extension during the stance phase is accompanied by external tibial rotation (Tiberio 1987).

In a theoretical model, Tiberio (1987) hypothesized that the synchronous actions of the STJ and the knee joint during the contact and mid-stance phase of gait are interdependent motions, and the tibial rotation is obligatory action that is necessary for normal kinematics of both joints. Furthermore, it was hypothesized that the biomechanical dilemma at the knee joint may occur when excessive and/or prolonged foot eversion occurs during the mid-stance phase of running and the tibia remains internally rotated as the knee joint extends (James et al. 1978; Tiberio, 1987; McNerney, 1998). However, it was found that movement transfer rates from the foot to the tibia were different from the transfer rates from the tibia to the foot, and transfer rate changed with change in loading, indicating that the coupling between the foot and the tibia is not determined by an universal joint mechanism (Hintermann et al. 1994 and Stacoff et al. 2000a). Furthermore, the ratio of transfer from foot in/eversion to external/internal tibial rotation was shown to be very subject specific (Stacoff et al., 2000a). Therefore, one may speculate that the knee joint may be exposed to a great risk of injuries only for runners with high transfer rate who exhibit excessive and/or prolonged foot eversion, which is accompanied with excessive tibial internal rotation as the knee extends during the mid-stance phase of running.

In order to allow the knee joint to extend when the tibia remains internally rotated, it was hypothesized in theoretical models that compensation of femoral internal rotation may occur (Tiberio, 1987; Powers, 2003). According to Tiberio's theory (1987), femoral internal rotation results in "relative" lateral tracking of the patella, increasing the compression between the lateral articular surface of the patella and the lateral femoral condyle. On the other hand, Powers (2003) proposed that internal rotation of the femur would move the patella medially, increasing dynamic Q-angle and force pulling the patella laterally. Either way, an abnormal biomechanical change in the patellofemoral joint is expected since rotations of the tibia and femur change patellofemoral contact area and pressure (Lee et al., 2003). Thus, injuries to the patellofemoral joint may be developed due to the compensatory movement of internal femoral rotation (Tiberio, 1987; Powers, 2003).

In the review of patient chart at sports medicine clinics, increases in foot pronation and corresponding increases in tibial internal rotation were commonly observed in injured runners (James et al., 1978; Clement et al., 1981). In a prospective study, it was found that runners who developed patellofemoral pain had higher foot eversion and internal tibia rotation compared to healthy runners (Bahlsen, 1989). However, several experimental studies comparing knee pain patients to healthy controls did not find differences in peak pronation, time to peak pronation and pronation velocity (Messier et al., 1991; Moss et al., 1992; Duffey et al., 2000; Powers et al., 2002). In addition, patellofemoral pain syndrome runners did not exhibit compensation of femoral internal rotation (Powers et al., 2002) when compared to healthy controls. Instead, greater internal tibia rotation with respect to the femur was shown to be related to patellofemoral pain syndrome (Stergiou, 1996). One possible reason may be that these studies did not control subject foot type. It was found that runners with pronated feet or low arched feet had greater foot eversion (McClay and Manal, 1998; Williams et al., 2001) and femoral internal rotation (Williams et al., 2001) compared to runners with normal and high arched feet, indicating foot alignment affects lower extremity movement. Foot malalignment and abnormal movement pattern may not be seen in all patellofemoral pain patients. However, if the movement transfer from foot eversion to internal tibial rotation is high, excessive and/or prolonged foot eversion and tibial internal rotation may be contributing to patellofemoral pain syndrome. To date, there are no data known to the author that show greater coupling ratio and/or greater internal rotation of the femur for pronating runners with patellofemoral pain syndrome compared to healthy controls. Therefore, the linkage between lower extremity movement and onset of patellofemoral pain syndrome is not clearly understood.

2.1.2.3 Joint loading and patellofemoral pain syndrome

During the stance phase of running the ground reaction force is acting on the human body. Effects of the ground reaction force are transmitted from distal to proximal in the body through bone, cartilage and soft tissue. The ground reaction force also creates moments with respect to the joints in the lower extremities. The body needs to counteract the external moments created by the ground reaction force in order to control the movement of the body and/or in order not to collapse. Therefore, internal moments are created by muscles and other passive structures. Increased ground reaction force and/or increased moment arm produce an increase in the external joint moments, resulting in greater loading of the joints.

There are only few studies that investigated joint moments for patients with patellofemoral pain syndrome (Stefanyshyn et al., 1999; Brechter and Powers, 2002a and 2002b). Knee joint moments were compared between subjects with and without patellofemoral pain syndrome for stair stepping (Brechter and Powers, 2002a), walking (Brechter and Powers, 2002b) and running (Stefanyshyn et al., 1999). Brechter and Powers (2002a and 2002b) examined knee extension moments along with estimated patellofemoral joint reaction force and patellofemoral joint stress. In these studies, it was found that peak knee extension moments and peak patellofemoral joint reaction forces were significantly smaller for patellofemoral pain group than for the asymptomatic group (Brechter and Powers, 2002a and 2002b). Patellofemoral joint stresses were not different for the two groups for stair stepping (Brechter and Powers, 2002a), but were significantly higher for the patellofemoral pain group during walking (Brechter and Powers, 2002b). Brechter and Powers (2002a and 2002b) explained that smaller knee extension moments and patellofemoral joint reaction forces were indicative of a quadriceps avoidance gait pattern, which is a strategy by which subjects with patellofemoral pain reduce the muscular forces acting across the patellofemoral joint (Powers et al. 1996).

Stefanyshyn et al. (1999) conducted a research project consisting of a case control study and a prospective cohort study to compare knee joint moments between runners with and without patellofemoral pain syndrome. The results of the case control study showed no significant differences for knee extension, abduction and external rotation moments between the patellofemoral pain syndrome group (n=20) and the control group (n=20). However, both the maximal knee abduction and the maximal knee external rotation moments were approximately 20% higher for the patellofemoral pain syndrome group than for the control group. For the prospective study, data from 145 runners were collected before a running season. Data for six runners who developed patellofemoral pain syndrome were compared to the data of the control group matched by training level, mass and gender (n=12). The results showed that knee extension moments were significantly smaller for the symptomatic group compared to the control group. The symptomatic group also showed approximately 45% higher maximum knee abduction and 50% higher maximal knee external rotation moments, although these differences were not statistically significant (Stefanyshyn et al. 1999). Combining the results from the prospective study and the case control study, it was speculated that increased knee abduction and increased knee external rotation moments may contribute to development of patellofemoral pain syndrome (Stefanyshyn et al. 1999).

In all the cited studies, it was found that the knee extension moment was significantly smaller for the patellofemoral pain syndrome group. Considering that smaller knee extension moment existed before patellofemoral pain syndrome was developed (Stefanyshyn et al. 1999), it is speculated that smaller knee extension moment may be a cause of patellofemoral pain syndrome but not a result such as quadriceps avoidance pattern as it was reported (Brechter and Powers, 2002a and 2002b). Given that knee extension moment is proportional to quadriceps muscle activity, it is speculated that the patella may be less compressed into the trochlear groove and more unstable for people with smaller knee extension moment (Farahmand et al., 1998; Powers et al., 2003). Higher knee abduction and external rotation moments that were found in runners who developed patellofemoral pain syndrome indicate that these runners had increased torsion in the knee joint, which may have affected patellofemoral joint mechanics. Especially, when the patella is unstable, higher torsional moments in the secondary plane may greatly affect patellofemoral joint mechanics, contributing to the onset of patellofemoral pain syndrome. At this point in time, no other studies are known to the author for secondary plane moments at the knee joint for runners with patellofemoral pain syndrome. However, the results from the cited prospective study along with the case control study strongly indicate that higher knee abduction and external rotation moments are contributing to the onset of patellofemoral pain syndrome.

2.1.2.4 Muscle dysfunction and patellofemoral pain syndrome

Patellofemoral pain syndrome has been related to the functioning of the quadriceps muscle group. The results of case control studies reported that patellofemoral pain patients had significantly weaker knee extensor muscles compared to healthy controls (Messier et al., 1991; Duffey et al., 2000; Powers et al., 1997). The trend of these findings were supported by a prospective study (Witvrouw et al., 2002), although the difference was not significant. All these cited studies tested knee extensor muscles as a group, therefore, contributions of individual muscle were not well specified.

The patella has a tendency to track laterally due to the Q-angle and due to a stronger passive structure on the lateral side compared to that on the medial side (Paulos, et al., 1980). Patella tracking is also influenced by the activities of quadriceps muscles because the tendons of four quadriceps muscles cover the patella before they insert onto the tibial tuberosity. The vastus lateralis contributes to lateral tracking of the patella. The vastus medialis oblique is the only dynamic medial stabilizer of the patella (Grelsamer and Klein, 1998). Therefore, the timing and amount of activity in the vastus lateralis and the vastus medialis oblique is critical to patellofemoral function (Paulos, et al., 1980; McConnell, 1996; Klarenaar, 1999; Powers, 2000; Malone et al., 2002). Often, patellofemoral pain syndrome is believed to be related to insufficient muscle activity of the vastus medialis oblique (Souza and Gross, 1991; Powers et al., 1996; Gilleard et al., 1998; Cowan et al., 1999 and 2001; Witvrouw et al., 2000; Tang et al., 2001).

Electromyography (EMG) has been used to study muscle activities in the vastus medialis oblique and the vastus lateralis muscles. The ratio of EMG amplitude for the vastus medialis oblique and vastus lateralis (VMO/VL ratio) is often used to infer imbalance in forces between the two muscles. Case control studies compared VMO/VL ratio between patients with patellofemoral pain syndrome and healthy controls for maximum voluntary knee extension (Boucher and King, 1992), level and ramp walking (Powers et al., 1996), stair climbing (Souza and Gross, 1995; Powers et al., 1996) and closed and open kinetic chain exercises (Tang et al. 2001). However, the results seem to be dependent on the task and reduced vastus medialis oblique muscle activity was not always found. It was reported that when patellar taping reduced pain in patellofemoral pain patients there were no changes in vastus lateralis muscle activity (Salsich et al., 2002) and VMO/VL ratio (Cerny, 1995). Therefore, the relevance of muscle activity in the vastus medialis oblique and the vastus lateralis and VMO/VL ratio in reduction of patellofemoral pain is not clear.

Other studies investigated the onset timing of EMG signal. Relative onset timing between the vastus medialis oblique and the vastus lateralis was not significantly different between patellofemoral pain patients and healthy controls for reflex response (Karst and Willet, 1995), for level walking, ramp walking and stair climbing (Powers et al., 1996) and for maximal voluntary knee extension (Owings and Grabiner, 2002). On the other hand, Cowan et al. (1999 and 2001) found 15-20 ms earlier onset of the vastus lateralis relative to the vastus medialis oblique for patients with patellofemoral pain syndrome while no such differences were found for asymptomatic group during stair ascending and descending. In addition, the results of a randomized prospective study by the same authors showed that improving the onset timing of vastus medialis oblique through physiotherapy was associated with reduction of patellofemoral pain (Cowan et al., 2002a). Taping of the patella which reduced pain level was also found to improve relative onset timing in patellofemoral pain patients (Gilleard et al., 1998; Cowan et al., 2002b).

Fatigue rate was also examined for the vastus lateralis and the vastus medialis oblique muscles using median frequency of the EMG signal (Callaghan et al., 2001). They compared fatigue in the quadriceps muscles, which is defined as a slope of median frequency of EMG signal during 60 seconds submaximal isometric voluntary contraction, between people with and without patellofemoral pain syndrome. The results showed no differences in fatigue for the rectus femoris but the fatigue for the vastus medialis oblique and the vastus lateralis muscles were significantly different between the two groups. The fatigue ratio which was defined as the ratio of the slopes of the vastus medialis oblique to the vastus lateralis was also significantly different between the two groups. The fatigue ratio was higher for the symptomatic group suggesting that the vastus medialis oblique fatigue faster than the vastus lateralis in the patellofemoral pain patients.

These results, however, must be evaluated carefully. There are many factors that influence the timing, frequency and intensity of EMG signal. The onset timing of EMG signal depends on spatial relation between electrode placement and innervation zone in the muscle (De Luca, 1997). There is time lag between EMG signal and force production of muscle, which depends on the fibre type composition of the muscle, viscoelastic properties of the muscle and tendon tissues (De Luca, 1997). Amplitude of EMG signal is also influenced by the spatial relation between muscle and electrode, and is not directly related to the force produced by muscle (Cram et al., 1998).

Nonetheless, recent prospective study by Witvrouw et al. (2000) reported that relative onset timing was a predictor for developing patellofemoral pain syndrome and delayed onset of the vastus medialis oblique relative to the vastus lateralis may contribute to the onset of patellofemoral pain syndrome. A recent simulation study reported that increased activity and relatively earlier onset of the vastus medialis oblique reduced patellofemoral joint loading (Neptune et al., 2000). Due to the lack of prospective studies, it is yet not known whether the insufficient activity of vastus medialis oblique is a cause or effect of patellofemoral pain. However, it is assumed that patellofemoral pain syndrome may be related to vastus medialis oblique muscle activity.

2.1.3 Treatment of patellofemoral pain syndrome

Most patellofemoral problems are currently successfully treated by non-operative treatment (Shelton and Thigpen, 1991). It was emphasized that proper diagnosis and customized program is most important for non-operative treatment (Shelton and Thigpen, 1991; McConnell, 1986 and 1996; Fulkerson, 2002). The aims of treatment for patellofemoral problems are to optimize the patellar position and to improve the lower limb mechanics (McConnell, 1996). Treatment for patellofemoral pain patients includes vastus medialis oblique and/or quadriceps muscle strengthening exercises, stretching of the tight lateral structures, proprioception improvement, foot orthoses, knee brace and taping, rest, ice and anti-inflammatory drugs (Shelton and Thigpen, 1991; Reid, 1993; McConnell, 1996; Juhn, 1999; Fulkerson, 2002; Post et al., 2002). However, there are only few clinical trials with randomized controlled design (Arroll et al. 1997; Juhn, 1999) and efficacy of each treatment is yet not established.

Nonetheless, strengthening of quadriceps and/or vastus medialis oblique muscle has been most commonly used in treatment programs (Shelton and

Thigpen, 1991; Thomeé, 1999). In a prospective study, restoration of good quadriceps strength and function of the affected knee was found to be important for good recovery of the patients (Natri et al., 1998). Reported success in patellofemoral pain treatment with quadriceps exercises was 70-84% (Doucette and Goble, 1992; Natri et al., 1998), and the success was associated with reduced lateral patellar tracking (Doucette and Goble, 1992) and increased knee extensor muscle strength (Bennett and Stauber, 1986).

Among few randomized control studies, two treatments were found to be effective; 1) use of foot orthoses, 2) use of glycosaminoglycan polysulfate when there is cartilage damage (Arroll et al., 1997). Eng and Pierrynowski (1993) examined the effects of soft orthoses in adolescent females who were diagnosed as patellofemoral pain syndrome and had abnormal foot structure. The result showed that using soft orthotic inserts combined with a quadriceps muscle strengthening exercise program was more effective in decreasing symptoms of patellofemoral pain than exercise only. More recent control study (Way, 1999) reported that intervention with thermoplastic custom orthoses in addition to exercise program reduced pain significantly more than exercise only for a patellofemoral pain syndrome patient with foot malalignment. Foot orthoses have been used for treatment of a variety of overuse injuries including patellofemoral pain syndrome and high success rates were reported in retrospective studies (James et al., 1978; Donatelli et al., 1988; Saxena and Haddad, 1998). It was found that forefoot valgus was strongly associated with the positive outcome to the treatment combining both exercise program and foot orthoses (Sutlive et al., 2004). Such malalignment may not exist in all the patellofemoral pain syndrome patients. However, when patients exhibit foot malalignment, foot orthoses may be utilized in treatment of patellofemoral pain syndrome (Gross and Foxworth, 2003).

2.2 Foot orthoses

Foot orthoses are commonly used for treatment of various musculoskeletal problems. Many types of foot orthoses are available with difference in material, shape and construction. Arch support, heel cushioning, medial or lateral wedged types are easily accessible commercially. Custom-made foot orthoses constructed with subject specific foot impressions and postings are prescribed by podiatrists. Arch support and medially wedged/posted orthoses are commonly used in runners. This is because excessive pronation during the stance phase is believed to cause overuse injury (Subotnick, 1975; James et al., 1978; Clement et al, 1981; Messier and Pittala, 1988; McNerney, 1998), and by supporting arch or posting the orthoses medially, it is believed that the foot does not overpronate and functions within normal range of motion i.e. close to subtalar joint neutral (James et al., 1978; Lockard, 1988). Custom-molded orthoses provide more precise fit than non-molded orthoses, and it is believed that they are more effective in controlling foot motion. The more rigid the orthoses are, the less they deform. Therefore, some specialists suggest that custom-made orthoses made from rigid to semi-rigid material provide the best control of the foot motion (Subotnick, 1975; MacLean, 2001). In the following, proposed effects of foot orthoses on the musculoskeletal system are discussed from injury related respects.

2.2.1 Kinematic effects of foot orthoses

2.2.1.1 Effects on rearfoot kinematics

Foot malalignment compensated by pronation of the subtalar joint, and abnormal movement during locomotion, i.e. excessive and/or prolonged foot eversion, have been associated with overuse injuries (James et al. 1978, Clement et al. 1981). Therefore, proper alignment of the skeleton has been proposed to be the most important function of foot orthoses. It has been proposed that foot orthoses can reduce excessive foot eversion and limit lower extremity movement (Subotnick, 1975; James et al., 1978). Therefore, the effects of foot orthoses on rearfoot kinematics have been investigated by many studies (Table 2-1).

Several studies have shown a reduction in foot eversion when using foot orthoses, thus supporting the above mentioned concept. For example, Smith et al. (1986) and Novic and Kelly (1990) reported a significant reduction of maximum foot eversion and maximum foot eversion velocity as a result of an intervention with rigid custom-made foot orthoses during running and walking

Table 2-1. Summary of findings quantifying the effects of foot orthoses on foot eversion.

Authors (Year)	Study type	Subject	Foot type	n	Orthoses	Max foot eversion	Max eversion velocity	Eversion excursion
Bates et al. (1979)	2D[s]			6	rigid custom made	1.0°		
Smith et al. (1986)	2D[s]			11	rigid custom made	**-1.2°**	**-14.1%**	
					soft custom made	-0.8°	**-20.4%**	
Novic and Kelly (1990)	2D[s]		pronator	20	rigid custom made	**-4.2°**	**-27.2%**	
Eng and Pierrynowski (1994)	3D[s]	PFPS	pronator	10	soft medial wedge			**-(1.7-2.5)°**
Brown et al. (1995)	2D	injured	pronator	24	arch support	0.0°	**-15.0%**	
					semirigid custom made	-0.5°	-5.4%	
Nawoczenski et al. (1995)	3D	injured	low/high arch	20	semirigid custom made			N.S.
Genova and Gross (2000)	2D	previous injury	pronator	13	semirigid/soft	**-2.2°**		
Stacoff et al. (2000)	3D	healthy	normal	5	medial rearfoot wedge	-1.0°	-1.8%	N.S.
Williams et al. (2003)	3D	previous injury	pronator	11	mold +15/25°post	1.6°		-0.8°
					custom made	1.2°		0.1°
Nigg et al. (2003)	3D			15	forefoot medial wedge	N.S.		N.S.
					full medial wedge	**-1.5°**		**-2.0°**
Münermann et al. (2003)	3D	healthy	pronator	20	full medial wedge	**-2.3°**	**-15.5%**	
					custom mold	0.6°	2.6%	
					mold + medial post	0.9°	4.2%	
Butler et al. (2003)	3D	healthy	normal	15	rigid custom made	-1.1°	-5.5%	-1.0°
					soft custom made	-1.7°	2.2%	0.0°
Stackhouse et al. (2004)	3D	healthy	normal	15	custom molded with 6°medial rearfoot post	-1.5°	N.S.	-1.1°

2D = based on two dimensional measurements

3D = based on three dimensional measurements

s= shoe marker was used

N.S. = not significant, value not reported

Significant differences compared to control condition are shown in bold.

respectively. Eng and Pierrynowski (1994) reported significant reduction in foot eversion when soft medial wedged orthoses were used for patellofemoral pain patients with foot malalignment. However, these studies were two dimensional and/or used markers on the shoe. Therefore, the results need to be interpreted with caution.

Recently, more studies used a three dimensional approach and directly placed markers on the foot in order to obtain better understanding of kinematic effects of foot orthoses. Nawoczenski et al. (1995) tested the effects of semirigid custom-made orthoses with running sandals. They reported no change in foot eversion excursion. Mündermann et al. (2003) also used running sandals and tested medial wedged orthoses, custom-molded orthoses and custom-molded and posted orthoses. In this study, only the medial wedged orthoses significantly reduced maximum foot eversion and maximum eversion velocity. Williams et al. (2003) and Stackhouse et al. (2004) placed reflective markers on the foot through small holes on the shoe, which were small enough to maintain integrity of the shoe. The results of both studies showed no significant differences in foot eversion between with and without custom-made foot orthoses. Stacoff et al. (2000) used bone pins to test medial wedged foot orthoses. The results of this study did not show a significant reduction of foot eversion.

The results of the cited studies are not consistent and suggest that most orthotic interventions do not change the actual movement of the foot significantly. Different structures of foot orthoses produce different responses in foot movement (Mündermann et al., 2003) and different foot structures respond differently to orthotic intervention (Gross et al. 1991). The differences in the results of the cited studies may be partially explained by such differences between studies. To the author's knowledge, there are no studies, which investigated the effects of foot orthoses on rearfoot kinematics and pain simultaneously during treatment of overuse injuries. Therefore, it is yet not known whether small changes in rearfoot kinematics are relevant in treatment of overuse injuries.

2.2.1.2 Effects of foot orthoses on tibia rotation

Excessive internal rotation of the tibia has been proposed to be associated with the development of overuse injuries (James et al., 1978; Tiberio, 1987; McNerney, 1988). Excessive tibia rotation has also been associated with strong coupling between calcaneus and tibia. However, not many studies quantified changes in tibia rotation due to foot orthotic intervention (Table 2-2). Eng and Pierrynowski (1994) found that soft medial wedged orthoses significantly reduced tibia internal rotation with respect to the foot for patellofemoral pain syndrome patients (n=10). However, shoe markers were used in their study and the result might have been affected by relative movement of the foot in the shoe. Nawoczenski et al. (1995) calculated tibia rotation from markers directly placed on the foot and shank. They reported that rigid custom-made orthoses significantly reduced internal tibia rotation compared to a control condition for injured runners with foot malalignments (n=20). Stacoff et al. (2000) quantified the effects of medial wedge orthoses using bone pins with healthy runners with normal foot alignment (n=5). They also found that excursion of internal tibia rotation was significantly reduced by the tested orthotic intervention. More

Table 2-2. Summary of findings quantifying the effects of foot orthoses on internal tibia rotation.

Authors (Year)	Study type	Subject	Foot type	n	Orthoses	Max tibia int. rotation	Tibia int. rotation excursion
Eng and Pierrynowski (1994)	3D[s]	PFPS	pronator	10	soft medial wedge		**- (1-3)°**
Nawoczenski et al. (1995)	3D	injured	low/high arch	20	semirigid custom made		**-2.1°**
Stacoff et al. (2000)	3D	healthy	normal	5	medial rearfoot wedge		**-1.6°**
Williams et al. (2003)	3D	previous injury	pronator	11	mold +15/25°post	**4.5°**	
					custom made	3.3°	
Münermann et al. (2003)	3D	healthy	pronator	20	full medial wedge	**-0.5°**	
					custom mold	**-0.6°**	
					mold + medial post	**-0.5°**	
Stackhouse et al. (2004)	3D	healthy	normal	15	custom molded with 6°medial rearfoot post	N.S.	

2D = based on two dimensional measurements

3D = based on three dimensional measurements

s= shoe marker was used

N.S. = not significant, value not reported

Significant differences compared to control condition are shown in bold.

recently, Mündermann et al. (2003) tested three types of foot orthoses (full medial post, custom-molded, and custom-molded with medial post orthoses) with healthy runners who were categorized as pronators (n=20). They found small but significant decreases in peak tibia internal rotation for all types of foot orthoses compared to the control condition.

On the other hand, no changes (Stackhouse et al. 2004) and increases (Williams et al., 2003) of tibia rotation due to orthotic intervention were also reported. Williams et al. (2003) compared standard custom-made orthoses (custom-molded with a 4° post) and inverted orthoses (custom-molded with 15 or

25° post) to control condition using runners who were pronators and had been treated successfully with the orthoses (n=11). The increase in tibia internal rotation was systematic with increase of degree of postings from no orthotic condition to inverted orthoses, and the difference between no orthoses and inverted orthoses was significant (Williams et al., 2003).

If excessive internal rotation of the tibia contributes to develop overuse injuries, foot orthoses should limit this movement. However, there are not many studies addressing this effect and the results are inconclusive. Hence, the effects of foot orthoses on reducing rotation of the tibia and its relevance in treatment of overuse injuries are not yet clear.

2.2.1.3 Knee joint kinematics

Despite the fact that the knee joint has been the most common site for overuse injuries in runners (James et al., 1978; Clement et al., 1981; Taunton et al., 2002) and foot orthoses have been claimed to successfully treat knee problems (James et al., 1978; Saxena and Haddad, 1998) there are not many studies that investigated the effects of foot orthoses on knee joint kinematics.

Lafortune et al. (1994) tested the effects of medial and lateral wedged shoes (10°) on knee joint kinematics using bone pins for healthy runners with normal foot alignment (n=5). While there were increases in tibial internal rotation with respect to the lab coordinate system, no changes were found for knee joint kinematics. Therefore, they speculated that increased tibial internal rotation was compensated at the hip joint by internally rotating the femur. The result that foot orthoses do not change knee joint kinematics was supported by other studies, which tested wedged type orthoses. Crenshaw et al. (1999) tested the effects of lateral wedged orthoses (5°) for healthy subjects (n=17) and found no changes in any kinematics at the ankle, knee and hip joint. Maly et al. (2002) tested 5° lateral wedged orthoses with patients with medial compartment knee osteoarthritis (n=12). There were no changes in knee internal rotation during walking. Nester et al. (2003) tested both medial and lateral wedged orthoses (10°) with healthy subjects (n=10). While significant increase and decrease in foot eversion were found for medial and lateral wedged orthoses respectively, changes in the knee and hip joint were small and not significant.

On the other hand, studies which tested foot orthoses consisting of custom molds and postings reported different results. Stackhouse et al. (2003) tested the effects of semirigid molded orthoses with rearfoot posting using healthy subjects with normal foot alignment (n=15). While changes in rearfoot kinematics were subject specific, they noted increase in knee adduction and decrease in knee internal rotation by approximately 2 degrees. Williams et al. (2003) tested custom-made orthoses and foot orthoses which consisted of the same shell but with aggressive medial posting (15 or 25 degrees). Compared to no orthotic condition they found systematic increase in knee adduction with increase of posting, but no changes in knee rotation.

Mündermann et al. (2003) found differences between the effects of molding and posting on rearfoot kinematics. Therefore, one would speculate that the reason why systematic increases of knee adduction with molded orthoses were found while there were no changes with wedged orthoses may be due to the different structure of foot orthoses. In addition, subject population and foot type were different between studies, which also may explain the differences in results. Further investigations are needed to understand the effects of foot orthoses on knee kinematics.

2.2.2 Effects of foot orthoses on joint loading

Although most of the foot orthotic studies examine the effect of foot orthoses with medial wedge/posting, lateral wedged foot orthoses are often investigated in terms of joint loading. This is because lateral wedged foot orthoses have been successfully used for treatment of medial compartment knee osteoarthritis (Marks and Penton, 2004) and it was hypothesized that lateral wedged orthoses may reduce external knee adduction moment and, consequently, medial knee joint loading and that, therefore, such orthoses may be resulting in relief of pain. Crenshaw et al. (1999 and 2000) are the first authors to investigate the effects of lateral wedged orthoses on knee joint loading during locomotion. They found significant reduction (7%) in resultant knee abduction moment and estimated medial knee joint load. Kakihana et al. (2004) found systematic decrease of resultant knee abduction moment with increasing the degree of lateral wedge (-9% for 3° wedge and -24% for 6° wedge) and the reduction with 6° wedge was statistically significant. However, some other studies reported small and no significant differences in knee abduction moments due to intervention with lateral wedged orthoses (Maly et al., 2004; Nester et al., 2003; Nigg et al., 2003). Kakihana et al. (2004) also reported a systematic increase of foot inversion moments with increase in degree of lateral wedge (19% for 3° wedge and 56% for 6° wedge). The increase of inversion moment with the 6° lateral wedge was statistically significant. However, other studies did not find any significant differences in inversion moment (Crenshaw et al., 2000; Nester et al., 2003; Nigg et al., 2003).

Changes in joint moments due to intervention with medially posted orthoses seem to have the opposite effects as laterally posted orthoses. It was reported that medially posted orthoses significantly reduced foot inversion moment (Novic and Kelly, 1990; Nigg et al., 2003; Mündermann et al., 2003; Williams et al., 2003; Stackhouse et al., 2004). In addition, inversion moments were systematically reduced with increase of the amount of medial posts (Williams et al., 2003). Changes in knee abduction moment were not consistent in the literature. Mündermann et al. (2003) found increases in maximum knee abduction moments in 13 of 20 pronating runners with full medial wedged orthoses and in 11 of 20 pronating runners with custom-molded and posted orthoses. However, these differences were not statistically significant (less than 1%). Nigg et al. (2003) found that 9 of 15 healthy male subjects increased and 6 decreased maximum knee abduction moments when running with full medial wedged orthoses. The average change was less than 7% and was not statistically significant. Nester et al. (2003) also found no significant changes (value not specified) with medial wedged orthoses for healthy subjects during walking. However, Williams et al. (2003) found systematic increase of knee abduction moments with increase of the amount of medial postings on custom-molded orthoses. The changes with custom orthoses (4° posts) and inverted orthoses (15° or 25° posts) were 18% and 27% respectively, and they were both statistically significant. Additionally, significant increase in knee external rotation moments during running was reported for medial wedge orthoses, custom-molded orthoses with/without medial posting (Nigg et al., 2003; Mündermann et al., 2003).

Considering the results from the cited studies, it seems that there are systematic changes in frontal plane moments at the ankle and the knee by changing the inclination of orthoses. That is, a) decrease of foot inversion moment with medial wedge/post orthoses while increase with lateral wedge/post orthoses, and b) increases in knee abduction moment with medial wedge/post orthoses while decreases with lateral wedge. This supports the idea that lateral wedged orthoses are effective in treatment of medial compartment knee osteoarthritis because the intervention reduces knee abduction moment and medial joint compartment load. However, it seems not logical, if medially posted foot orthoses increase knee abduction and external rotation moment, that medially posted orthoses would successfully treat patellofemoral pain syndrome, because one of the proposed factors developing patellofemoral pain syndrome is increased knee abduction and external rotation moment. To date, there are no studies, which examined the effects of foot orthoses on joint moments for patients with patellofemoral pain syndrome and other overuse running injuries. Therefore, it is yet not known how knee joint moments change with orthotic intervention for runners with specific overuse injuries, and whether it is relevant in treatment.

2.2.3 Muscle activity and foot orthoses

Nigg et al. (1999) proposed a new paradigm possibly explaining the functioning of foot orthoses. According to this proposed paradigm, the skeleton has a *preferred movement path* for a given task. If interventions such as foot orthoses support the preferred movement path of the skeleton, muscle activity as a reaction to the orthotic intervention would be minimal. If the interventions attempt to produce a movement path that is different than the preferred movement path, muscle activity would be increased to avoid such changes. Consequently, optimal foot orthoses would minimize additional muscle activity (Nigg et al., 1999). There is some initial evidence, supporting this proposed paradigm (Nawoczenski and Ludewig, 1999; Mündermann, 2003). However, additional evidence is needed to conclusively support or reject this proposed paradigm.

Tomaro and Burdett (1993) are the first authors who reported EMG response to orthotic intervention. They reported results from subjects (n=10) who had been successfully treated from lower limb injuries by the chosen orthotic intervention. However, the responses to custom-made orthoses during walking were subject specific for the tibialis anterior, peroneus longus and gastrocnemius muscles. They reported significantly longer duration of activity for the tibialis anterior following the heel strike with custom-made orthoses. Subject specific changes in muscle activities with custom-made orthoses were also reported for running (Nawoczenski and Ludewig, 1999). However, systematic changes were also found in some muscles with the mean EMG RMS values for the first 50% of stance phase being significantly increased for the tibialis anterior (37.5%) and decreased for the biceps femoris (-11.1%). More recently, muscle responses for orthotic intervention during running were quantified for full medial wedge, custom-molded and custom-molded with medial post orthoses (Mündermann, 2003). While subject specific changes were observed, the result showed consistent changes in muscle activity across subjects for some muscles due to the selected orthotic interventions. For example, muscle activity for the tibialis anterior was increased for the custom-molded and the custom-molded with medial post orthoses but was not changed with the medial wedge orthoses.

Based on the results of the cited studies, it can be concluded that muscle responses to orthotic interventions may not always be subject specific and that certain muscles show systematic changes to orthotic interventions. Furthermore, changes in muscle activity due to orthotic intervention were increases in most muscle-orthoses combinations (Mündermann, 2003). The interpretation of these increases is not clear. It could be a contradiction to the new paradigm (Nigg et al., 1999) or it could be a support of the new paradigm if the orthotics were interventions, which acted against the preferred movement path.

Changes in onset of muscle activity were also investigated. Rose et al. (2002) tested short term effects of semi-rigid custom-made orthoses on time response of lower extremity muscles for pronators after perturbation in a single leg standing. They did not find any changes in the onset for the vastus medialis, vastus lateralis, biceps femoris, medial gastrocnemius and medial and lateral hamstrings muscles. On the other hand, Bird et al. (2003) reported significant changes in the onset timing of muscle activation with foot orthoses during walking compared to a barefoot condition. They measured EMG for the erector spinae and gluteus medius muscles for healthy subjects using three types of foot orthoses (heel lift, forefoot medial wedge, and forefoot lateral wedge). The results showed significantly earlier onset timing for the erector spinae with heel lift and forefoot lateral wedge orthoses, and significantly delayed onset for the gluteus medius muscle for the heel lift condition compared to the barefoot condition.

Changes in muscle activity pattern in intensity and timing were also reported when shoe material was changed (Wakeling et al., 2001a and 2002a). Wakeling et al. (2001a and 2002a) resolved the EMG intensities into time-frequency space simultaneously by using recently developed wavelet technique (von Tscharner, 2000). There were significant changes in the intensity and the timing of the muscle activity between different shoes for impact loading (Wakeling et al., 2001a) and running (Wakeling et al. 2002a). They also found significant changes for the frequency components of the EMG signal. Major determinants of frequency of EMG signal are the differences due to different signals from fast and slow motor units (Wakeling et al., 2002b). Therefore, changes in EMG frequency indicate that different shoe characteristic may change motor unit recruitment patterns during running (Wakeling et al. 2002a). Mündermann et al. (2002) reported that changes in EMG intensity due to orthotic intervention were greater for high frequency band (fast twitch fibres) than low frequency band (slow twitch fibres). Therefore, it is speculated that foot orthoses may change motor unit recruitment patterns as well as the intensity and timing of muscle activity. However, its relevance in treatment of overuse injuries is not yet understood.

2.2.4 Foot orthoses in treatment for overuse injuries

Foot orthoses have been successfully used in clinical treatment. James et al. (1978) reviewed clinical trials of 180 runners. Custom-molded foot orthoses which were made from either flexible (n=44) or rigid (n=39) materials were prescribed for 46% of patients. 78% of these 83 runners showed a reduction of pain. Gross et al. (1991) distributed questionnaires to runners who participated in a race. Three hundred forty seven runners (69.4%) who used foot orthoses answered the questionnaire. 75.5% of these runners reported a reduction of pain due to various types of lower extremity injuries. However, an increase in pain was reported by 13.5% of runners, as a result of a poor fit of the used foot orthoses. Saxena and Haddad (1998) reviewed 102 patients with knee pain who were treated with semiflexible molded orthoses. They found that 76.5% of the tested patients reported a reduction of pain with 2% became asymptomatic.

Donatelli et al. (1988) conducted a post treatment survey of 53 patients who were treated by semirigid plastic or fiberglass orthoses with or without combination of other treatments. A total of 96% of the tested patients experienced a relief from pain and 90% of the patients who were treated only with a foot orthoses reported a reduction of pain.

These studies used retrospective survey design for which data were used only when subjects completed follow ups and/or answered the questionnaire. Additional treatments which were used in combination with foot orthoses may have contributed to the success rate. Therefore, it is well possible that the real success rate might have been overestimated. To the author's knowledge, there are only few controlled studies which can prove the efficacy of foot orthoses. Eng and Pierrynowski (1993) used soft medial wedged orthoses for the treatment of patellofemoral pain syndrome with and without muscle strengthening exercises. The patients were all adolescent young females who had foot malalignment compensated by subtalar joint pronation. The results of this study showed that both a muscle exercise program and using soft orthoses in addition to the muscle exercise significantly reduced pain. Using soft orthoses with an exercise program was more effective in decreasing symptoms of patellofemoral pain than exercise only (Eng and Pierrynowski, 1993). Another control study treated a patellofemoral pain syndrome patient with pronated feet using custom-made orthoses made from thermoplastic material. Compared to basic physical therapy, it was found that using foot orthoses in addition to the physical therapy significantly reduced pain (Way 1999). Therefore, although the reported success rate of 70-90% may not represent the true success rate, foot orthoses in combination with exercise programs seem to be beneficial for those who have pronated feet and suffer from overuse injuries.

2.3. Summary

The knee joint is the most common site of running injuries and patellofemoral pain syndrome has been the most common diagnosis for runners. Malalignment of the foot and leg, abnormal movement pattern of the lower extremities, excessive joint loading and muscle dysfunction have been proposed as the most likely risk factors for the development of patellofemoral pain syndrome. However, evidence showing a relationship between these risk factors and the development of patellofemoral pain syndrome is missing.

Treatment modalities for patellofemoral pain syndrome include quadriceps strengthening exercises, foot orthoses and patellar taping and there is evidence that they have been effective. Foot orthoses have been successfully used to reduce overuse pain for subjects with patellofemoral pain syndrome. Proposed positive effects of foot orthoses include aligning the skeleton, changing joint loading and changing muscle activity pattern. However, there is little scientific evidence to support that foot orthoses produce such effects and that such effects are the reason for a reduction in pain. The following reasons may account for the controversial results on this topic: First, the cited studies often used methods that were different and, thus, the results can not be easily compared. Second, different types of foot orthoses which may have different effects were tested. Third, subject populations were not very well specified in most of the studies. Therefore, the responses to the orthotic intervention may not have been systematic. In addition, most of the studies tested the effects of foot orthoses with healthy subjects. Thus, the effects of foot orthoses on a specific injured population, who may benefit from the orthotic intervention most, have not been studied and are, therefore, not understood thoroughly. To date, no studies have investigated the biomechanical effects of foot orthoses in relation with patellofemoral pain syndrome or with any other clinical situation in a prospective design. Therefore, the relevance of biomechanical effects of foot orthoses in treatment of overuse injuries is not well understood.

3 THE EFFECTS OF CUSTOM-MADE FOOT ORTHOSES ON PAIN AND LOWER EXTREMITY KINEMATICS AND KINETICS FOR RUNNERS WITH PATELLOFEMORAL PAIN SYNDROME

3.1 Introduction

Running, one of the most popular sport activities in North America, has a high incidence of injuries (van Mechelen, 1992). Running injuries most frequently occur at the knee joint (James et al., 1978; Clement et al., 1981; Matheson et al., 1989; Taunton et al., 2002). Patellofemoral pain syndrome is the most commonly diagnosed running injury (James et al., 1978; Clement et al., 1981; Taunton et al., 2002). It was reported that foot orthoses were successfully used to treat runners with overuse injuries including patellofemoral pain syndrome (James et al. 1978; Donatelli et al. 1988; Gross et al., 1991; Saxena and Haddad, 1998; Eng and Pierrynowski, 1993; Way, 1999). Therefore, the question arises as to how foot orthoses affect mechanics of the lower extremities and relieve overuse symptoms.

Several risk factors of overuse running injuries have been proposed, including malalignment of the lower extremity (Clement et al., 1981), excessive foot eversion (Messier and Pittala, 1988), excessive internal rotation of the tibia (McNerney et al., 1998), increased internal rotation of the femur (Tiberio, 1987), increased impact peak and loading rate of the ground reaction force (Hreljac et al., 2000) and increased joint moments in the secondary plane (Stefanyshyn et al., 1999; McClay and Manal, 1999). It was suggested that foot orthoses may reduce or eliminate some of these risk factors. Reducing foot eversion has been the most discussed topic and it was proposed that the reduction of foot eversion with the use of foot orthoses is one reason for the positive effects of foot orthoses in overuse treatment (James et al., 1978; Lockard, 1988; Eng and Pierrynowski, 1994).

However, the results of earlier studies for rearfoot kinematics are inconclusive and there are only limited studies examining the mechanical effects of foot orthoses other than rearfoot kinematics. Therefore, based on the literature, no strong statements can be made for the mechanical effects of foot orthoses and the mechanisms of foot orthotic treatment are still unclear. The conflicting results in the literature studying rearfoot kinematics may be explained by the differences in the methodology between studies (Razeghi and Batt, 2000). For example, results from shoe markers are most likely not representative for the foot eversion with respect to the tibia (Reinschmidt et al., 1997a). Furthermore, different types of foot orthoses have been used in these studies. However, different types of foot orthoses have different mechanical effects (Mündermann et al., 2003). In addition, typically, the effects of foot orthoses have been studied in a healthy and not in an injured population for which foot orthoses would be most useful.

In order to understand the role of foot orthoses in treatment of overuse injuries, further investigations are needed to examine the responses to the orthotic intervention in a specific injured population. Since patellofemoral pain syndrome is the most frequently diagnosed running injury, it offers itself as an excellent injured population. Examining not only foot eversion but general kinematics and kinetics of the lower extremities is essential. Furthermore, studies must include pain assessment along with biomechanical tests using pre- and post treatment design.

Therefore, the purpose of this study was to investigate the effects of custom-made foot orthoses on pain and three dimensional kinematics and kinetics of the ankle and knee joints in runners diagnosed with patellofemoral pain syndrome.

It was hypothesized that foot orthoses, which result in a reduction of pain

a) reduce rearfoot eversion,
b) reduce internal tibial rotation with respect to the foot and the femur and
c) reduce abduction and external rotation moments at the knee joint.

3.2 Methods

3.2.1 Subjects

Eight volunteers (28.5 ± 10.6 yrs, 167.2 ± 10.6 cm, 63.6 ± 10.7 kg, mean ± SD) were recruited for the study. All subjects were involved in sports activity in a regular basis. The characteristics of the participants are summarized in Table 3-1. All subjects were diagnosed with patellofemoral pain syndrome but were otherwise fit and healthy. The subjects had pronated feet, which were assumed

Table 3-1. Subject characteristics.

Subject	Gender	Age [years]	Height [cm]	Weight [kg]	Test leg	Speed [m/s]	History of PFPS	Sports activity
1	F	29	166.4	54.4	L	2.9	12 mths	run 40-50Km/ wk
2	F	22	165.1	63.5	L	3.1	2 mths	run 5x / wk (35-40Km)
3	F	48	177.8	81.2	R	2.0	1+ yr	run 2x / wk (8-10Km) soccer 1x/ wk
4	M	38	162.6	58.1	L	3.2	5 mths	run 3x / wk (30-35Km)
5[a]	F	31	170.0	57.0	L	2.6	8 yrs	cycle, run, hike, ski, gym workout
6	M	24	185.4	79.4	R	2.7	12 mths	gym workout, run
7[b]	F	14	152.4	56.8	R	1.9	4 mths	soccer, run, exercise
8	F	22	157.5	58.0	R	3.0	4 mths	run 3x (25-30Km), cycle 40Km, swim 2x / wk
Average		28.5	167.2	63.6				
SE		3.8	3.8	3.8				

[a] Subject 5 was excluded form the analysis due to technical errors in the kinematic data

[b] Subject 7 was withdrawn due to inability to perform the task properly

PFPS = patellofemoral pain syndrome

to have contributed to their symptoms. Written consent was obtained from all subjects prior to the study based on the requirements of the University of Calgary committee for Medical Bioethics.

To ensure a homogeneous population, subjects were selected very carefully. After approval was obtained from the University of Calgary committee for Medical Bioethics, participants were recruited from local runners/athletes in Calgary through health professionals and advertisement. Upon initial contact, the testing protocol was explained to runners/athletes and questions were asked for pre-screening. Those who were fulfilling the eligibility criteria (Table 3-2) were invited to participate in the study.

Table 3-2. Inclusion / exclusion criteria for screening process

TEST	Inclusion criteria
Pre-screening	
Age	14 - 60 years old
Area of pain	In front of the knee or under the patella
Swelling	None
History of traumatic knee injury/surgery	None
Duration of having pain	Short enough not to accommodate the pain (≤one year)
Treatment	No treatment at least 3 months prior to the study
Foot orthoses	No prior experience of using foot orthoses
Fitness ability	Be able to run 30 minutes twice a week
Diagnosis	
Physical examination	No restriction of knee joint range of motion
	No effusion
	Tender medial patellar facet
	No ligament laxity
	No evidence of bursitis or tendinopathy
	No hip pathology
X-Ray	No bony and/or articular deformities
Podiatric assessment	
Forefoot-rearfoot alignment	Anyone with forefoot varus ≥4°
Rearfoot-leg alignment	Anyone with rearfoot varus ≥3°
Tibial stance position	Tibial varum ≥3°
Relaxed calcaneal stance position	Anyone with eversion ≥6°
Maximum pronation test	Eversion ≤5°
Podiatric assessment	**Exclusion criteria**
Leg length discrepancy	≥ 1.5 cm

After written consent was obtained, the subjects were assessed by Dr. Preston Wiley at the Sports Medicine Center, University of Calgary for inclusion criteria. Those who were not diagnosed as patellofemoral pain syndrome were excluded. The remaining subjects then underwent a podiatric assessment by Dr. Neil Humble at the NorthWest Foot Clinic, Calgary. Runners/athletes who had pronated feet were included for biomechanical data collection. See Figure 3-1 for the detailed screening process.

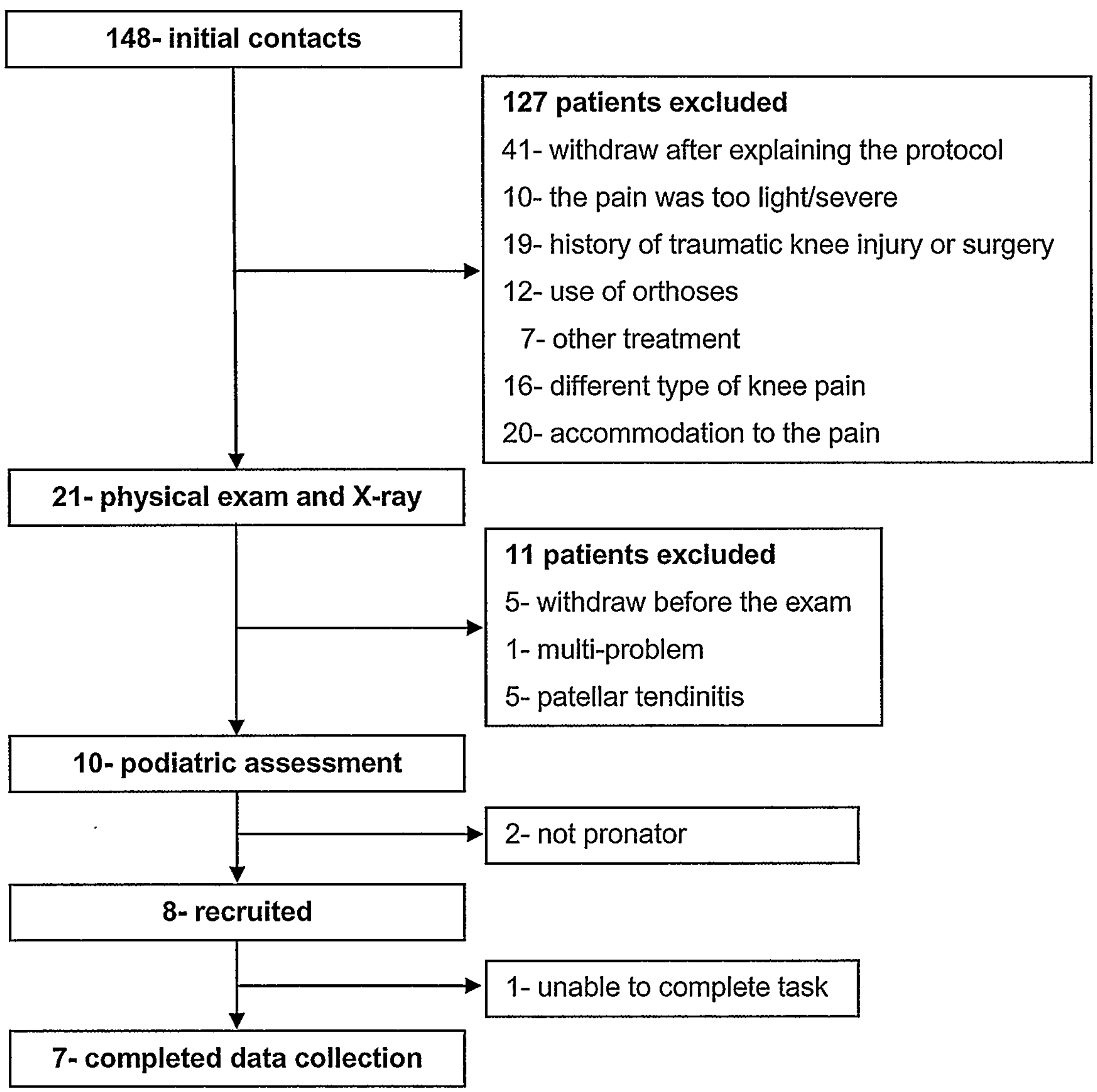

Figure 3-1. Flow chart describing the progress of participants through trial.

3.2.1.1 Diagnosis

In this study, patellofemoral pain syndrome was defined as "a syndrome presenting with a history of peripatellar or retropatellar pain that worsens with activity or prolonged flexion and occurs in the absence of trauma, osteoarthritis and patellar instability. Physical exam reveals medial facet tenderness with or without retinacular or lateral facet tenderness and absence of articular or bony deformities or dysfunction in the connective tissue" (McClelland, 1998). The diagnosis was confirmed by Dr. Preston Wiley at the Sports Medicine Centre, University of Calgary. Patients who met all inclusion criteria of pre-screening saw Dr. Wiley for physical examination. Patients with tender medial patellar facet without evidence of bursitis or tendinopathy, ligament laxity and effusion were diagnosed with patellofemoral pain syndrome. Finally, X-Ray of the knee joint were taken from anterior-posterior, lateral and skyline for those who meet all inclusion criteria in the physical examination. If the X-Rays were normal, the patient was referred to Dr. Neil Humble for the podiatric assessment. See Table 3-2 for details for criteria.

3.2.1.2 Podiatric assessment

The podiatric assessment was conducted by Dr. Neil Humble at the NorthWest Foot Clinic in Calgary. The podiatric assessment included non-weight bearing and weight bearing forefoot-rearfoot and rearfoot-leg alignments as well as passive and active range of motions of the lower extremity joints and muscle strength tests.

Subjects were placed on prone on an examination bench with both feet being unsupported. The subtalar joint was positioned in its neutral position. A goniometer was used to measure forefoot-rearfoot alignment (forefoot position) and rearfoot-leg alignment (rearfoot position). Bisection lines were marked on the rearfoot and on the lower leg. Weight bearing rearfoot-leg alignment (relaxed calcaneus stance position) and tibial stance position were assessed with subject standing with the body weight equally distributed on both legs. The feet were aligned with the hip joint. A goniometer was used to measure the angle between the bisection lines on the rearfoot and the lower leg which represents eversion angle (Valmassy 1996). The inclusion criteria are shown in Table 3-2. Leg length discrepancy was determined using a standard anthropometric clinical measure (distance from ASIS to medial malleolus) with the subject supine. A bilateral difference greater than 1.5 cm resulted in subject exclusion (Magee, 1997). The characteristics of lower extremity alignment are shown in Table 3-3.

The range of motion test included hip external and internal range of motion, hip flexion (with knee joint extended), subtalar joint range of motion and ankle dorsiflexion. Normal range of motion for hip rotation and flexion are greater than 45°, and for the subtalar joint are greater than 30°. Ankle dorsiflexion less than 5° with the knee joint extended and/or less than 10° with the knee joint flexed were subject to gastroc-soleus equinus. First metatarsal-phalangeal joint dorsiflexion was tested with the first ray loaded and unloaded to test a chance of

Table 3-3. Lower extremity alignment data for podiatric assessment.

Subject	Forefoot position [°]		Rearfoot position [°]		Tibial stance position [°]		Relaxed calcaneus stance position [°]		maximum pronation test [°]		Leg length [cm]	
	R	L	R	L	R	L	R	L	R	L	R	L
1	2	3	**3**	**3**	**8**	**8**	2	4	**<2**	**<2**	90	90
2	3	**4**	**3**	**3**	**10**	**8**	2	0	**2-5**	**2-5**	91.5	91
3	**5**	**7**	2	2	**6**	**6**	3	5	**2-4**	**2-4**	96	96
4	**4**	**4**	2	**3**	**3**	2	2	**6**	3-6	3-6	87.5	87
5	**3-5**	**3-5**	**3**	**3**	**4**	**8**	0	0	<6	<6	94	94
6	2	3	2	2	2	2	**10**	**8**	**<2**	**<2**	103	103
7	**4**	**4**	**3**	**3**	**5**	4	**7**	**6**	**0-2**	**0-2**	81	81
8	3	2	**4**	2	**7**	2	2	**3**	**2-4**	**2-4**	85.5	85.5

Values within inclusion criteria are in bold. R for the right leg and L for the left leg.

structural and functual hallux limitus. Some of the patients exhibited range of motion outside the normal range and/or chance of gastroc-soleus equines. However, the patients had structural abnormality of the foot that was likely to have contributed to develop patellofemoral pain syndrome. Therefore, all the patients with foot malalignment compensated by abnormal pronation were included in this study. The muscle strength test was conducted to make sure that the subjects were free from neurological problems. The characteristics of range of motion and muscle strength test for all subjects are shown in Table 3-4 and 3-5.

3.2.1.3 Justification for subject selection

Foot malalignment causing overpronation has been proposed to be a risk factor for overuse running injuries. As a result, foot orthoses are often prescribed

Table 3-4. **Lower extremity range of motion data.**

Subject	1st MPJ extension unloaded [°]		1st MPJ extension loaded [°]		Subtalar joint ROM [°]		Ankle joint with knee extended [°]		Ankle joint with knee flexed [°]	
	R	L	R	L	R	L	R	L	R	L
1	78	72	35	32	50	48	16	12	25	26
2	66	66	32	32	42	38	18	16	22	20
3	68	72	25	25	40	40	*8*	*6*	*5*	*5*
4	68	65	20	20	42	38	16	16	20	20
5	110	110	40-50	40-50	38	46	10	*6*	22	18
6	76	74	72	72	46	44	*4-5*	*4-5*	10-15	10-15
7	76	65	WNL	WNL	42	46	20	20	25	25
8	88	88	40	40	37	34	13	16	20	20

Values outside the normal range of motion are in italic. R for the right leg and L for the left leg. WNL; within normal range.

for patients with foot malalignment. Inconclusive results in the literature may partially be attributed to not well defined subject populations, as different types of subjects may use different strategies to respond to orthotic intervention (Nigg et al., 1999). In addition, for the understanding of the role of foot orthoses in treatment of overuse injuries, it is important to test the effects of foot orthoses for an injured population. Patellofemoral pain syndrome is the most common overuse injury in runners. Therefore, the subject population in this thesis was chosen to be runners who were diagnosed with patellofemoral pain syndrome and who had an excessively pronating foot, which may have contributed to the development of the pain. Since the purpose of the study was to test the effects of foot orthoses on subjects with patellofemoral pain syndrome, the subjects were required to be diagnosed with patellofemoral pain syndrome but were otherwise fit and healthy.

Table 3-5. Hip joint range of motion and lower extremity muscle strength.

	Hip flexion [°]		Hip medial rotation [°]		Hip lateral rotation [°]		Muscle strength test[1]	
Subject	R	L	R	L	R	L	R	L
1	90	85	*40*	*40*	60	60	5	5
2	60	60	45	45	45	45	5	5
3	45	45	*40*	*20*	50	60	5	5
4	45	45	*30*	45	*35*	45	5	5
5	80	80	50	50	50	50	5	5
6	85	80	*20*	*20*	60	60	5	5
7	65	50	*30*	*40*	60	50	5	5
8	70	70	*35*	*40*	*40*	45	5	5

[1] measured on a scale 1 to 5; 5 = highest
Values outside the normal range of motion are in italic. R for the right leg and L for the left leg.

In order to have a homogeneous population, further screening was conducted. Patients with history of traumatic knee injuries and surgery were excluded as their knee joints were not considered to be normal. Any other treatments were considered to be confounding factors. Therefore, patients who were receiving any treatment for their knee pain were excluded. Brown et al. (1995) reported that previous use of foot orthoses influenced the response to orthotic intervention. Thus, patients who have worn foot orthoses before the study were excluded. It was speculated that when runners/athletes continue their training with pain for a long period of time, they may have got accommodated to their pain and the response to an orthotic intervention may be different. To eliminate such possible effects, patients with relatively short history of patellofemoral pain syndrome were selected. The onset of knee pain for Subject

5 was eight years ago, however, the subject has been away from such activities that caused knee pain. Therefore, this subject was considered not to have accommodated the pain and was included for the study.

3.2.2 Footwear

All experiments were performed with subjects wearing running sandals (Women's model; Bryce Canyon, Men's model; Greely, The Rockport Company, Canton, MA, USA). It was reported that the rearfoot movement with respect to the shank was overestimated when markers placed on the shoe were used in the calculations due to the relative movement of the foot with respect to the shoe (Stacoff et al., 2000b). Using the running sandals allowed the reflective markers to be placed directly on the foot. Hence, the skeletal movement of the foot was measured more accurately.

Baseline data were collected in the running sandals with the original inserts. *Treatment data* were collected by replacing the original inserts with custom-made foot orthoses (Figure 3-2). Custom-made foot orthoses were chosen as they are believed to be the most effective treatment device among other types of shoe inserts and foot orthoses. The foot orthoses were prescribed by Dr. Humble and were consisted of polypropylene shell with a Spenco cover (Spenco Medical Corporation, Waco, TX). Negative neutral suspension casts with subjects in prone position were made from both feet in STJ neutral position. These negative casts were optically digitized by a laser scanner and positive a)

b)

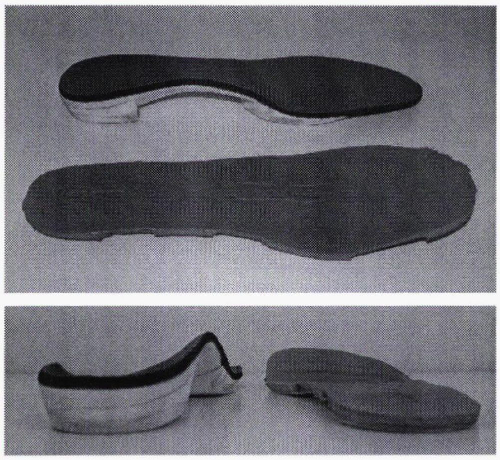

Figure 3-2. Testing condition used in this study. Original insert: a) bottom and b) right. Custom-made foot orthoses: a) top and b) left.

models were produced using an automated orthotic scanning system. There was intrinsic forefoot posting up to 3 degrees varus and minimal arch fill performed as the only digital cast dressing. Once the casts were digitally dressed they were sent to a computer numerically controlled milling workstation where a positive 3-D model was milled from multidensity fibre board. Custom-made foot orthoses (Paris Orthotics Ltd., Vancouver, Canada) were framed around the semirigid polypropylene shell, with the thickness adjusted for patients' weight. The orthoses were running specific devices including a deep heel cup (16 mm) and a medial flange. Forefoot varus posting above 3 degrees was done extrinsically to the tip of the orthotic with 50-55 durometer EVA. Rearfoot posting was all extrinsically applied with a 50-55 durometer EVA. The amount of the forefoot and rearfoot postings for each subject is summarized in Table 3-6.

Table 3-6. The amount of rearfoot and forefoot posting prescribed for the subject.

	Subject	1	2	3	4	5[a]	6	7[b]	8
Rearfoot post [degree]	Right	3	3	2	2	3	2	3	4
	Left	3	3	2	3	3	2	3	2
Forefoot post [degree]	Right	2	2	4	3	3	2	4	2
	Left	3	4	6	3	3	3	4	2

[a] Subject 5 was excluded from data analysis due to technical problem in kinematic data.
[b] Subject 7 was withdrawn due to inability of complete task.

3.2.3 Data collection

3.2.3.1 Procedure

The study followed a prospective study design. This project was a part of a more comprehensive study. The subjects visited the lab twice a week for six weeks (12 sessions per subject). The six weeks were divided into three functional phases of a clinical trial. Week 1 and 2 were defined as baseline period as the subjects had pain but were not given any treatment. Week 3 and 4 were defined as accommodation period. Subjects received the custom-made orthoses and accommodated themselves to the orthoses by gradually increasing the wearing time. Week 5 and 6 were defined as treatment period and the subjects were required to wear the foot orthoses for all sport activities as well as all daily activities if possible. In each testing session, the subjects performed 30 minutes of running at their regular running speed (2.0 - 3.2 m/s) to assess their subjective pain related to activity. Biomechanical data were collected once during the baseline period (session 4) without using foot orthoses and once during the treatment period (session 12) with the custom-made foot orthoses. Biomechanical test included kinematics and kinetics of the lower extremities during running. Finally, a follow up clinical visit was made at least two weeks after the completion of biomechanical data collection to the podiatrist to assess overall improvement of the pain (Table3-7).

3.2.3.2 Kinematic and kinetic data

Kinematic and kinetic data were collected in the Human Performance Laboratory, University of Calgary. The experimental setup is shown in Figure 3-3. The subjects performed one neutral standing trial followed by running trials. For the neutral trial, subjects were aligned with laboratory coordinate system (LCS) and were asked to stand still with their feet hip-width apart and parallel to the force plate. The speed of the running trials was selected as subject's natural running speed and was monitored by infrared timing lights placed 1.9 m apart. The symptomatic knee was chosen to be a test leg. When the subject had

Table 3-7. Testing procedure.

Week	**1**		**2**		**3**		**4**		**5**		**6**		**After 9**
Functional period	Baseline				Accommodation				Treatment				
Orthoses	None				Gradual accommodation				All sport / daily activities				
Test condition	With out orthoses				With orthoses				With orthoses				
Testing session	1	2	3	4	5	6	7	8	9	10	11	12	
Biomechanical test				o								o	
Pain assessment	o	o	o	o	o	o	o	o	o	o	o	o	o

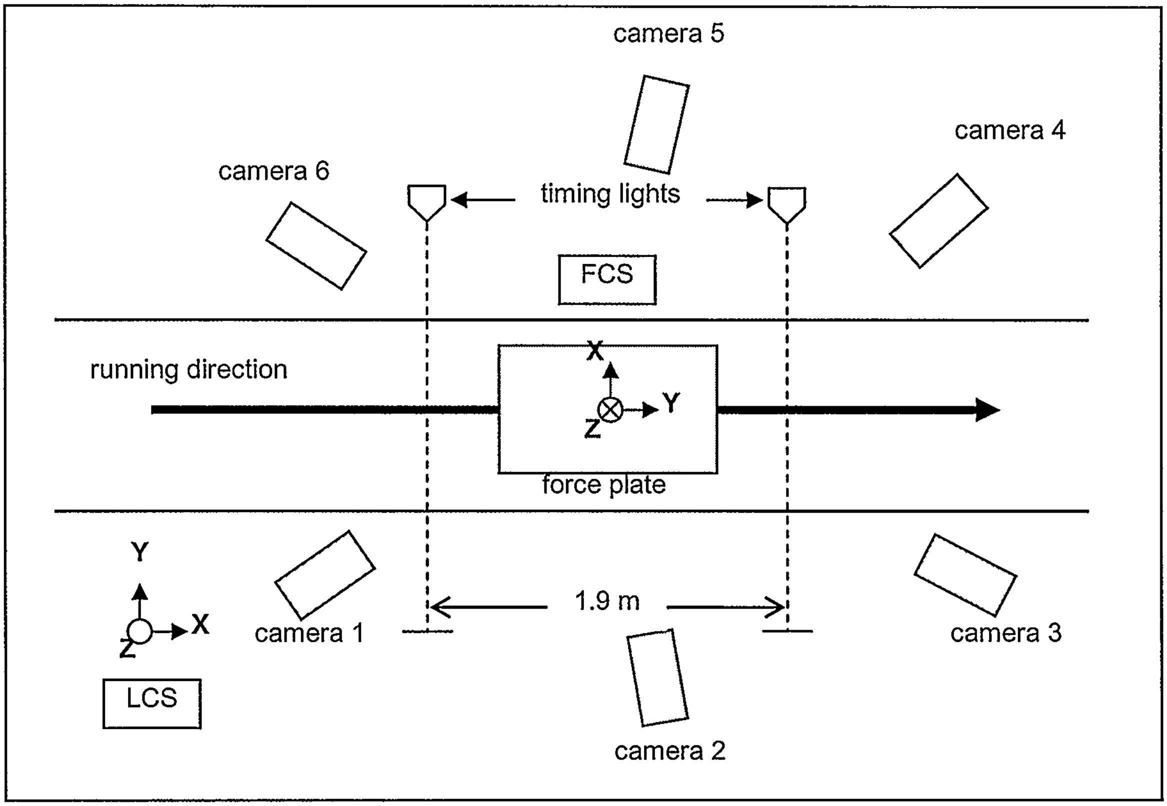

Figure 3-3. **Schematic diagram of the experimental setup. The force plate coordinate system (FCS) and the lab coordinate system (LCS) were defined as shown.**

bilateral pain, the knee with the worst pain was chosen for the test leg. Three reflective markers were attached to each segment of interest (rearfoot, shank and thigh) of the test leg using medical adhesive spray (Hollister Inc. Libertyville, IL, USA). Additional markers were attached to the anterior superior iliac spine, the greater trochanter of the femur, the medial and lateral epicondyles of the femur, the centre of the patella, the medial and lateral malleolus and the insertion of the Achilles tendon during a neutral standing trial (Figure 3-4). Three dimensional kinematic data were collected using six high-speed infrared cameras (Motion Analysis Corporation, Santa Rosa, CA, USA) with sampling frequency at 240 Hz. Ground reaction forces were collected at 2400 Hz using a force plate

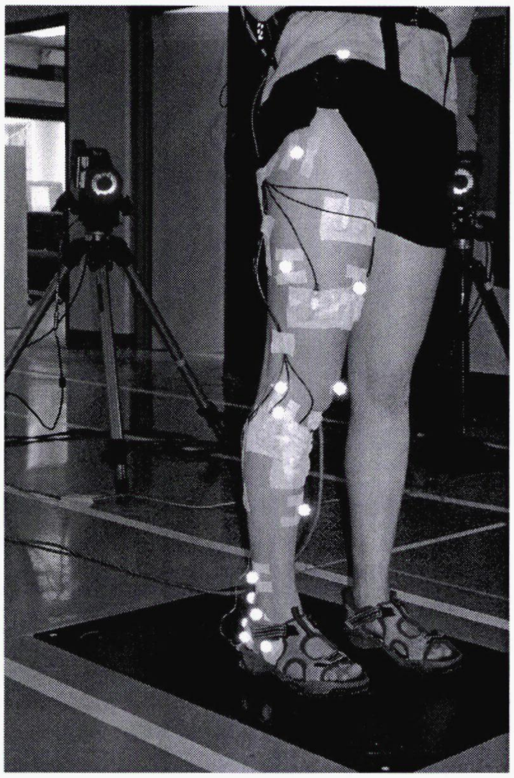

Figure 3-4. Placement of reflective markers.

(Kistler Instrumente AG, Winterthur, Switzerland) which was located in the middle of the runway.

3.2.3.3 Pain assessment

Pain level was assessed using a Visual Analogue Scale (VAS). VAS has shown to be a valid measurement of knee pain (Chesworth et al. 1989, Flandry et al. 1991). The VAS consisted of a 10 cm horizontal line with words "No pain" at the left end and "Worst pain imaginable" at the right end. This type of VAS has been used for measurement of pain for patients with patellofemoral pain (Kannus and Nittymäki, 1993; Natri et al., 1998; Cowan et al., 2002b; Crossley et al., 2002; Mascal et al., 2003). The symptoms of knee pain were different between subjects as some patients experienced the worst pain during running while the other patients experienced the worst pain after running. Therefore, pain during and after running were assessed. Finally, one follow up clinical visit was made at least two weeks after the final biomechanical test. The overall improvement of the pain by foot orthotic treatment was confirmed by asking the subject whether their knee is better (+), equal (0) or worse (-).

3.2.4 Data processing and analysis

3.2.4.1 Kinematic data

Reconstruction of three dimensional marker positions was conducted using Expert Vision Three-Dimensional Analysis software (Motion Analysis Corporation, Santa Rosa, CA, USA). A set of programs were written by the author in Matlab™ (MathWorks, Natick, MA, USA) to calculate inter-segmental rotation and joint moments.

After the three dimensional reconstruction, raw marker traces were filtered using a recursive 2nd order Butterworth low pass filter (cut-off frequency 12 Hz). From a neutral standing trial, the joint centres for the ankle, knee and hip joint were defined using the additional markers. Segment coordinate systems (SCSs) were defined for the foot, shank and thigh in a way that the origin of the SCS located at the proximal joint centre of the segment and axes of SCS were aligned with the LCS. The SCS for the shank and thigh were then aligned anatomically so that the long axis of the segment connected the proximal and distal joint centres.

For the running trial data, transformation matrix relating the marker coordinates in the LCS to the same marker coordinates in SCS were calculated for each sampling point. A program (soder.m) from KineMat (ISB website) using a singular value decomposition method (Soderkvist and Weiden, 1993) was used to compute transformation matrices. The inter-segmental motion was then calculated using joint coordinate system, JCS, (Grood and Suntay, 1986; Cole et al., 1993). The proximal segment was always used as the reference in calculating the rotation at the ankle and knee joint. This means that for the ankle joint, plantar/dorsiflexion occurred around a medio-lateral axis of the shank, foot ab/adduction around the floating axis and foot in/eversion around the anterior/posterior axis of the foot. For the knee joint, flexion/extension occurred around the medio-lateral axis of the thigh, ab/adduction around the floating axis, and internal/external rotation around the proximal/distal axis of the shank. The joint angles for a neutral position were subtracted from the absolute value of inter-segmental rotation during running trials in order to reduce shifts of the curve due to between day variability of marker placement (Carson et al., 2001). The joint angles during the stance phase (from heel contact to toe-off) were normalized to 101 data points for each trial. The variables were defined as shown in Table 3-8. The variables which have been proposed to be related to

Table 3-8. Kinematic variables.

Variable names	Definition
Primary variables	
Peak foot eversion	Peak internal rotation angle of the foot with respect to the shank about the long axis of the foot
Total foot eversion	Difference between initial foot eversion angle at the heel contact and peak foot eversion
Peak internal tibia rotation	Peak rotation angle of the foot with respect to the shank about the floating axis
Total tibia rotation	Difference between initial tibial rotation angle at the heel contact and peak internal tibia rotation
Peak knee rotation	Peak internal rotation angle of the shank with respect to the thigh about the long axis of the shank
Total knee rotation	Difference between initial knee rotation angle at the heel contact and peak internal knee rotation
Secondary variables	
Peak dorsiflexion	Peak rotation angle of the foot with respect to the shank about the medio-lateral axis of the shank
Total dorsiflexion	Difference between initial dorsiflexion angle at the heel contact and peak dorsiflexion
Peak knee flexion	Peak rotation angle of the shank with respect to the thigh about the medio-lateral axis of the thigh
Total knee flexion	Difference between initial knee flexion angle at the heel contact and peak knee flexion
Peak knee adduction	Peak rotation angle of the shank with respect to the thigh about the floating axis
Total knee adduction	Difference between initial knee adduction angle at the heel contact and peak knee adduction

patellofemoral pain syndrome were chosen as primary variables. Secondary variables were calculated as they may provide supplemental information which may be useful. Mean value of each variable was calculated for each session for each subject.

3.2.4.2 Kinetic data

The ground reaction forces were filtered using a recursive 2nd order Butterworth low pass filter (cut-off frequency 100 Hz). Loading rate was calculated from the slope of the ground reaction forces. The point of application of the ground reaction forces and free moment were determined for each sampling point of the stance phases by solving the following vector equation.

$$\sum_{i=1}^{4} \vec{r}_i \times \vec{F}_i = \vec{r}_{POA} \times \vec{F}_{gr} + \vec{T}_z$$

where: $\vec{r}_i$, $\vec{r}_{POA}$ = position vectors for the force transducer 1 - 4 of the force plate and the point of application of the ground reaction force.

$\vec{F}_i$, $\vec{F}_{gr}$ = forces measured by force transducer 1 - 4 of the force plate and the ground reaction force.

$\vec{T}_z$ = free moment

Once the ground reaction force and its point of application were obtained, resultant joint forces and joint moments at the ankle and knee joints were calculated using inverse dynamics approach solving the following vector equations.

$$\sum \vec{F} = m \bullet (\vec{a} - \vec{g})$$
$$\sum \vec{M} = I \bullet \vec{\alpha} + \vec{\omega} \times (I \bullet \vec{\omega})$$

where: $\vec{F}$ = forces acting on the segment.

$\vec{a}$ = acceleration of the segment calculated from position data.

$\bar{g}$ = gravity.

m = mass of the segment (Clauser et al., 1969).

$\vec{M}$ = moments acting on the segment.

I = moment of inertia of the segment (Dempster, 1955).

$\bar{\omega}$ = angular velocity of the segment, using the transformation matrix of position data (Berme et al., 1990).

$\bar{\alpha}$ = angular acceleration of the segment determined as derivative of the angular velocity.

Ground reaction forces and joint moments during the stance phase (from heel contact to toe off) were normalized to 101 data points for each trial. Definitions of variables are shown in Table 3-9. Mean values were calculated for each variable for each session for each subject.

3.2.4.3 Pain assessment

Pain score was defined as the distance from the left end of the scale to the line which the subject marked. For each session, pain scores for during running and after running were assessed. Means for baseline condition (without foot orthoses) and treatment condition (with foot orthoses) were calculated for each subject.

Table 3-9. Kinetic variables.

Variable names	Definition
Primary variables	
Peak knee extension moment	Peak extension moment of the knee joint about the medio-lateral axis of the shank SCS
Peak knee abduction moment	Peak abduction moment of the knee joint about the anterio-posterior axis of the shank SCS
Peak knee external rotation moment	Peak external rotation moment of the knee joint about the long axis of the shank SCS
Secondary variables	
Peak plantarflexion moment	Peak plantarflexion moment of the ankle joint about the medio-lateral axis of the foot SCS
Peak foot abduction moment	Peak foot abduction moment of the ankle joint about the anterio-posterior axis of the foot SCS
Peak foot inversion moment	Peak inversion moment of the ankle joint about the long axis of the foot SCS
Impact peak	Maximum of the vertical ground reaction force during the impact phase
Average loading rate	Slope of 20% to 80% impact peak
Peak loading rate	Peak slope of the vertical ground reaction force

3.2.4.4 Statistical analysis

SPSS software (Chicago, IL, USA) was used for statistical analysis. Pain and biomechanical data for baseline condition (no orthoses) and treatment condition (with orthoses) were compared using paired sample T-test. Only the primary variables are used to test the hypothesis. Statistical tests for the secondary variables were conducted in order to gain supplemental information. Significance was set at $\alpha = 0.05$. If result of paired sample T-test showed significant or trend of difference ($p<0.10$), Pearson's correlation coefficient was calculated between the change in the variable and the change in pain. Pearson's correlation coefficients were also calculated between VAS score and kinematic and kinetic variables.

3.3 Results

3.3.1 Kinematic variables

Average curves for ankle and knee joint kinematics for baseline condition (without orthoses) and treatment condition (with orthoses) for one representative subject are shown in Figure 3-5. Differences in primary and secondary kinematic variables for all subjects are shown in Figure 3-6. Due to a technical problem, Subject 5 was excluded from the analysis.

Among the primary variables, there was a significant reduction in total knee rotation ($p<0.01$) for the treatment condition compared to the baseline condition. All subjects reduced total knee rotation. The average reduction in total knee rotation was 2.5 degrees. Peak knee rotation also showed a strong trend of reduction, but the differences were not significant ($p=0.06$). There was a strong trend of reduction in total foot eversion ($p=0.06$) with four of six subjects showing decreases between 1.2 - 4.8 degrees. The average reduction in total foot eversion was 1.7degrees. Four of the six subjects reduced total internal tibia rotation (2.9 - 4.0 degrees). However, one subject showed an increase of 4.2 degrees with the orthoses and the changes between treatment and baseline condition were not significant ($p=0.13$). There were no differences in peak foot

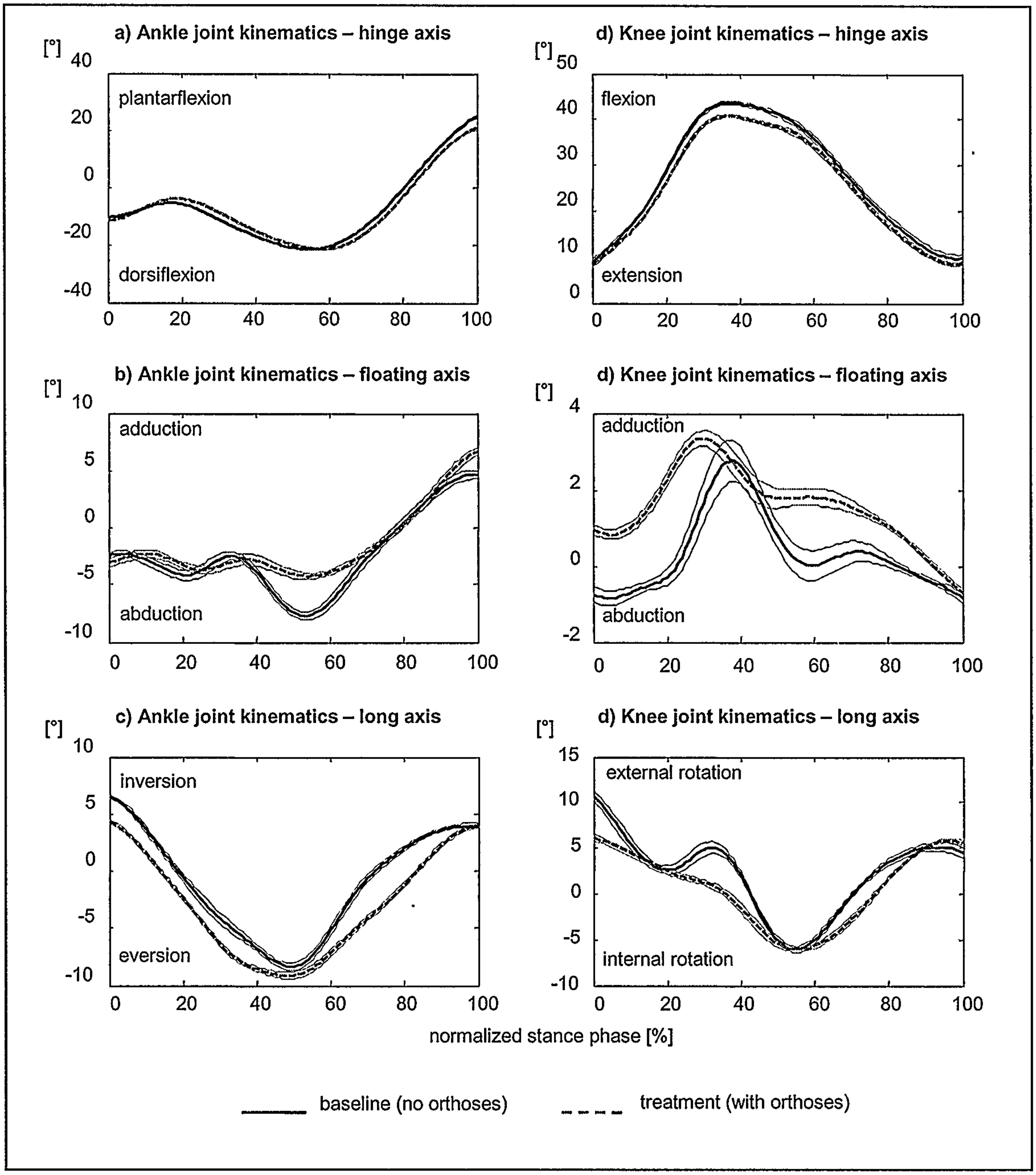

Figure 3-5. **Average (with standard error) for ankle and knee joint kinematics for one representative subject (subject 1). The solid line indicates the baseline condition (no orthoses, n=9) and the dashed line indicates the treatment condition (with orthoses, n=15).**

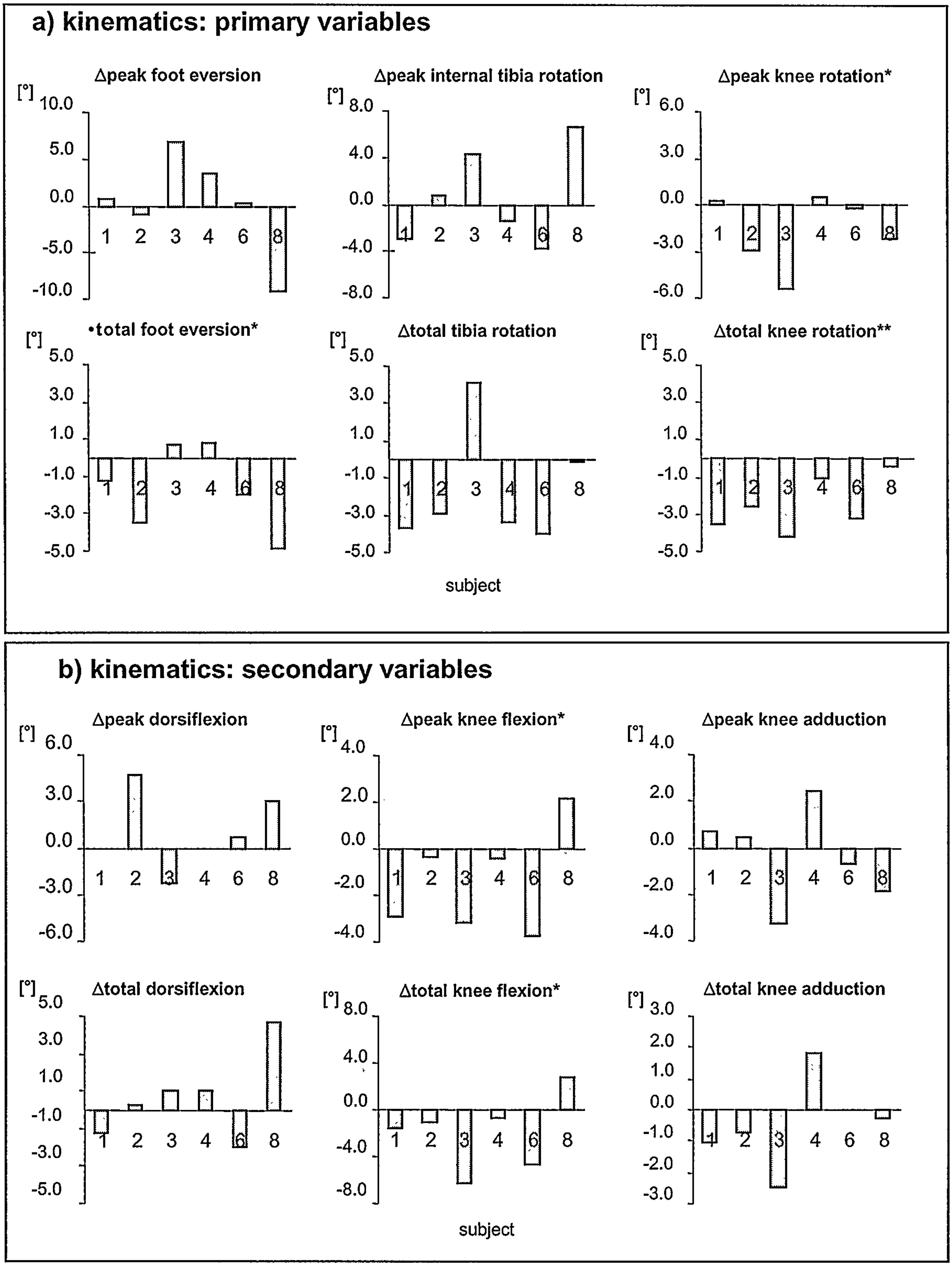

Figure 3-6. **Differences in kinematic variables from treatment (with orthoses) to baseline (no orthoses) condition for all subjects. ** p<0.05 and * p<0.10.**

eversion and peak internal tibia rotation between baseline and treatment conditions.

For the secondary kinematic variables, there were trends of reduction in peak and total knee flexion ($p<0.10$) for the treatment condition compared to the baseline condition with five of six subjects showing a reduction and one showing an increase. There were no differences in peak and total dorsiflexion and peak and total knee adduction.

3.3.2 Kinetic variables

Average curves for ankle and knee joint kinetics and vertical ground reaction force for baseline condition (without orthoses) and treatment condition (with orthoses) for one representative subject are shown in Figure 3-7. Differences in primary and secondary kinetic variables for all subjects are shown in Figure 3-8.

For the primary variables, changes between treatment and baseline condition were subject specific. There were no significant differences between conditions in peak knee abduction moment, peak knee external rotation moment and peak knee extension moment.

For the secondary variables, there was a trend of reduction in peak plantarflexion moment for the treatment condition compared to the baseline condition ($p=0.08$). Five of the six subjects showed reductions in impact peaks by 5 to 10%. However, one subject increased the impact peak by 11% and, thus,

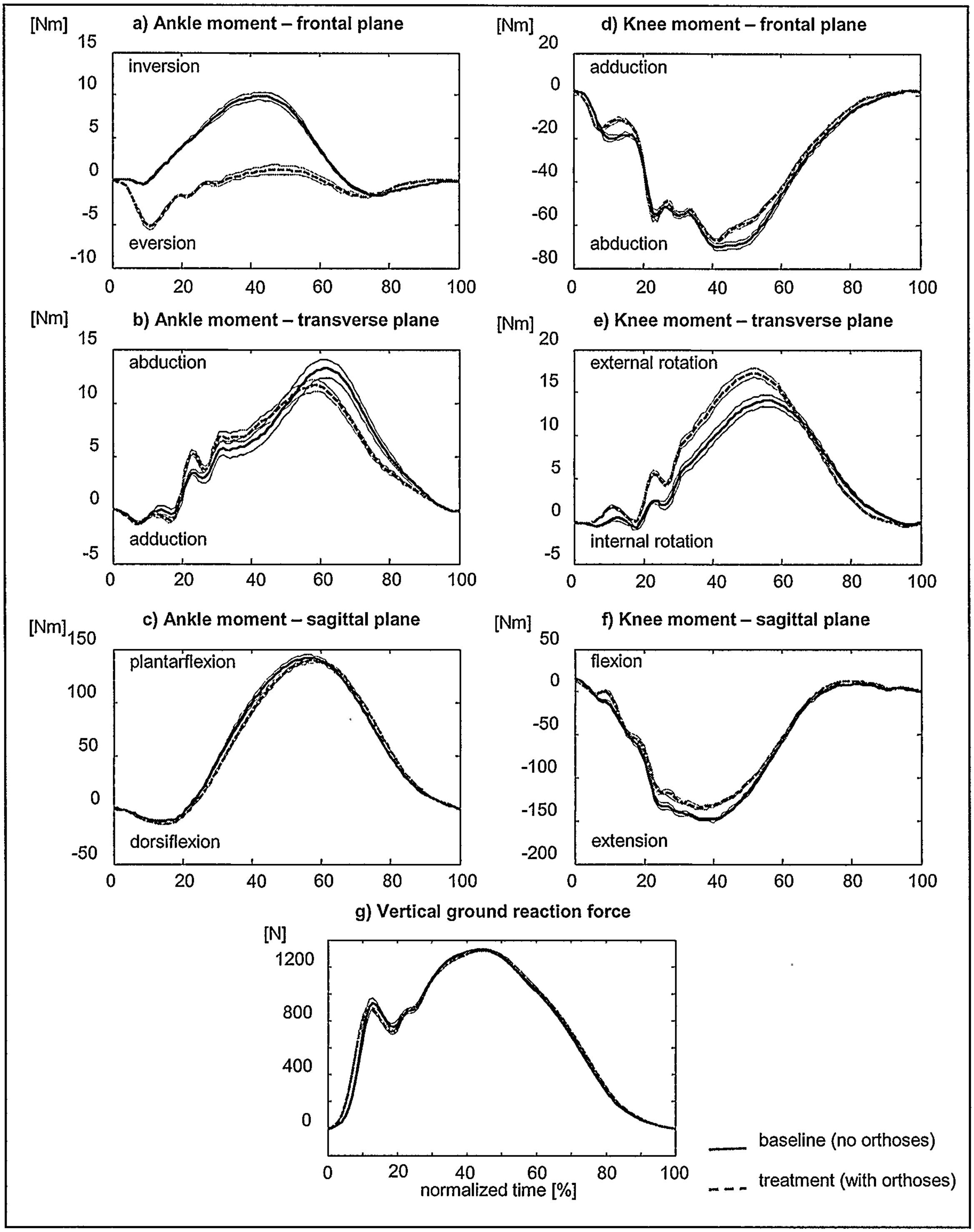

Figure 3-7. Average curves (and standard error) for ankle and knee joint moment and vertical ground reaction force for one representative subject (subject 1). Solid line represents baseline condition (no orthoses, n=9) and dashed line represents treatment condition (with orthoses, n=15).

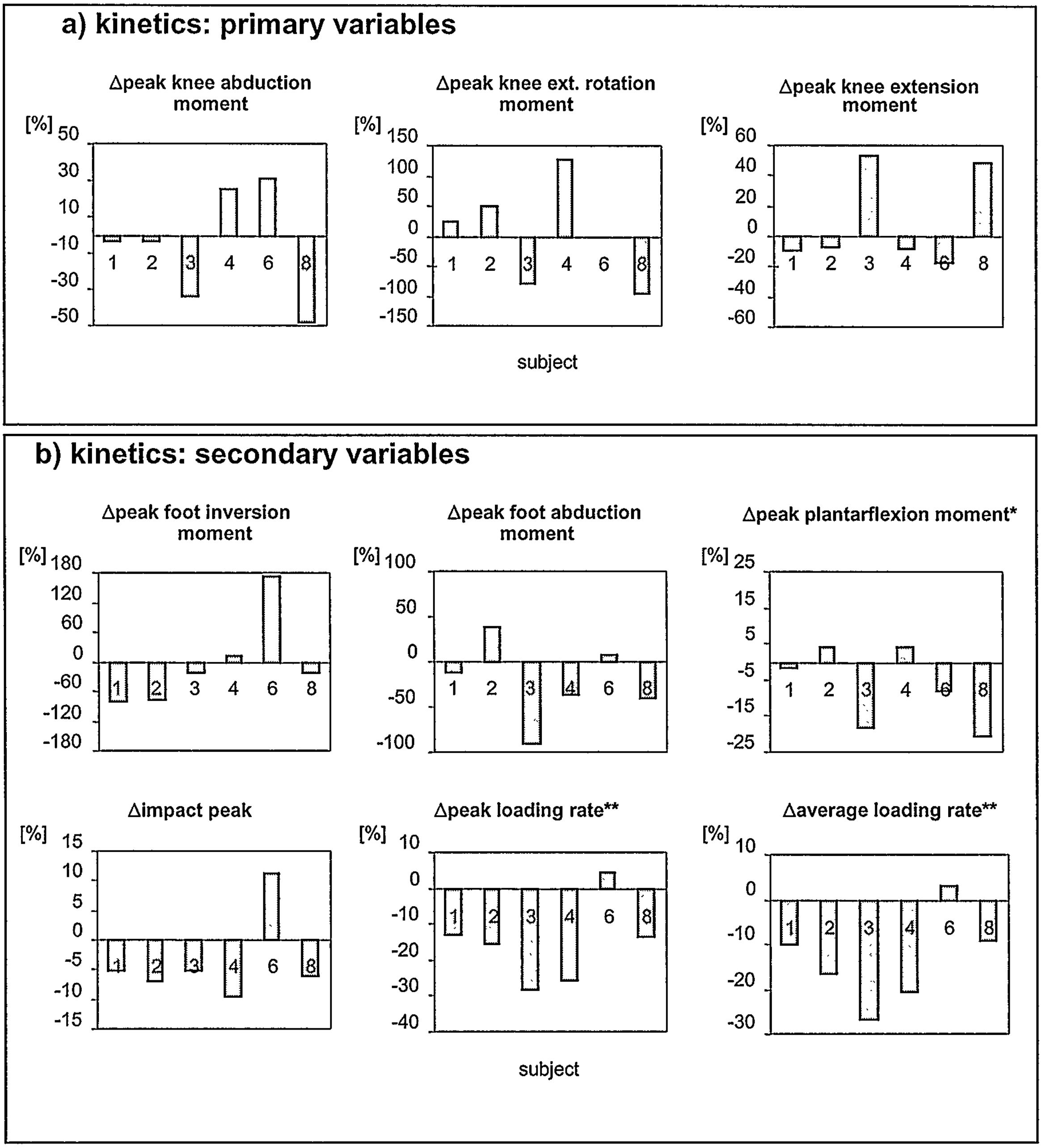

Figure 3-8. **Differences in kinetic variables between treatment (with orthoses) and baseline (no orthoses) for all subjects. ** p<0.05 and * p<0.10.**

the changes in impact peak were not significant (p=0.12). There were significant reduction in peak and average loading rate with five of the six subjects showing a decrease (p<0.01 and p<0.02, respectively). Average reduction was 15.3% for peak loading rate and 13.3% for average loading rate.

3.3.3 Pain score

The results of VAS scores for all the subjects for baseline and treatment condition are shown in Figure 3-9. There were significant reductions in VAS score for both pain during running (p<0.05) and pain after running (p<0.01) with all subjects showing reductions. The average reduction of the VAS score was 1.4 (42.9%) for pain during running and 1.9 (58.5%) for pain after running. Reduction of pain was confirmed in the follow-up visit in six weeks or later from the start of using foot orthoses.

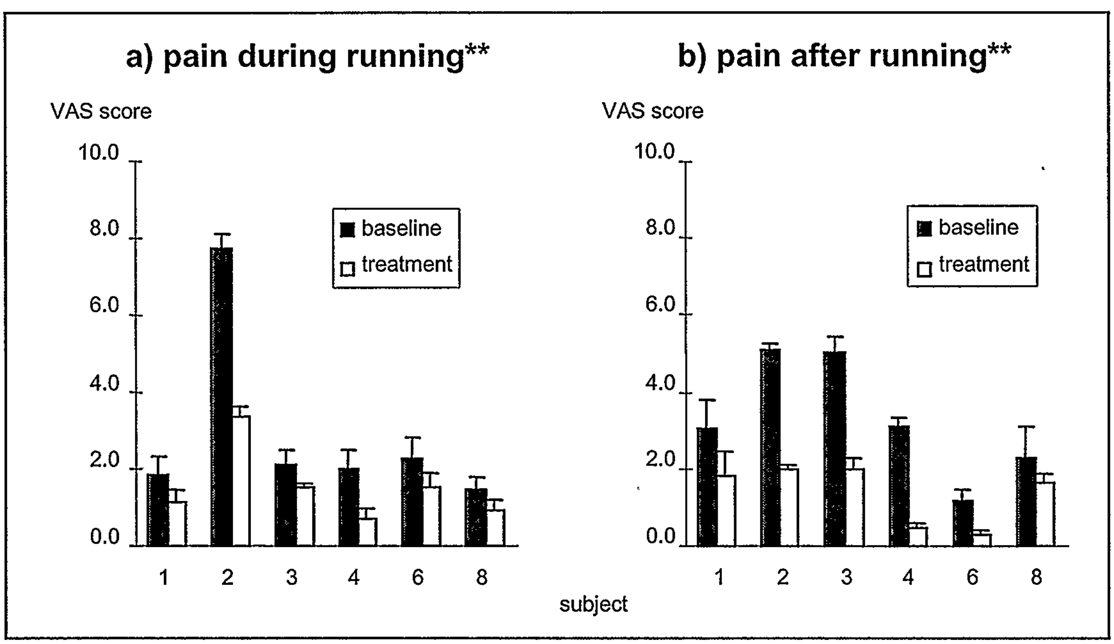

Figure 3-9. **Mean (and standard error) VAS scores for baseline (dark) and treatment (white) periods for all subjects for a) pain during running and b) pain after running. ** p<0.05 for the differences between baseline and treatment.**

Table 3-10. Pearson's correlation coefficient between changes in pain and changes in variables showing significant or trend of difference between two conditions (p<0.10).

	Δpain during run [%]	Δpain after run [%]
Primary variables		
Δtotal knee rotation [°]	-0.538	0.132
Δpeak knee rotation [°]	-0.372	-0.195
Δtotal foot eversion [°]	-0.055	-0.612
Secondary variables		
Δtotal knee flexion [°]	-0.432	0.492
Δpeak knee flexion [°]	-0.372	-0.195
Δpeak plantarflexion moment [%]	-0.847**	-0.259
Δpeak loading rate [%]	0.299	0.075
Δaverage loading rate [%]	0.276	0.148

** significant correlation ($p < 0.05$)

3.3.4 Relation between pain and biomechanical variables

Table 3-10 summarizes the relationship between changes in pain and changes in kinematic and kinetic variables. Foot orthoses reduced both pain and some of the kinematic and kinetic variables. Nonetheless, there were no significant positive correlations between changes in pain and changes in kinematic and kinetic variables. Instead, a strong negative correlation was found for changes in pain and changes in plantarflexion moment.

Table 3-11 is a summary of Pearson's correlation coefficients between the VAS score and the kinematic and kinetic variables. A significant positive correlation ($p<0.05$) and a strong positive correlation ($p=0.05$) were found between the VAS score for pain during running and the total knee rotation for the orthotic condition and no orthotic condition, respectively. Significant positive

Table 3-11. Pearson's correlation coefficient between VAS score and variables showing significant or trend of difference between two conditions (p<0.10).

	pain during running		pain after running	
	baseline	treatment	baseline	treatment
Primary variables				
total knee rotation [°]	0.728	0.739**	0.676	0.445
peak knee rotation [°]	0.376	-0.083	0.593	0.191
total foot eversion [°]	0.444	0.072	0.189	-0.141
Secondary variables				
total knee flexion [°]	0.005	-0.032	-0.143	-0.018
peak knee flexion [°]	0.296	0.197	-0.599	-0.406
peak plantarflexion moment [Nm]	-0.010	0.330	-0.134	-0.419
peak loading rate [kN/s]	0.814**	0.840**	0.744**	0.699
average loading rate [kN/s]	0.823**	0.802**	0.733**	0.712

** significant correlation ($p < 0.05$)

correlations were also found between VAS score for pain during running and peak and average loading rate in both conditions ($p<0.05$). A significant and a strong positive correlation were also found between VAS score for pain after running and peak and average impact loading rate for no orthotic and with orthotic conditions, respectively (no orthotic, $p<0.05$; with orthotic, $p<0.10$). However, Subject 2 reported greater VAS scores for pain during running than the rest of subjects and seemed to be an outlier. When subject 2 was excluded, there was no significant relationship between VAS score and total knee rotation (Figure 3-10) and the correlations between VAS scores and loading rates were not significant except for the relation between pain after running and peak loading rate in orthotic condition ($p<0.05$).

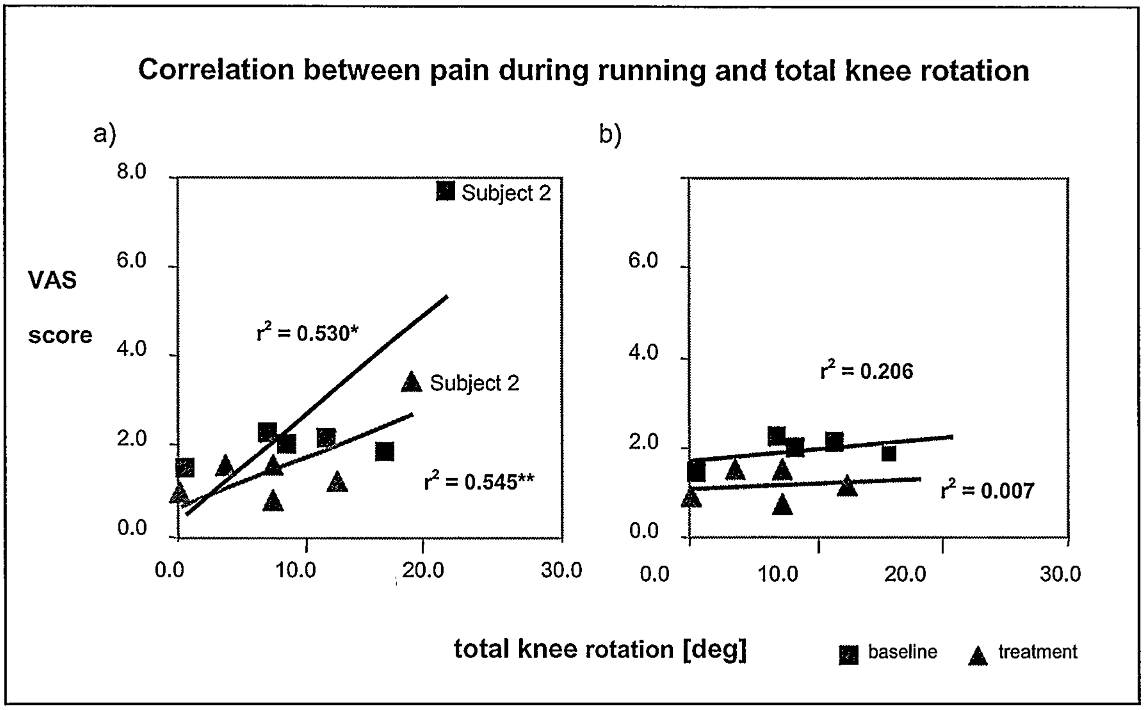

Figure 3-10. The relationship between the total knee internal rotation and the VAS score for pain during running. Squares represent data for the baseline condition (no orthoses) and triangles represent data for the treatment condition (with orthoses). a) Correlation was calculated using data for all subjects. Strong positive correlations were found indicating that more knee rotation was associated with more pain. b) Correlations were calculated by excluding the outlier (Subject 2). ** $p<0.05$ and * $p<0.10$.

3.4 Discussion

The purpose of this study was to investigate the effects of custom-made foot orthoses on pain and three dimensional kinematics and kinetics in the ankle and knee joints in runners diagnosed with patellofemoral pain syndrome. The results of this study showed that

1. after the treatment with custom-made foot orthoses, patellofemoral pain was significantly reduced,

2. among the primary variables, such foot orthoses significantly reduced total knee internal rotation, showed a tendency to reduce foot eversion and internal rotation of the tibia, but did not change knee joint moments and
3. among the secondary variables, such foot orthoses significantly reduced peak and average impact loading rate and showed a tendency to reduce knee flexion and peak plantarflexion moment.

Among the primary variables, only the total knee rotation was significantly reduced with the orthotic intervention. Lack of significant differences may be due to the small sample size (n=6) as well as the day-to-day variability because the measurements were four weeks apart. The results for the knee joint moments were the most sensitive to the day-to-day variability because of the calculation methods. Using the data (means and SDs) from this study, a power calculation (α=0.05 and β =0.8) showed that, with the number of subjects tested (n=6), the significant difference in knee external rotation moment that could have been detected was greater than 16 Nm. This is greater than the measured knee external rotation moments for most of the subjects (average knee external moments for without and with orthoses were 13.9 Nm and 8.9 Nm, respectively). In order to detect the difference of 6 Nm (approximately a 50 % change, which may be clinically relevant based on the data by Stefanyshyn et al., 1999), a sample size of 30 would be required. For the kinematic variables, in order to reduce day-to-day variability of the data, inter-segmental angles for neutral position were subtracted from absolute inter-segmental angles for each sample point during running trials (Carson et al., 2001). In addition, excursion values (value at heel strike to peak value), which were shown to be more reliable than the peak values when comparing data from different days (Ferber et al., 2002), were calculated as well as peak values. In spite of day-to-day variability of data, the results showed systematic reductions in primary kinematic variables. A power calculation (α=0.05 and β =0.8) showed that with a sample size greater than 24, the observed reduction of 1.7 degree in foot eversion and internal tibial rotation would have been significant. This was a good indication that foot orthoses may affect these variables.

One of the strengths of this study was that the subject population was homogeneous. Although this study looked at only six subjects, the systematic changes that were found in this study may be found in a larger sample size for this particular population. Another strength was that this study was, to the author's knowledge, the first that tested biomechanical effects of foot orthoses prospectively. When custom-made foot orthoses are prescribed to patients, the patients are required to gradually accommodate to the orthoses, then they are required to wear the foot orthoses all the time, indicating a possible adaptation process to the orthotic condition. Therefore, immediate effects of foot orthoses and testing subjects with and without foot orthoses after orthotic treatment may not truly reflect the effects of foot orthoses over a treatment period. With a prospective design, we could show what biomechanical variables were changed over the treatment with foot orthoses.

Finally, this was the first study that tested effects of foot orthoses on pain and on kinematics and kinetics at the same time. Thus, changes in kinematics and kinetics can be speculated to be the reason for changes in pain.

Significant reductions in patellofemoral pain after treatment with foot orthoses were found with all subjects reporting reduced pain. It was proposed that patellofemoral pain syndrome is related to excessive foot eversion coupled with excessive internal rotation of the tibia (James et al., 1978; Bahlsen, 1989), excessive knee rotation (McNerney, 1998) and large abduction and external rotation moments at the knee joint with reduced knee extension moment (Stefanyshyn et al., 1999; Brechter and Powers, 2002a and b). The results of this study showed that total knee rotation was significantly reduced for the orthotic condition ($p<0.01$) with all subjects showing a decrease. There was a trend of reduction in foot eversion ($p=0.06$) and internal tibia rotation ($p=0.13$) for orthotic condition with four of six subjects showing a decrease in both variables. Knee abduction, external rotation and extension moments were not changed with foot orthoses compared to the non-orthotic condition. Therefore, based on the results of this study one should conclude that the reduction of knee rotation with foot orthoses may be the primary reason for the reduction of pain for pronating runners who are diagnosed with patellofemoral pain syndrome treated with custom-made foot orthoses. For some subjects, reductions in foot eversion and internal tibia rotation may also have contributed to the reduction of pain.

However, the results did not show a significant positive correlation between the reduction in pain and the reduction in knee rotation, foot eversion nor internal tibia rotation, indicating that the amount of reduction in these variables was not associated with the amount of pain reduction. There were differences in the range of motion, joint configuration and initial pain level between subjects, which may be one of the reasons why there was no positive correlation between the change in pain and the changes in biomechanical variables. There was a significant positive correlation between the VAS score for pain during running and the total knee rotation, indicating that more severe pain was associated with more internal knee rotation. However, when Subject 2 who showed extreme results and could have been an outlier was excluded, there was no significant correlation between total knee rotation and VAS score. The calculated Pearson's correlation coefficient was sensitive to the outliers because VAS score is a subjective measure and only six subjects were tested. Therefore, whether pain level is related to knee rotation is still inconclusive. Hence, the results of this study failed to show the relevance of reduction in knee rotation in reduction in pain.

Reduction of knee rotation was previously reported when medial wedged foot orthoses were used for patellofemoral pain patients (Eng and Pierrynowski, 1994). Patellofemoral pain syndrome has been proposed to be associated with abnormal patella tracking (Paulos et al., 1980, McConnell, 1996). Relative rotation between the tibia and femur influences the patella tracking since the tendon from the quadriceps muscles covers the patella and inserts into the tibial tuberosity (Lee et al., 2003). Reduction in knee rotation with orthotic intervention, i.e. reduction in internal tibia rotation with respect to the femur, indicates that the abnormal patella tracking may also have been reduced with the tested orthotic intervention (Klingman et al., 1997). Therefore, it is speculated that reduction in knee rotation may have contributed to the reduction of pain. However, the reported reduction of 0.4° (Eng and Pierrynowski, 1994) and the average reduction in this study (2.5°) were small and it is yet not known how much changes occurred to the patella tracking with such a small reduction of the rotation angle. Knee rotation is one of the factors that are assumed to influence patella tracking. Other factors such as muscle activity patterns for vastus lateralis and vastus medialis oblique (McConnell, 1996) also may have been changed with orthotic intervention and have contributed to reduction in pain.

Finally, among the secondary variables, impact loading rate was significantly reduced with the orthotic intervention. In addition, the results found unexpected positive correlations between VAS score and loading rate for both pain during and after running, which was not due to the speed effects, although a high linear correlation has been observed between running speed and loading rate (Boyer and Nigg, 2004). This result may suggest that reduction of loading rate may contribute to reduce patellofemoral pain. However, the correlations were sensitive to the outlier (likewise the knee rotation) and there was no relation between VAS score and loading rate when the outlier was excluded except for the correlation between pain after running and peak loading rate in orthotic condition. Loading rate has not been proposed as a risk factor for patellofemoral pain syndrome. In addition, the amount of change in loading rate was not related to the amount of reduction of pain. Therefore, it is possible that the findings of significant relations between pain and loading rate might be a coincidence. Another possibility is that high impact loading rate may increase vibration, causing laxity in the joint due to creep in ligaments (Solomonow et al., 2000). Therefore, the patella may be less stabilized and vulnerable to abnormal tracking when the impact loading rate is high. High impact loading rate has been proposed to be a risk factor for running injuries (Hreljac et al., 1999) although it was not proposed for patellofemoral pain syndrome. Significant reduction in loading rate with orthotic interventions was previously reported (Mündermann et al., 2003). Therefore, it is speculated that reducing loading rate may be one of the important effects of foot orthoses in treatment of overuse injuries. Further studies are needed to support or reject such hypothesis.

3.5 Summary

Overuse injuries are common in runners. Foot orthoses have been successfully used in the treatment of overuse injuries in runners. Several mechanisms have been proposed to explain the positive results of foot orthoses. However, scientific evidence supporting these proposed mechanisms is missing. The lack of evidence may be related to the fact that mechanical aspects of foot orthoses have been tested in isolation from clinical aspects. In any case, the mechanisms how foot orthoses reduce pain and improve comfort are not well understood.

The purpose of this study was to quantify the effects of custom-made foot orthoses on pain and three dimensional kinematics and kinetics of the ankle and knee joint in runners diagnosed with patellofemoral pain syndrome. Baseline data were collected without using foot orthoses when the subjects had pain. The subjects received 2-week gradual accommodation to the orthoses followed by a full treatment with foot orthoses. Treatment data were collected using foot orthoses in the second week of the full treatment period.

After treated with custom-made foot orthoses, pain was reduced in all subjects. Total internal knee rotation was decreased in the orthotic condition compared to the no orthotic condition (2.5°) with all subjects showing a decrease. Peak and average loading rate was also reduced with five of the six subjects showing a decrease (15.3% and 13.3%). There were trends of reduction in foot eversion, knee flexion and peak plantarflexion moment for the orthotic condition compared to the no orthotic condition. Patellofemoral pain syndrome was proposed to be related to knee rotation, tibial rotation, foot eversion and knee joint moments. Based on these results it is speculated that the reduction of internal knee rotation with custom-made foot orthoses may have contributed to reduction of pain for runners with patellofemoral pain syndrome. However, no correlation was found between the magnitude of change in pain and the magnitude of change in internal knee rotation. Thus, it is suggested that the described mechanical changes may only be a part of the effects of foot orthoses and that the main effects of foot orthoses may be explained using other variables such as muscle activity.

4 THE EFFECTS OF CUSTOM-MADE FOOT ORTHOSES ON PAIN AND LOWER EXTREMITY MUSCLE ACTIVITY PATTERNS FOR RUNNERS WITH PATELLOFEMORAL PAIN SYNDROME

4.1 Introduction

Overuse injuries are common in runners (van Mechelen, 1992). The knee joint is the most common site for running injuries (James et al., 1978; Clement et al., 1981; Matheson et al., 1989; Taunton et al., 2002) and patellofemoral pain syndrome has been the most common diagnosis among all running injuries (James et al., 1978; Clement et al., 1981; Taunton et al., 2002). Foot orthoses are often used by runners in order to reduce pain from overuse injuries. It was reported that the success rate for foot orthotic treatment for overuse injuries is between 70-90% (James et al. 1978; Donatelli et al. 1988; Gross et al., 1991; Saxena and Haddad, 1998). Some case control studies also reported that compared to physiotherapy alone, using foot orthoses in combination with physiotherapy was a better rehabilitation for patients with patellofemoral pain syndrome who had lower extremity malalignment (Eng and Pierrynowski, 1993; Way, 1999).

Over the past two decades, it has been proposed that the main effects of foot orthoses may be limiting abnormal movement of the lower extremity such as foot eversion and internal tibia rotation, and this may be the reason for reduction of pain from overuse injuries (Subotnick, 1975; James et al., 1978; Lockard, 1988; Eng and Pierrynowski, 1994). However, there is little scientific evidence that supports the idea that foot orthoses reduce foot eversion. Many studies found no changes or significant but very small reduction in foot eversion when using foot orthoses (Smith et al., 1986; Brown et al., 1995; Stacoff et al., 2000b; Nigg et al., 2003; Williams et al., 2003; Stackhouse et al., 2004). Recently, a new concept has been proposed suggesting that the main effects of foot orthoses may be changing muscle activity rather than foot and/or leg kinematics as traditionally proposed (Nigg et al., 1999).

Muscle dysfunction has been proposed as a source for the development of patellofemoral pain syndrome. It was found that patients with patellofemoral pain syndrome had weaker knee extensors than healthy controls (Duffey et al., 2000). Additionally, imbalances between vastus medialis oblique (VMO) and vastus lateralis (VL) muscle activities which causes patella maltracking were proposed to be related to patellofemoral pain syndrome (Paulos, et al., 1980; McConnell, 1996; Klarenaar, 1999; Powers, 2000; Malone et al., 2002). Physiotherapy aiming to alter function of vastus lateralis and vastus medialis oblique muscles has been reported to be successful for treatment of patellofemoral pain syndrome with a success rate ranging between 70-84 % (Doucette and Goble, 1992; Natri et al., 1998). If foot orthoses are effective in the treatment of patellofemoral pain syndrome (as has been reported), it should be expected that foot orthoses alter muscle activity patterns, which may be one of the reasons for a reduction of pain.

However, only few studies tested the effects of foot orthoses on muscle activity. Subject specific responses in EMG intensity have been reported when using orthotic interventions (Tomaro and Burdett, 1993; Nawoczenski and Ludewig, 1999; Mündermann, 2003). For some specific orthotic interventions and some muscles, systematic and significant changes in EMG intensity were found (Nawoczenski and Ludewig, 1999; Mündermann, 2003). Significant changes in EMG onset timing and frequency content were also reported for orthotic interventions (Bird et al., 2003) and for different shoe materials (Wakeling et al., 2001a and 2002a).

There is initial evidence that foot orthoses may change muscle activity pattern (Nawoczenski and Ludewig, 1999; Mündermann, 2003; Bird et al., 2003). However, these studies tested muscle activity with or without foot orthoses for the immediate effects in healthy subjects or for patients that have been successfully treated from overuse injuries with orthotic interventions. Therefore, comparisons of conditions with and without foot orthoses may not really reflect changes between before and after treatment with foot orthoses.

For understanding why foot orthoses reduce overuse pains, the most important variable in studies analyzing the effect of foot orthoses is the pain experienced by these subjects. However, none of the cited studies simultaneously tested change in muscle activity and pain level for the injured population. Thus, the effects of foot orthoses on muscle activity pattern over a treatment period and the related effects on the subjective pain are yet not well understood. As patellofemoral pain syndrome is the most common diagnoses in runners and its etiology is related to muscle problems, it will be an ideal population to study.

Therefore, the purpose of this study was to investigate the effects of custom-made foot orthoses on pain and muscle activity pattern in runners diagnosed with patellofemoral pain syndrome.

It was hypothesized that if custom-made foot orthoses reduce pain,

1. relative EMG intensity of VL to VMO decreases when foot orthoses are used,
2. relatively earlier activation of VMO to VL occurs with foot orthoses compared to non-orthotic condition and
3. subject specific changes are shown for the other lower extremity muscles with orthotic intervention.

4.2 Methods

4.2.1 Subjects

Participants were selected from a population of injured runners/athletes around the University of Calgary over a period of 17 months. Eight volunteers (28.5 ± 10.6 yrs, 167.2 ± 10.6 cm, 63.6 ± 10.7 kg, mean ± SD) were recruited from 148 responses after passing a screening process (Figure 3-1). All subjects were diagnosed with patellofemoral pain syndrome by a sports medicine physician. Furthermore, a podiatrist confirmed that they had pronating feet.

Written consent was obtained from all subjects prior to the study based on the requirements of the University of Calgary committee for Medical Bioethics.

Patellofemoral pain syndrome in this study was defined as "a syndrome presenting with a history of peripatellar or retropatellar pain that worsens with activity or prolonged flexion and occurs in the absence of trauma, osteoarthritis and patellar instability. Physical exam reveals medial facet tenderness with or without retinacular or lateral facet tenderness and absence of articular or bony deformities or dysfunction in the connective tissue" (McClelland, 1998). Upon initial contact, all the patients (n=148) were screened for the following criteria; 1) having anterior knee pain but otherwise fit and healthy, 2) the history of the anterior knee pain were more than 1 months but not longer than 15 months, 3) no previous use of foot orthoses, 4) no history of traumatic knee injuries or surgeries, 5) minimum fitness ability to complete two 30 minutes runs per week, 6) no treatment for the knee pain. Patients who met the criteria (n=21) were referred to a sports medicine physician for physical exam and X-rays were taken. If the physician diagnosed the patients with patellofemoral pain syndrome, the patient (n=10) was referred to a podiatrist for clinical assessment of their lower extremities. The patients were considered as pronators if one of the following criteria were met; 1) forefoot varus $\geq 4°$, 2) rearfoot varus $\geq 3°$, or 3) relaxed calcaneal stance position $\geq 6°$. Leg length discrepancy between the left and the right leg was required to be less than 1.5 cm. (see details in 3.2.1.1, 3.2.1.2., Table 3-3 to 3-5).

Table 4-1. Summary of the performed testing procedure, explaining the three functional phases of testing.

Week	1		2		3		4		5		6		**After 9**
Functional period	Baseline				Accommodation				Treatment				
Orthoses	None				Gradual accommodation				All sport / daily activities				
Test condition	Without orthoses				With orthoses				With orthoses				
Testing session	1	2	3	4	5	6	7	8	9	10	11	12	
EMG	o	o	o	o	o	o	o	o	o	o	o	o	
Pain assessment	o	o	o	o	o	o	o	o	o	o	o	o	o

4.2.2 Procedure

The study followed a prospective study design. The subjects visited the lab twice a week for six weeks (12 sessions per subject). The six weeks were divided into three functional phases of a clinical trial (Table 4-1). Week 1 and 2 were defined as baseline period where the subjects had pain but did not have any treatment. Week 3 and 4 were defined as accommodation period. Subjects received the custom-made orthoses and adapted to the orthoses by gradually increasing the wearing time. Week 5 and 6 were defined as treatment period. The subjects were required to wear the foot orthoses for all sport activities as well as all daily activities if possible. In each session, the subjects performed 30 minutes of running at their regular running speed (2.0 - 3.2 m/s) around an indoor running track. Electromyographic (EMG) data from the lower extremity muscles and pain level was assessed. Data were collected four times for each functional period. Subjects were required to continue wearing the foot orthoses as treatment until a follow up visit. The follow up clinical visit was made to the podiatrist office at least two weeks after the completion of all measurements.

4.2.3 Experimental conditions

This project was a part of a comprehensive study including kinematic and kinetic measurements. Therefore, running sandals, which were advantageous for kinematic measurements were selected as the test footwear condition (Women's model; Bryce Canyon, Men's model; Greely, The Rockport Company, Canton, MA, USA). *Baseline data* were collected in the running sandals with the original inserts. *Treatment data* were collected by replacing the original inserts with custom-made foot orthoses. The foot orthoses were prescribed by a podiatrist for each subject. The orthoses consisted of polypropylene shell which were made from the negative cast at subtalar joint neutral position and covered with Spenco (Spenco Medical Corporation, Waco, TX). Subject specific post was added to the fore- and rearfoot if necessary (See 3.2.2 for details of construction of the custom-made foot orthoses used, Figure 3-2 and Table 3-6).

4.2.4 Data collection

4.2.4.1 Pain assessment

Pain assessment was conducted using a Visual Analogue Scale (VAS). VAS has shown to be a valid measurement of knee pain (Chesworth et al. 1989, Flandry et al. 1991). The VAS consisted of a 10 cm horizontal line with words “No pain” at the left end and “Worst pain imaginable” at the right end. This type of VAS has been used for measurement of pain for patients with patellofemoral pain (Kannus and Nittymäki, 1993; Natri et al., 1998; Cowan et al., 2002b; Crossley et al., 2002; Mascal et al., 2003). The symptoms of knee pain were different between subjects as some patients experienced the worst pain during running while the other patients experienced the worst pain after running. Therefore, during and after running pain were assessed. At least two weeks after the final biomechanical test one follow up clinical visit was made. The overall change of pain as a result of the foot orthotic treatment was quantified by asking the subject whether their knee pain level was better, equal or worse (+, 0 and -).

4.2.4.2 Measurement of muscle activity

Muscle activity was measured using surface electromyography (EMG). For each measurement, the subjects performed a 30 minute run at their self-selected speed. The leg with the worst pain was selected as a test leg and EMG data were measured from the rectus femoris (RF), vastus medialis oblique (VMO), vastus lateralis (VL), biceps femoris (BF), tibialis anterior (TA), gastrocnemius medialis (GM) and peroneus longus (PL) muscles. Bipolar surface EMG electrodes (Ag/AgCl) were placed on each muscle belly after removing the hair and cleaning of the skin using isopropyl wipes, and then secured using Cover-Roll stretch tape (Beiersdorf AG, Hamburg, Germany). Each electrode was 10 mm in diameter and had an inter-electrode spacing of 22 mm. A ground electrode was placed on the tibial lateral condyle. An accelerometer was placed on the heel of the testing leg in order to identify the time of heel strikes. The EMG signals were pre-amplified at source (Biovision, Wehrheim, Germany) and data were collected on a laptop via a DAQ-Card700 12-bit analogue-to-digital converter (National Instruments, Texas, USA) and a MiniDAT wireless transmitter (ViaSat, California, USA). EMGs were recorded at 2000 Hz (this frequency is limited by the band-width of the telemetry system) for 10 seconds for each lap while the subject was running the straight part. Time when data collection was started for each lap was recorded and called sample time and was used to calculate lap time. All equipment was powered by batteries and thus independent of noise from the power supply. The electrode placements were marked with a permanent marker in order to secure same electrode placements through all 12 testing sessions. Subject 7 was excluded from the study due to the failure of completing given tasks.

4.2.5 Data analysis

4.2.5.1 Pain assessment

Pain score was defined as the distance from the left end of the scale to the line which the subject marked. For each session, pain scores for during running and after running were assessed. Mean pain levels for baseline (without foot orthoses) and treatment (with foot orthoses) were calculated for each subject. If the reduction of pain was shown in VAS score and the final assessment support the change in VAS score, EMG data for the subject were analyzed.

4.2.5.2 Muscle EMG

Heel strikes were determined by rapid changes in acceleration data collected by the accelerometer mounted on the heel of the footwear. The EMG data were separated into each stride using the defined heel strike. Stride durations were calculated from heel strike to heel strike. EMG data for 10 strides from each lap were entered for analysis. All EMG data for each stride for each of seven muscles were checked visually and were eliminated if data contained noise. If more than half of the data were missing due to data reduction and/or technical problems, data for the session were excluded from the analysis. Data for lap 0 (right after start of run) were excluded from analysis since it is likely that there were warm up effects (ANOVA showed significant difference between lap

0 and lap 1 for the biceps femoris muscle post heel strike intensities for each of six subjects at $p<0.05$ level).

For each stride, EMG signals were resolved into their intensities in time-frequency space using wavelet analysis (von Tscharner, 2000). Intensity is the power of EMG signal contained within a particular frequency band. Intensities for a high (150-300 Hz; wavelet 6-8) and a low (25-75 Hz; wavelet 2 and 3) frequency band where it has been shown that changes in intensity occur during 30 minutes runs (Wakeling et al. 2001b) were calculated by summing the intensities of corresponding wavelet frequency bands at each sample point. In addition, total intensity was calculated as a sum of the intensities within 10 to 430 Hz (wavelet 1-10). Signals at frequencies less than 10 Hz (wavelet 0) were not included in the analysis since they often are the results of movement artifact. Details about wavelet EMG analysis can be found elsewhere (Wakeling et al., 2001a and 2002b). Data were calculated for pre-heel strike (from 150 ms before to heel strike) and post-heel strike (from heel strike to 200 ms after). In addition, relative activation timing and intensity ratio between the VL and VMO were calculated for each of three frequency band. Relative timing was calculated for 10 % of peak intensity and peak intensity. The variables were defined as shown in Table 4-2.

As data collection was conducted over 30 minute runs, time effects on the variables were possible. In a previous EMG study using a similar protocol (Wakeling et al., 2001b), EMG intensities showed frequency dependent changes

Table 4-2. Definition of EMG variables.

Variable names	Definition
Pre-heel strike total intensity	Sum of total intensity across sample point from 150 ms before heel strike to heel strike
Pre-heel strike low-frequency band intensity	Sum of intensity in low frequency band across sample point from 150 ms before heel strike to heel strike
Pre-heel strike high-frequency band intensity	Sum of intensity in high frequency band across sample point from 150 ms before heel strike to heel strike
Post-heel strike total intensity	Sum of total intensity across sample point from heel strike to 200 ms after heel strike
Post-heel strike low-frequency band intensity	Sum of intensity in low frequency band across sample point from heel strike to 200 ms after heel strike
Post-heel strike high-frequency band intensity	Sum of intensity in high frequency band across sample point from heel strike to 200 ms after heel strike
VL/VMO intensity ratio	Sum of intensity across sample point from 150 ms before to 200 ms after heel strike for VL divided by that of VMO
Relative 10% timing	Difference in timing when 10% of peak intensity occurs. Time for the VL was subtracted from that of VMO
Relative peak timing	Difference in timing when peak intensity occurs. Time for the VL was subtracted from that of VMO

over a course of a 30 minute run, which was interpreted as sub-maximal fatigue. Therefore, linear regression analysis was conducted for each subject-muscle-day combination for all variables. The model for regression analysis was defined as

$$\text{Model: variable(i)} = \beta_0 + \beta_1 \times \text{(sample time)}$$

and the hypothesis whether β_1 is zero or not was tested at $p<0.05$ level. If the results showed that β_1 was significantly different from zero and the model explains more than 10 % of the data (model fit given as $R^2 \geq 0.1$), it was assumed that there was practically significant time effect on the variable, which probably was due to fatigue. Then, for each subject-muscle-condition-variable combination, if more than half the testing sessions with the condition had systematic time effects, it was assumed that there was time effect on the subject-muscle-condition combination for the variable.

For those who did not show time effects, mean values were calculated for each day (day mean) by pooling all data. Mean value for each condition was calculated for each subject using day means. For those who showed time effects in either condition, only the data from the laps where data were successfully collected from all days entered in analysis were used. Mean values were calculated for each day using data from the selected laps, and then mean of a condition was calculated for each subject using day means. Table 4-3 summarizes the number of steps used in the analysis.

Table 4-3. Number of steps used to make day means.

subject	1	2	3	4	6	8
Maximum number of steps that can be used	110	120	70	120	100	120
Muscle						
Vastus lateralis	109-110^t	68-70	70^t	40^t	50^t	90-120
Rectus femoris	110	88-90^t	70^t	40^t	70-100	60-120
Vastus medialis oblique	80-110	90^t	70^t	40^t	70-100	70-120
Tibialis anterior	110^t	110	70^t	40^t	70-100	40^t
Peroneus longus	80-110	21-30^t	70^t	40^t	70-100	40^t
Gastrocnemius medialis	110	70^t	70^t	70-120	50^t	90-120
Biceps femoris	110^t	70^t	70^t	40^t	70-100	90-120

^{t} time effect was shown for the subject-muscle combination.
If the number is different between days, range (minimum-maximum) is shown.

4.2.6 Statistical analysis

SPSS software (Chicago, IL, USA) was used for statistical analysis. Data for baseline condition (no orthoses) and treatment condition (with orthoses) were compared using paired sample T-test. Significance was set at $\alpha = 0.05$. When there was a significant difference between two conditions, Pearson's correlation coefficients were calculated between the change in pain and the change in the variable in order to understand its relation with changes in pain.

4.3 Results

4.3.1 Running speed and step duration

The subjects ran at a constant speed and step duration during the 30 minute runs. The greatest variation of running speed and step frequency (given as SE/mean) was less than 3 % and 1 % respectively, within 30 minutes run. Independent t-test showed no differences in running speed and step duration between two testing conditions for each of the six subjects at $p < 0.05$ level.

4.3.2 Pain score

The pain score showed a reduction for all seven subjects. However, the results of the final pain assessment did not show a reduction of pain for Subject 5.

Thus, to discuss the factors responsible for a reduction of pain, the results of subject 5 were excluded and the data for the remaining six subjects were analyzed. The results showed that VAS scores for all six subjects for treatment condition were significantly reduced compared to baseline condition for both pain during running and pain after running ($p<0.01$) with all subjects showing a reduction. The average reduction of the VAS score was 1.4 (42.9%) for pain during running and 1.9 (58.5%) for pain after running (see Figure 3-9).

4.3.3 EMG intensity

The EMG intensity variables contained between-day variability of approximately 20 %. The mean between day variability in the same condition for each muscle (calculated from correlation of variability, CV, for all subject-variable-condition combination (n=72)) was 19.2 % for the VL, 13.7 % for the RF, 17.9 % for the VMO, 22.4 % for the TA, 22.8 % for the PL, 18.0 % for the GM and 20.2 % for the BF.

EMG intensity was tested for forty-two combinations (2 time windows x 3 frequency bands x 7 muscles). Table 4-4 summarizes the results for all 42 combinations. Among the 42 combinations, only seven showed significant differences between treatment (with orthoses) and baseline (no orthoses) conditions and changes in intensity due to orthotic intervention for the other 35 combinations were subject specific and not systematic. The VMO and PL muscles showed systematic changes for the post-heel strike time window, the BF

Table 4-4. p-values of the results of paired sample T-test testing the differences between baseline (no orthoses) and treatment (with orthoses).

muscles	total intensity	intensity in the low frequency band	intensity in the high frequency band
Vastus lateralis			
pre-heel strike	0.382	0.495	0.145
post-heel strike	0.209	0.158	0.346
Rectus femoris			
pre-heel strike	0.100	0.082	0.144
post-heel strike	0.156	0.180	0.138
Vastus medialis oblique			
pre-heel strike	0.473	0.397	0.218
post-heel strike	**0.032**	**0.034**	0.338
Tibialis anterior			
pre-heel strike	0.358	0.445	0.209
post-heel strike	0.147	0.131	0.172
Peroneus longus			
pre-heel strike	0.228	0.142	0.336
post-heel strike	**0.041**	**0.029**	0.087
Gastrocnemius medialis			
pre-heel strike	0.481	0.437	0.369
post-heel strike	0.392	0.408	0.403
Biceps femoris			
pre-heel strike	**0.012**	**0.022**	**0.024**
post-heel strike	0.426	0.479	0.414

Numbers in bold are statistically significant.

muscle for the pre-heel strike time window. Figure 4-1 shows individual results for these three muscles. Compared to no orthotic condition, there were significant increase in the total VMO intensity ($p<0.05$) when custom orthoses were used with 5 of 6 subject showing an increase. There were significant increases of VMO intensity in the low frequency band ($p<0.05$) with 4 of the 6 subjects showing an increase. The average increases were 40.8 % and 47.5 % for total intensity and

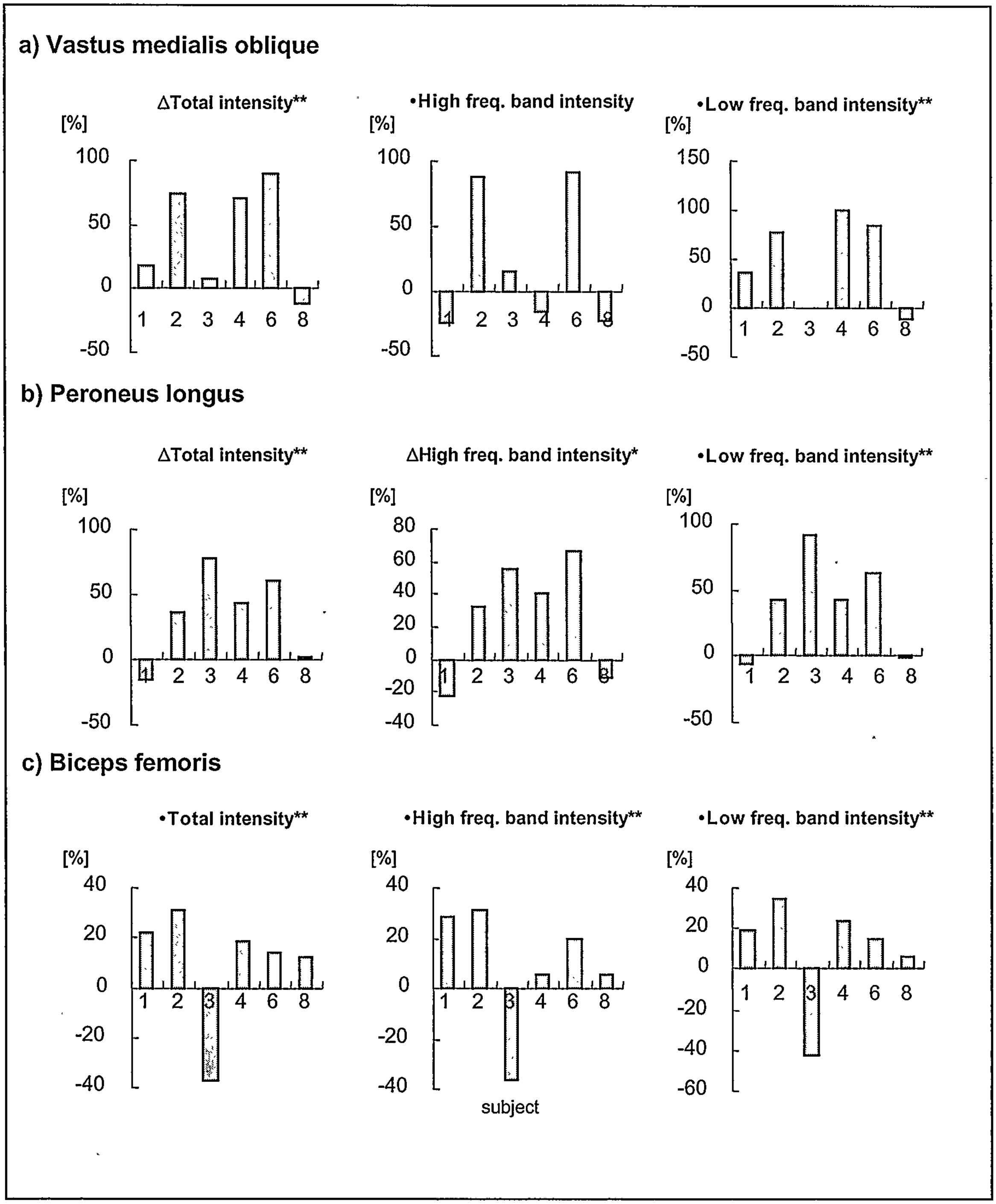

Figure 4-1. Individual results for change in EMG intensity between treatment (with orthoses) and baseline (no orthoses) for the total intensity and the intensity in low- and high frequency bands. a) vastus medialis oblique post-heel strike time window. b) peroneus longus for post-heel strike time window. c) biceps femoris for pre-heel strike time window. ** $p<0.05$, * $p<0.10$.

the intensity in the low frequency band respectively. The between-day variability in the same condition for total and low frequency intensities were 16.6 % and 19.5 %, respectively. Significant increase of PL intensity was shown for the orthotic condition for the total intensity ($p<0.05$) and for the intensity in the low frequency band ($p<0.05$). The average increases for the total intensity were 33.8 % and 38.3 % for the intensity in the low frequency band with four subjects showing an increase greater than 20 %. The average between-day variability for these variables was 13.7 % and 16.2 %. There were significant increases of BF intensity in the total intensity ($p<0.02$), the intensity in the low frequency band ($p<0.05$) and the intensity in the high frequency band ($p<0.05$). The average between-day variability was 10.7 %, 12.8 % and 8.2 %, respectively. Five of the 6 subjects showed increases greater than 5 % for the orthotic condition. However, one subject showed a decrease greater than 35 % and the average increase of BF intensity was 10.0 %, 9.0 % and 9.4 % for total intensity, intensity in the low- and high frequency, respectively.

4.3.4 EMG intensity ratio (VL/VMO)

There were significant reductions in the VL/VMO ratio for the total intensity ($p=0.002$) and the intensity in the low frequency band ($p=0.002$) when custom-made orthoses were used. All subject systematically showed a decrease and the average reductions in the VL/VMO ratio were 22.2 % and 24.0 % for the total intensity and the intensity for the low frequency band respectively. The change for high frequency band was subject specific and non-systematic (Figure 4-2).

4.3.5 Relative timing between VL and VMO

The results showed that there were increases in the relative 10 % timing for the orthotic condition compared to the no orthotic condition. Significant increases were found for the total intensity ($p<0.05$) and the intensity in the low frequency band ($p<0.05$) with 5 subjects showing an increase. The average increases were 5.6 ms for the total intensity and 6.7 ms for the intensity in the low frequency band. The change in the high frequency band showed a trend of increase but was not significant ($p<0.10$).

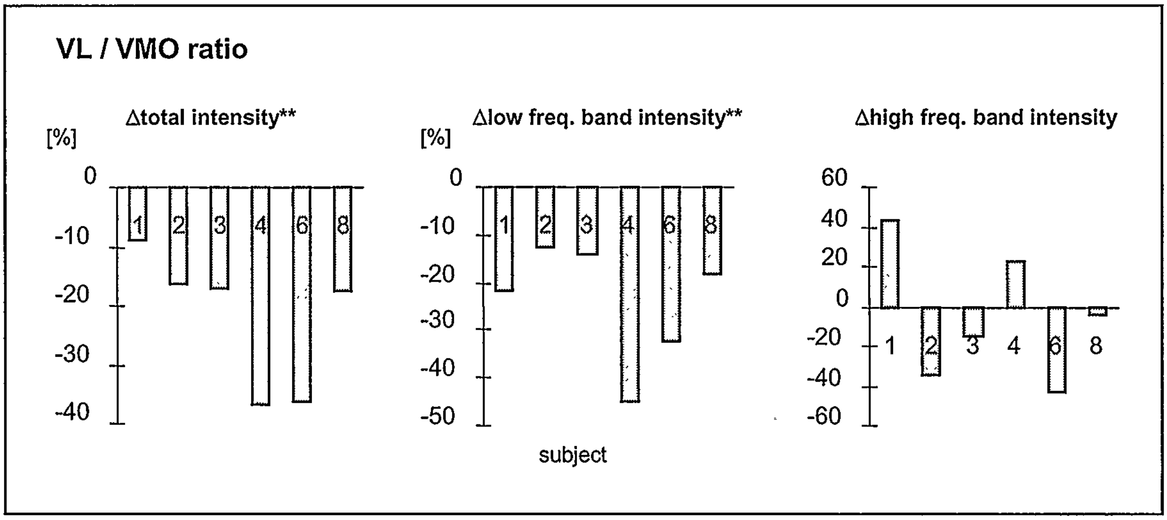

Figure 4-2. **Individual results for change in VL / VMO ratio from treatment condition (with orthoses) to baseline (no orthoses) for total intensity and intensity in low- and high frequency bands. ** p<0.05 and * p<0.10.**

In contrast to the relative 10 % timing, there was a trend of reduction in the relative peak timing in the orthotic condition compared to the no orthotic condition. A decrease was shown in five subjects for the total intensity (p=0.051) and the intensity in the high frequency band (p=0.15) and in four subjects for the intensity in the low frequency band (p=0.08). The average decreases were 4.6 ms, 4.7 ms and 2.3 ms for the total, the low- and the high frequency band intensity respectively (Figure 4-3).

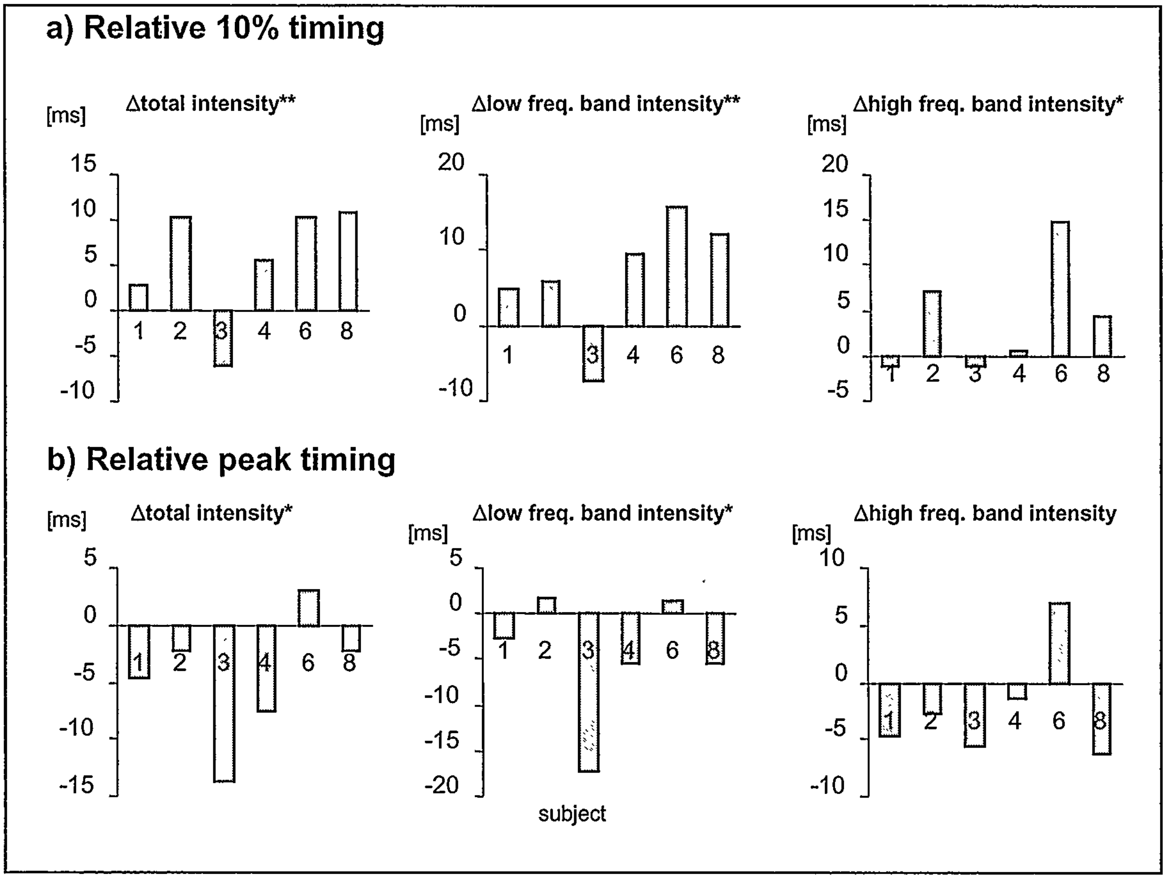

Figure 4-3. **Individual results for change in relative timing between the VMO and VL from treatment condition (with orthoses) to baseline (no orthoses) total intensity and intensity in low- and high frequency band. a) changes in relative 10 % timing and b) changes in relative peak timing. ** p<0.05 and * p<0.10.**

4.3.6 Relation between pain and EMG variables

Table 4-5 summarizes the relation between changes in pain and changes in EMG intensity variables which showed significant differences between the two conditions. There was a significant negative correlation between change in pain after running and change in VMO intensity for the total and the low frequency band (Figure 4-4). A negative correlation was found for the change in pain during running and the change in VMO intensity. However, the correlation was not significant for both total intensity (p=0.15) and low frequency band intensity (p=0.07). There was no correlation between the change in pain and the change in EMG intensity for the PL and BF.

Table 4-6 summarizes the correlation between changes in pain and changes in VL/VMO ratio, and relative timing variables which showed a trend or significant differences between the two conditions. The results showed that there was a significant positive correlation (p<0.05) between the change in pain after

Table 4-5. Pearson's correlation coefficient between change in pain and change in EMG intensity variables showing significant differences between the two conditions.

	ΔVMO post-HS [%]		ΔPL post-HS [%]		ΔBF pre-HS [%]		
	total	low freq.	total	low freq.	total	low freq.	high freq.
Δpain during running [%]	-0.509	-0.686	0.078	0.152	-0.598	0.221	-0.682
Δpain after running [%]	-0.811**	-0.794**	-0.716	-0.670	0.024	0.437	-0.113

** significant correlation (p < 0.05). post-HS: post-heel strike. pre-HS: pre-heel strike.

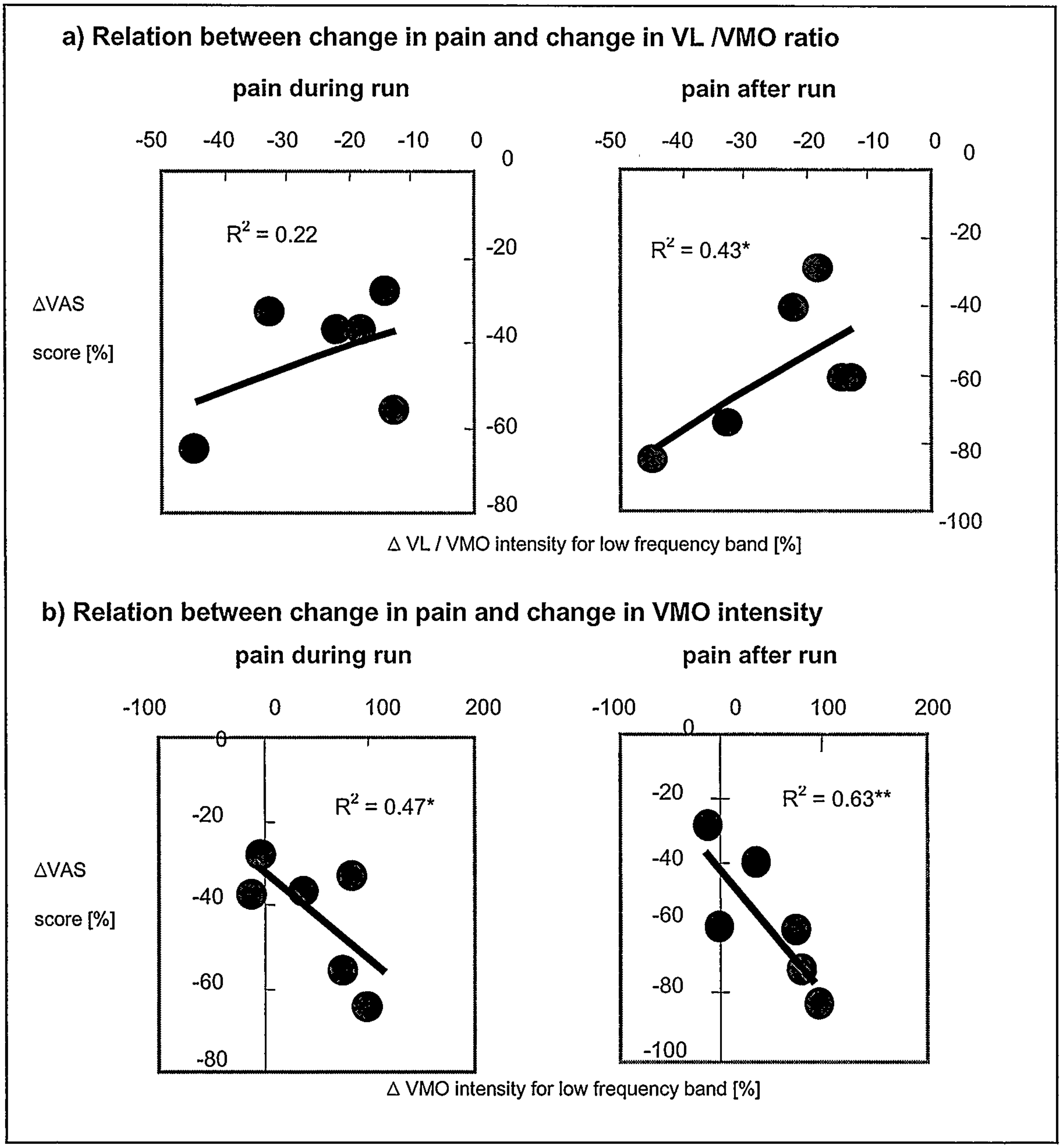

Figure 4-4. **Relationship between change in pain and change in EMG variables; a) VL/VMO ratio and b) VMO intensity, for the low frequency band. Positive correlations between pain and VL/VMO ratio indicate that a greater reduction of pain is associated with a greater decrease in VL/VMO ratio. Negative correlation between pain and VMO intensity indicates that a greater reduction of pain was associated with a greater increase of VMO intensity. ** p<0.05 and * p<0.10.**

Table 4-6. **Pearson's correlation coefficient between change in pain and change in VL/VMO ratio and relative timing variables showing significant or trend of difference between the two conditions.**

	ΔVL/VMO [%]		Δrelative 10% timing [ms]			Δrelative peak timing [ms]	
	total	low freq.	total	low freq.	high freq.	total	low freq.
Δpain during running [%]	0.334	0.466	-0.374	-0.269	0.075	-0.024	-0.372
Δpain after running [%]	0.791**	0.656	0.075	-0.067	-0.252	0.072	-0.070

** significant correlation ($p < 0.05$).

running and the change in VL/VMO ratio for total intensity. A trend of positive correlation was also shown for the low frequency band intensity ($p<0.10$). Pearson's correlation coefficients were positive for the correlation between the change in pain during running and the change in VL/VMO ratio, however, the correlation was not significant (Figure 4-4). There was no correlation between the change in pain and the change in relative timing for both 10 % and the peak intensity.

4.4 Discussion

The major findings in this study were:

1) Foot orthoses systematically change EMG intensity and timing of EMG activity for some selected muscles.
2) The measured changes in EMG intensity due to orthotic interventions were in all tested cases increases.

3) Systematic changes were seen predominantly in the low frequency band of the EMG signal.
4) There were significant correlations between the change in pain and the change in the vastus medialis oblique EMG intensity.

These findings are discussed in detail.

4.4.1 Effects of foot orthoses on EMG activity

It was proposed (Nigg et al., 1999) that for a given movement task (e.g. running) each joint has a preferred movement path: a path for which the resistance is minimal. The body system is programmed to avoid any deviation from this path and appropriate muscles will be activated if any interventions (e.g. foot orthoses, shoes and inserts) try to change the skeletal preferred movement path. Based on the preferred movement path theory, a new paradigm for foot orthoses (Nigg et al., 1999) proposed that the primary effect of foot orthoses is to alter muscle activity rather than to align the skeleton, as it has been traditionally proposed. However, the preferred movement path is individually specific and results for EMG reactions to the same orthotic interventions, in most cases, may not be systematic. However, if substantial changes in EMG intensity are shown systematically with orthotic interventions, it would be a support for this new concept (Nigg et al., 1999) that the main effect of foot orthoses is to alter muscle activity.

Changes in EMG intensity due to the tested orthotic interventions were generally, as expected, subject specific and not systematic. However, there were systematic changes in EMG intensity with orthotic interventions for some muscles. Systematic and non-systematic changes in EMG intensity as a response to orthotic interventions have been previously reported (Nawoczenski and Ludwig, 1999; Mündermann, 2003). The reported systematic changes were different between these studies, and different from the results of this study. The reasons for these differences may be in the different types of foot orthoses investigated in these studies, different subject populations and/or different study protocols. Regardless, the results of all studies suggest that foot orthoses systematically change muscle activity and related EMG intensities supporting the new concept of foot orthoses (Nigg et al., 1999).

In addition to changes in EMG intensity, it was found that the tested foot orthoses systematically changed the relative timing of muscle activity between the VL and VMO. Muscles are coordinated in terms of level of activity as well as timing of contraction, as it was shown that similar pattern of EMG were obtained within and between subjects during locomotion (Winter, 1991). Therefore, if the skeleton has a preferred movement path and foot orthoses support or counteract the preferred movement path (Nigg et al., 1999), it is expected that there may be systematic change in timing of muscle activity as well as the change in intensity. Change in timing of EMG with orthotic intervention was reported earlier for the erector spinae and the gluteus medius muscles (Bird, et al., 2003). The authors noted that such change may be clinically relevant since delayed onset of trunk muscles was reported for lower back pain patients. Relative timing of VL and VMO muscle activity was shown to affect joint loading in the patellofemoral joint (Neptune et al., 2000). Therefore, it is possible that change in EMG timing may be one of the important effects of foot orthoses.

4.4.2 EMG intensity response to the orthotic interventions

In this study, all the systematic changes in EMG intensity with orthotic interventions were increases. This result agrees with a previous study (Mündermann, 2003). Increase was found for the VMO and PL post-heel strike total intensity and intensity in the low frequency band as well as the BF pre-heel strike total intensity and the intensity in the low- and high frequency bands. According to the new concept (Nigg et al., 1999), increase of muscle activity with orthotic interventions occurs when the foot orthoses do not support the preferred movement path of the skeleton. It was found that compared to the baseline (no orthoses), some kinematic variables were systematically changed when the subjects were tested with the foot orthoses after the treatment, indicating that foot orthoses may have counteracted the preferred movement path. For example, there was a trend of reduction in foot eversion with the orthotic intervention (see chapter 3). In response, there was a significant increase in the intensity of the PL (foot evertor) for post-heel strike time window. Reduction of foot eversion and increase of intensity for the PL in response was also reported previously (Mündermann, 2003). These results support the new concept that muscle activity may increase when foot orthoses do not support the preferred movement path. The new concept also proposed that the optimal foot orthoses may decrease muscle activity (Nigg et al., 1999). As the pain was reduced with the tested foot orthoses, these orthoses are considered to be optimal in clinical sense. However, these foot orthoses increased muscle activities and do not support the new concept. It should be noted that the tested subjects in this study were injured and the overpronation may have contributed to their symptoms. If the movement pattern for the baseline is assumed to be their preferred movement path, the preferred movement path is not necessarily to be ideal in terms of injury. Therefore, contrast to the new concept, it is suggested that optimal foot orthoses do not necessarily reduce muscle activity.

The increase of EMG intensity was also found for the BF. The idea of preferred movement path (Nigg et al., 1999) may not be able to explain the change in BF intensity, because the change was shown for pre-heel strike time window (swing phase) and unlike the stance phase, the swing leg should be able to move freely without being constrained by foot orthoses. Pre-activation of the muscles before heel strike corresponds to the muscular preparation to accept the weight upon heel strike by stabilizing the joint and to minimize soft tissue vibration caused by the impact at heel strike (Nigg, 1997 and 2001). It was found that changing impact loading by changing mid-sole hardness of the shoe caused differences in muscle tuning before the heel contacts to the ground (Wakeling et al., 2001a and 2002a). The tested foot orthoses were made from semi-rigid polypropylene shell and were more rigid than regular shoe inserts. Significant change was found in loading rate between the two tested conditions (see chapter 3). Therefore, it is speculated that the changes found for BF pre-heel strike intensities may be related to change in muscle tuning due to the change in rigidity of shoe inserts.

4.4.3 Frequency response to the orthotic intervention

It was shown that the low frequency components of the EMG signal correspond to the myoelectric activity of the slow-twitch fibres while the high frequency components correspond to the myoelectric activity of the fast-twitch fibres when EMG was collected using fine wire electrode in animals (Wakeling et al., 2002b). Recently, a study testing EMG in man using surface electrodes (Wakeling and Rozitis, 2004) showed higher frequency components in EMG signal when the faster motor units were assumed to be active. The authors (Wakeling and Rozitis, 2004) reported their results as support for previous suggestions (Wakeling et al. 2001b) that distinct populations of low- and high frequency (peaking at about 50 and 170 Hz) myoelectric activity observed during human locomotion may result from activity of different motor units.

The frequency band chosen in this study was based on the previous study (Wakeling et al. 2001b) and it is likely that the different frequency bands correspond to the different motor units. In this study, the systematic changes in EMG intensity and timing occurred in the low frequency band, but not in the high frequency band except for the EMG intensity for the BF. This result that changes occurred predominantly in the low frequency band did not agree with a former study (Mündermann, 2003) where it was reported that the change in EMG intensity with orthotic interventions occurred in both low- and high frequency bands with greater changes observed in the high frequency band. The difference in results may be explained by different methodology between studies.

The major difference between the cited study (Mündermann, 2003) and this study was that the subjects in this study had two weeks of accommodation period to their foot orthoses, while there was no such accommodation in the cited study. Since high frequency component of EMG corresponds to the fast twitch fibres (Wakeling et al., 2002b), reported increase of intensity in the high frequency bands (Mündermann, 2003) indicates earlier onset of fatigue. However, once patients accommodate to foot orthoses, the foot orthoses are supposed to be used for all sports activities as well as daily activities. Therefore, foot orthoses must be comfortable and should not elicit earlier fatigue. In other words, the effects of foot orthoses should mainly occur in the low frequency band of EMG which corresponds to the fatigue resistant muscle fibres. The difference in results between the cited study and this study indicates that there may be a shift of EMG response from its high frequency to low frequency component over an accommodation period. Although the function of the accommodation period is not clearly understood, gradual accommodation is usually recommended for patients when foot orthoses are prescribed. Based on the results of the cited study and this study, it is speculated that such accommodation may be functionally important as there may be a proprioceptional change as well as learning effects for orthotic intervention.

4.4.4 Relation between pain and change in muscle activity pattern

It was proposed that patellofemoral pain syndrome is related to abnormal patella tracking (Paulos, et al., 1980; McConnell, 1996). It has been reported that patients with patellofemoral pain syndrome have delayed onset of VMO relative to VL (Cowan et al., 2001) and when patients were treated successfully, the onset of VMO relative to VL was improved (Cowan et al., 2002a and b). Contrast to the cited study (Cowan et al., 2002a and b), the result of this study found that after successful treatment of pain with custom-made foot orthoses, there was a significant delay of VMO onset timing as indicated by the increase of relative 10% timing. However, there was a trend of reduction in relative peak timing, indicating that the timing when peak VMO intensity occurred relative to that of VL was advanced with orthotic condition. Delay of VMO activity is an indication of lateral patella tracking, while advance of VMO activity is an indication of medial patellar tracking. With delay at onset but advance in peak timing of VMO, it is not clear how change of timing with foot orthoses affected patellar tracking. The results showed that there were no relation between change in pain and change in relative 10% timing or relative peak timing. Patellofemoral pain syndrome is a multifactorial problem. The tested subjects were categorized as pronators and their symptoms may be mainly caused by abnormal lower extremity movement pattern related to their malalignment. Based on the result, change in activation timing of the VL and VMO may not be a primary reason of reduction in pain for patellofemoral pain syndrome runners who have pronating feet.

It was also proposed that patellofemoral pain syndrome is related to weak vastus medialis oblique muscle (Gilleard et al., 1998). Previous studies found smaller VMO EMG activity relative to that of VL for patients with patellofemoral pain syndrome compared to healthy controls (Souza and Gross, 1991; Powers et al., 1996; Tang et al., 2001). In this study, we found that the custom-made foot orthoses significantly decreased VL/VMO intensity ratio, indicating that the intensity of the VMO became relatively higher compared to that of VL after treated with the foot orthoses. Positive correlations were found between the change in pain during running and the change in VL/VMO ratio, and the change in pain after running and the change in VL/VMO ratio with latter showing significant. The results indicate that greater reduction of pain was associated with greater reduction of VL/VMO ratio. Since, significant increase was found for the VMO intensity while no change was found for the VL intensity, the decrease of VL/VMO ratio was due to the increase of VMO intensity. There was a strong negative correlation between the change in pain during running and the change in VMO intensity, and a significant negative correlation between the change in pain after running and the change in VMO intensity, suggesting that increase of VMO intensity was associated with reduction of pain. It is speculated that increase of VMO intensity as itself, as well as relative to intensity of VL are associated with greater medial pull of the patella. Thus, such increase of the

VMO intensity suggests that the patella tracking occurred in a normal range when the subjects used the custom-made foot orthoses. Increase of VMO intensity was found for five of the six subjects who showed reduction in pain. Increase of VMO intensity relative to that of VL was found for all subjects. Based on the results, it is concluded that increase of VMO intensity with custom-made foot orthoses may be a reason for reduction of pain for runners diagnosed with patellofemoral pain syndrome who had pronating feet.

4.5 Summary

Although foot orthoses have been successfully used in treatment of overuse running injuries, the mechanisms how foot orthoses reduce pain are still not well understood. A new concept proposed recently suggesting that the main changes produced by foot orthoses may be changes in muscle activity and not changes in kinematics.

Thus, the purpose of this study was to quantify the effects of custom-made foot orthoses on pain and lower extremity muscle activity pattern in runners diagnosed with patellofemoral pain syndrome. EMG data from seven lower extremity muscles were collected during 30 minutes running and pain was assessed using a 10 cm visual analogue scale (VAS). The intensity of the EMG signals, the intensity ratio and relative timing for the VL and VMO muscles were determined. Data were compared between baseline (before orthotic intervention) and treatment (after orthotic intervention).

Compared to baseline, pain was significantly reduced. Custom-made foot orthoses increased the intensity of EMG for some muscles, decreased the VL/VMO intensity ratio and changed the relative timing of the EMG between the VL and VMO muscles. These changes were shown predominantly in the low frequency band. A strong negative correlation was found between the change in pain and the change in VMO intensity, indicating greater reduction of pain was associated with greater increase of VMO intensity. Based on these results, it is concluded that foot orthoses do affect muscle activity patterns and the increases in VMO intensity with orthotic intervention may be related to the quantified reduction of pain for the subjects with patellofemoral pain syndrome.

5 POSSIBLE MECHANISMS OF FOOT ORTHOSES IN THE TREATMENT OF MUSCULOSKELETAL PAIN

The purposes of this thesis were to investigate the effects of foot orthoses on lower extremity kinematics, kinetics and muscle activity pattern and to understand why foot orthoses reduce pain related to overuse injuries in runners. In the previous chapters, the mechanical and neuromuscular effects of foot orthoses were investigated and the relations of mechanical and neuromuscular effects with pain were discussed individually. This chapter focuses on how the mechanical and neuromuscular effects of foot orthoses may relate to the reduction of pain in the injured runners.

By comparing the pain level before and after treatment with custom-made foot orthoses, it was found that the tested foot orthoses significantly reduced pain perceived during and after running for the runners who were diagnosed with patellofemoral pain syndrome. Risk factors for patellofemoral pain include mechanical and neuromuscular factors. Previously it was shown that runners with patellofemoral pain syndrome had greater foot eversion (Bahlsen, 1989), internal tibial rotation with respect to the foot (Bahlsen, 1989) and thigh (Stergiou, 1996), large knee abduction and external rotation moments (Stefanyshyn et al., 1999), delayed onset timing of the VMO relative to the VL (Cowan et al., 1999 and 2001) and insufficient muscle activity of the vastus medialis oblique compared to VL (Souza and Gross, 1991; Powers et al., 1996; Tang et al., 2001). Foot orthoses that reduce pain should, therefore, be expected to have systematic effects on some of these proposed risk factors. The results of this study showed that foot orthoses may systematically affect lower extremity kinematics and muscle activity pattern for the VL and VMO. However, foot orthoses may not systematically affect knee joint moments. In addition, the results found that only the change in EMG intensity of the VMO had a strong correlation with the change in pain. This indicates that the other effects of foot orthoses had no or only indirect effects on the change in pain.

The change in patellofemoral pain due to treatment with foot orthoses may be explained as follows: The medial posting of the foot orthosis reduces calcaneus eversion angle with respect to the ground (Novic and Kelly, 1990) and therefore reduces foot eversion with respect to the tibia (Genova and Gross, 2000). Due to the coupling mechanism of the ankle joint complex (Hintermann et al., 1994; Stacoff et al., 2000a) a reduction of foot eversion leads to a reduction of internal tibial rotation with respect to the foot and the femur (Eng and Pierrynowski, 1994). Consequently, in the orthotic condition, the lower extremity is more varus positioned during the stance phase compared to the non-orthotic condition (D'Amico and Rubin, 1986; Williams et al., 2003). In order to counteract the varus position of the leg, muscle activity in the medial side of the leg should increase, resulting in an increase of VMO activity. Therefore, a greater force acts on the patella on the medial side when foot orthoses are used. This increased force helps to stabilize the patella medially and prevent abnormal lateral patella tracking (Klingman et al., 1997). Therefore, as a result, foot orthoses reduce pain for patellofemoral pain syndrome.

The author believes that the above described linkage between mechanical and neuromuscular effects of foot orthoses is a general mechanism why foot orthoses reduce pain in the runners with patellofemoral pain syndrome. However, the results found that the mechanical linkage and increase of the VMO intensity were not always seen in all the tested subjects (Table 5-1). Such individual differences in response to the orthotic interventions were previously reported (Stacoff et al., 2000b; Nigg et al., 2003; Mündermann et al., 2003). Therefore, the mechanism prescribed above is only one possible explanation for

Table 5-1. Summary of expected results and findings of the study.

	Expected results	Foot orthoses	Individual results					
			1	2	3	4	6	8
PFPS risk factors								
Foot eversion	-	-	-	-	=	+	-	-
Internal tibia rotation	-	-	-	-	+	-	-	-
Internal knee rotation	-	**-**	-	-	-	-	-	-
Knee abduction moment	-	=	=	=	-	+	+	-
Knee ext. rotation moment	-	=	+	+	-	+	=	-
VMO onset timing	-	**+**	+	+	-	+	+	+
VMO peak timing	-	-	-	-	-	-	+	-
VMO activity	+	**+**	+	+	+	+	+	-
VL/VMO ratio	-	**-**	-	-	-	-	-	-
Other								
Knee flexion	=	-	=	=	-	=	-	+
Plantarflexion moment	=	-	=	=	-	=	-	-
Impact loading rate	=	**-**	-	-	-	-	+	-
PL intensity	=	**+**	-	+	+	+	+	=
BF intensity	=	**+**	+	+	-	+	+	+

PFPS=patellofemoral pain syndrome.
Significant changes with foot orthoses are shown in bold. Signs for individual results were shown as flows; - for change ≤-5%, + for 5% ≤change and = for -5% < change < 5%.

how foot orthoses may reduce pain for patellofemoral pain syndrome patients. Patellofemoral pain syndrome is a multifactorial problem and subjects with patellofemoral pain syndrome have different strategy they can use to reduce pain.

For example, Subject 3 showed no change in foot eversion and increase in internal tibia rotation with orthotic intervention while others showed a decrease. However, this subject, likewise others, decreased internal knee rotation, indicating that rotation of the hip joint may be used to reduce knee internal rotation. This subject showed an advanced onset timing of VMO relative to VL with orthotic intervention, while the others showing a delay. In addition, both knee abduction and external rotation moment were reduced in the orthotics condition. Delayed onset of VMO and large knee joint moments are one of the proposed risk factors for patellofemoral pain syndrome. Therefore, it is speculated that the improvement of VMO activation timing and reduction of knee joint moment may be the main reason of reduction in pain for Subject 3. In case of Subject 8, the intensity of VMO activity was not increased but VL/VMO ratio was decreased in the orthotic condition. As a result, it is speculated that there was a greater force pulling the patella medially, which may have helped stabilizing the patella. In addition, knee joint moments were decreased with orthotic condition, which may have contributed for reduction in pain for subject 8.

Table 5-2 summarizes the possible strategies to reduce pain and individual solutions used by the tested subjects. Decrease of knee rotation and VL/VMO ratio were found in the orthotic condition for all tested subjects.

Table 5-2. Possible strategies to reduce pain and individual solutions used by the tested subjects.

	subject					
strategy	1	2	3	4	6	8
reduce coupling movement of foot eversion and internal tibia rotation	✓	✓			✓	✓
reduce internal knee rotation	✓	✓	✓	✓	✓	✓
increase VMO activity relative to the VL	✓	✓	✓	✓	✓	✓
advance VMO activation timing relative to VL			✓			
reduce knee joint moments			✓			✓

Knee rotation and imbalance between the VMO and VL are assumed to affect patellofemoral joint mechanics (Lee et al., 2003; McConnell, 1996) and differences in these variables were shown between patellofemoral pain syndrome patients and healthy controls (Stergiou, 1996; Souza and Gross, 1991). Therefore, it is speculated that reduction in knee rotation and VL/VMO ratio may be the key to reduce patellofemoral pain with orthotic intervention.

It should be noted that one of the limitations of this study is that data may contain day-to-day variability due to the prospective design of the study. Change in the opposite direction or no change while the other subjects showed systematic changes could be an error or a failure of measurement for a certain individual due to a large variability that may have existed in the data. Day-to-day variability of data is inevitable if the treatment effects of foot orthoses are to be tested using pre- and post treatment design. Including a control group may help to understand whether the findings of this study really are the treatment effects of foot orthoses or not.

Finally, it should be noted that this investigation was conducted using a very narrowly defined subject population. Although we found that the custom-made foot orthoses significantly reduced pain in the tested subjects and that there were some systematic responses to the orthotic intervention, such responses may be restricted to the selective population. Patellofemoral pain syndrome patients with trauma related development of symptoms and longer history of the pain may not respond the same way as it was shown in the tested subjects. Furthermore, the results showed that foot orthoses systematically changed variables which were not discussed in the above, such as impact loading rate. Different injuries have different etiologies. Therefore, it is possible that different types of injury may be treated differently with orthotic interventions.

6 SUMMARY AND CONCLUSION

Foot orthoses are commonly used in runners for treatment of overuse injuries. Proposed effects of foot orthoses include aligning the skeleton, reducing joint loading, reducing impact loading and changing muscle activity. However, scientific evidence is missing providing support for these proposed effects of foot orthoses. Furthermore, there is a lack of investigations testing biomechanical effects of foot orthoses together with clinical effects. Therefore, the mechanisms how foot orthoses reduce overuse pain are not well understood. Thus, the purposes of this thesis were

1. to quantify the effects of foot orthoses on lower extremity kinematics and kinetics for the runners who were diagnosed with patellofemoral pain syndrome,
2. to quantify the effects of foot orthoses on lower extremity muscle activities for runners who were diagnosed with patellofemoral pain syndrome and
3. to quantify the relationship between change in pain and changes in lower extremity kinematics, kinetics and muscle activity pattern due to foot orthotic intervention.

Eight patients were qualified as suitable subjects after screening 148 responses. All subjects were clinically diagnosed with patellofemoral pain syndrome and were classified as pronators. Custom-made foot orthoses were prescribed for each subject. Seven subjects completed 6-week data collection consisting of three functional periods of orthotic interventions; 2-week baseline (no orthoses), 2-week accommodation (break in) and 2-week treatment (full time use) periods. Three dimensional kinematics and kinetics, EMG data from seven lower extremity muscles and subjective pain were assessed. Baseline data were collected in the non-orthotic condition. Treatment data were collected in the orthotic condition. Data were compared between baseline and treatment to test the effects of custom-made foot orthoses. Major findings of this thesis were as follows.

- Custom-made foot orthoses significantly reduced pain for runners with patellofemoral pain syndrome.
- Such foot orthoses systematically changed some of the lower extremity kinematics, kinetics and muscle activity patterns.
- Among such variables, reduction of internal knee rotation and increase of the EMG intensity of the VMO relative to the VL were shown for all subjects.
- The amount of reduction of pain was related to the amount of increase of EMG intensity for the VMO.

Knee rotation and imbalance between the VMO and VL muscles affect patella tracking. Greater knee rotation and weaker VMO activity to the VL have been shown for patients with patellofemoral pain syndrome. Therefore, it is concluded that decrease of internal knee rotation and increase of VMO activity to

VL with orthotic intervention may be the reasons that foot orthoses reduced pain for pronating runners with patellofemoral pain syndrome.

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APPENDIX A: ETHICS APPROVAL

UNIVERSITY OF CALGARY

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2002-10-05

Dr. B.M. Nigg
Faculty of Kinesiology
Human Performance Lab, KNB 218
University of Calgary
Calgary, Alberta

Dear Dr. Nigg:

RE: Functional Foot Orthotics for Patellofemoral Pain Syndrome
Student: Ms. Y. Toyoda Degree: MKin

Grant-ID: 16705

The above-noted thesis proposal including, the Revised Subject Consent Form for Adults (dated September 4, 2002), the Revised Consent Form for Children (dated September 4, 2002), and the Recruitment Poster (dated August 22, 2002) have been submitted for Committee review and found to be ethically acceptable. Please note that this approval is subject to the following conditions:

(1) a copy of the informed consent form must have been given to each research subject, if required for this study;
(2) a Progress Report must be submitted by 2003-10-05, containing the following information:
 (i) the number of subjects recruited;
 (ii) a description of any protocol modification;
 (iii) any unusual and/or severe complications, adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research;
 (iv) a summary of any recent literature, finding, or other relevant information, especially information about risks associated with the research;
 (v) a copy of the current informed consent form;
 (vi) the expected date of termination of this project;
(3) a Final Report must be submitted at the termination of the project.

Please note that you have been named as a principal collaborator on this study because students are not permitted to serve as principal investigators. Please accept the Board's best wishes for success in your research.

Yours sincerely,

Ian Mitchell, MB, FRCPC
Acting Chair, Conjoint Health Research Ethics Board

c.c. Adult Research Committee
Dr. W. Herzog (information)
Ms. Y. Toyoda