Therapeutic Footwear Can Reduce Plantar Pressures in Patients With Diabetes and Transmetatarsal Amputation

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OBJECTIVE — To compare how footwear (full-length shoe or short shoe), a total contact insert, a rigid rocker-bottom (RRB) sole, and an ankle-foot orthosis (AFO) affect peak plantar pressure (PPP) on the distal residuum and contralateral extremity of patients with diabetes and transmetatarsal amputation (TMA).

RESEARCH DESIGN AND METHODS — Thirty patients with diabetes and TMA participated (mean age 62 ± 4 years). In-shoe plantar pressures during walking were measured in six types of footwear. Each measurement occurred after a 1-month adjustment period. Repeated measure analysis of variance (ANOVA) was used to compare treatments.

RESULTS — All five types of therapeutic footwear reduced plantar pressures compared with regular shoes with a toe-filler ($P < 0.05$). A full-length shoe, total contact insert, and RRB sole resulted in lower pressures on the distal residuum (222 vs. 284 kPa) and forefoot of the contralateral extremity (197 vs. 239 kPa), compared with a regular shoe and toe-filler. Footwear with an AFO showed reduced PPP on the residuum, but most patients complained of reduced ankle motion during walking. A short shoe reduced pressures on the residuum, but not on the contralateral extremity, and many patients had complaints regarding cosmesis of the shoe.

CONCLUSIONS — The full-length shoe, total contact insert, and an RRB sole provided the best pressure reduction for the residuum and contralateral foot, with the optimal compromise for cosmetic acceptance and function.

Patients with transmetatarsal amputation (TMA) are at high risk for skin breakdown and higher amputation. Multiple studies indicate that skin breakdown, wound failure, or higher amputation can arise in 17–44% of patients with TMA, with an average rate of ~30% (1–6).

Two primary factors contributing to skin breakdown or higher amputation are sensory neuropathy and lower extremity ischemia (4,7). Sensory neuropathy is a critical risk factor for patients experiencing unnoticed, repeated trauma during walking that can lead to skin breakdown (7,8). In an early description of TMA surgery, McKittrick et al. (5) reported that in patients with diabetes and insensitive skin, plantar ulcers recur after TMA "in almost all instances" and "in spite of any precautions we have been able to take." The combination of repeated trauma, neuropathy, and peripheral vascular disease places these patients at high risk for skin breakdown, and ultimately, a higher, less functional, amputation (7–9).

Trauma to the plantar foot during normal walking is a potentially treatable factor (7,8) and is estimated by measuring peak plantar pressure (PPP) (8,10,11). Location of PPP on the feet of patients with peripheral neuropathy has been associated with the location of skin breakdown (8,10,11).

Current therapeutic footwear for patients with peripheral neuropathy is designed to reduce excessive PPP on the foot. There is no consensus, however, on the optimal footwear to prescribe for patients with diabetes and a TMA who are at particularly high risk of skin breakdown. Some suggest that no formal footwear besides a toe filler, and perhaps a reinforced sole, may be required (5,12–14). Those working with patients with peripheral neuropathy recommend using a total contact insert (8,11,15). Others suggest a rigid rocker-bottom (RRB) sole may be helpful to substitute for the metatarsal phalangeal joints and facilitate motion during the push-off phase of walking (16–18). There is evidence to indicate that an RRB sole can reduce PPP under a full-length foot by 20–50% when compared with regular footwear (16,17). Bauman et al. (18) demonstrated reduced PPP under the feet of patients with Hansen's disease and shortened feet when using an RRB sole.

Other authors recommend using a custom-made, shortened shoe with an RRB sole for some patients with TMA to improve the fit of residuum to foot (11,19). Still others have speculated that an ankle-foot orthosis (AFO) may help to protect the residuum, immobilize the ankle, provide overall support to the patient, and reduce PPP (20). There has been no research, however, to compare these various shoe components in their ability to reduce PPP.

The primary purpose of this study was to determine how footwear (full-length shoe or short shoe), a total contact insert, an RRB sole, and an AFO affect PPP on the distal residuum and contralateral extremity of patients with diabetes and TMA. A secondary purpose was to determine how these shoe components affect walking speed and problems encountered by the patient during wearing time (skin breakdown, cosmesis, function).

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AFO, ankle-foot orthosis; ANOVA, analysis of variance; PPP, peak plantar pressure; RRB, rigid rocker-bottom; TMA, transmetatarsal amputation.

Table 1—*Subject characteristics* (n = 30)

Age (years)	61.7 ± 11.3 (34–83)
Height (m)	1.72 ± 0.13 (1.48–1.98)
Weight (kg)	95.8 ± 19.8 (60–145)
BMI (kg/m²)	30.3 ± 5.2 (21–45)
Duration since TMA (months)	27.4 ± 28.1 (2–132)
Duration of diabetes (years)	19.9 ± 10.1 (2–39)
Type I diabetes	6
Type II diabetes	24
Sex	
Male	20
Female	10
Loss of protective sensation*	16
Bilateral amputation	
TMA	4
Transtibial	2

Data are means ± SD (range) or *n*. *Patients who were unable to sense the 5.07 Semmes-Weinstein Monofilament on any portion of their foot.

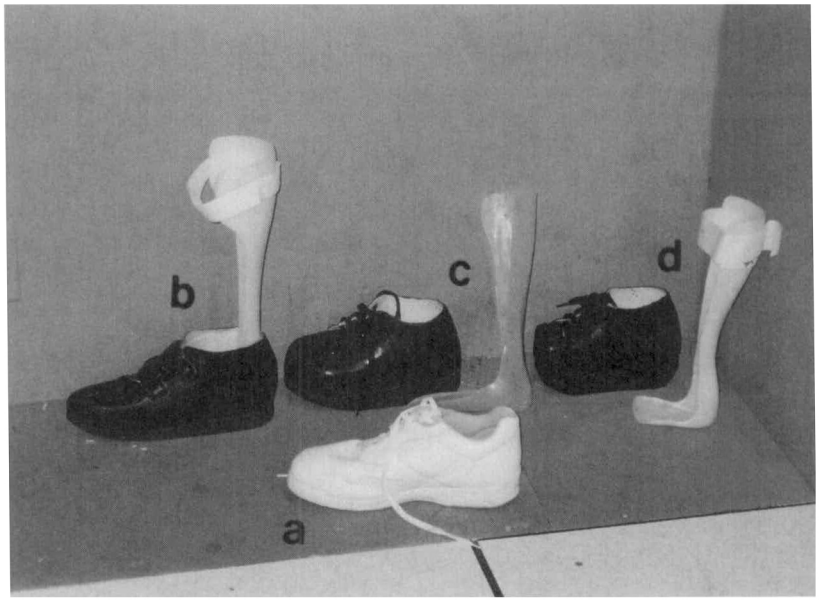

Figure 1—A: *footwear combination 1, regular shoe with a toe filler.* B: *footwear combination 2, full-length shoe, total contact insert, and an AFO.* C: *footwear combination 3 and 4, full-length shoe, total contact insert, and an RRB sole, with and without an AFO.* D: *footwear combination 5 and 6, short shoe, total contact insert, RRB sole, with and without an AFO.*

RESEARCH DESIGN AND METHODS

Subjects

Thirty patients with diabetes and TMA were recruited from the diabetic foot center of an academic medical center and from patients of a local prosthetic and orthotic company. Mean age was 61.7 ± 4.0 years, and there were 20 men and 10 women. Inclusion criteria were a history of diabetes, a history of TMA with healed incision site, and the ability to walk independently. The mean duration of diabetes was 19.9 ± 10.1 years, and the mean time since TMA was 27.4 ± 28.1 months (Table 1).

Description of footwear

The following footwear combinations were assessed (Fig. 1):

1. Full-length shoe (i.e., shoe length before surgery), with a toe filler (Fig. 1*A*).
2. Full-length shoe, total contact insert, and an AFO (Fig. 1*B*).
3. Full-length shoe, total contact insert, and a RRB sole (Figs. 1*C* and 2).
4. Full-length shoe, total contact insert, RRB sole, and an AFO (Fig. 1*C*).
5. Short shoe (i.e., length of residuum), total contact insert, and RRB (Fig. 1*D*).
6. Short shoe, total contact insert, AFO, and RRB sole (Fig. 1*D*).

Footwear was provided to patients in the order of the following 3 clusters; 1 or 2, then 3 or 4, then 5 or 6. Order of footwear within the cluster was random. Complete randomization was not possible without a substantial increase in cost of footwear fabrication: short shoes could be made from long shoes, but long shoes could not be made from short shoes.

Except for the short-shoe combinations, footwear for the contralateral extremity matched the extremity with TMA (although an AFO was not used). For the short-shoe combinations (5 and 6), subjects wore the full-length shoe with a total-contact insert and RRB sole on the contralateral extremity just as they had in combinations 3 and 4.

Patients were instructed to bring in their "best fitting" pairs of shoes for combination 1. Of these pairs of shoes, the optimal pair was selected using defined criteria (15, p. 553). Lamb's wool was used for a toe filler. Twelve subjects had no regular footwear, and tennis shoes were supplied (Fig. 1). This footwear combination was included because it is a typical prescription outlined by several sources (5,12–14).

A total contact, half-inch thick, white plastazote (2, Alimed, Boston) insert was used in combinations 2–5 (Fig. 2). The AFO was fabricated from a total contact plaster cast. Ankle equinous deformities were accommodated. One-half inch white plastazote was vacuum formed and trimmed to the plantar surface of the positive residuum. Then, 3/16 inch polypropylene plastic was vacuum formed over the positive plaster mold and plastazote insert. Medial-lateral trim lines were posterior to the medial and lateral malleolus. The plantar trim line extended to the distal residuum.

Bilateral, lower quarter, custom shoes were fabricated for combinations 2–6. The AFO, insert, and the corrected positive cast were used for a shoe last. The midsole was a combination of cork and latex. The outsole and rocker were fabricated of crepe. The rocker was a traditional rocker sole of about 20 degrees. Slight modifications were required for certain individual patient differences. The apex of the rocker was just proximal to the distal residuum or metatarsal heads (18). The long shoe was converted to a short shoe by cutting off the end and recapping with leather.

Procedures

A certified orthotist and physical therapist determined appropriate fit and patient safety for each footwear combination. The patient was excluded from continued use of a given footwear combination for any of the following reasons: *1)* orthotist or physical therapist decided the patient was not safe due to instability during walking or stair climbing; *2)* excessive motion was occurring between the residuum and the footwear (i.e., the heel rises ≥1 cm out of the footwear during walking); or *3)* the patient refused footwear combination due to safety or cosmetic reasons.

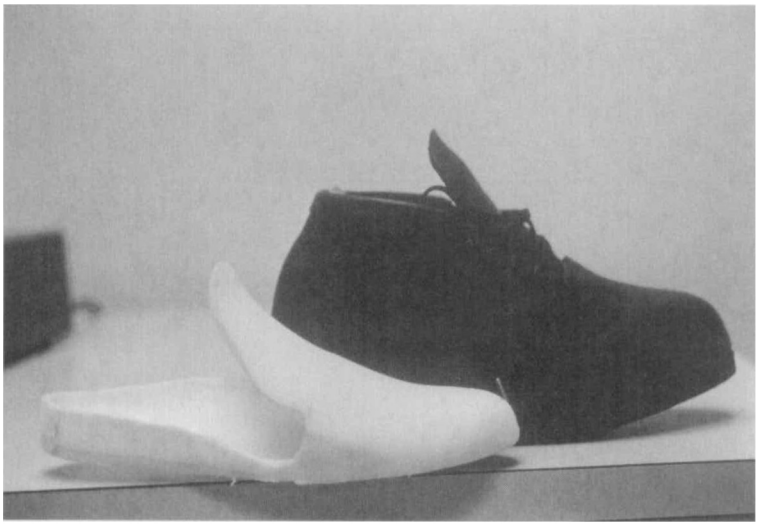

Figure 2—*Footwear combination 3. The insert used for combinations 2–6 is in front of the shoe.*

Patients were educated in footwear application, skin protection, and a wearing schedule. If the footwear was judged adequate by the patient, orthotist, and physical therapist, the patient wore the footwear for 1 month to become fully adjusted to the combination. Data were collected 4 weeks later. If the footwear was judged inadequate by the patient, orthotist, or physical therapist, data were collected on that date, as able, and the patient was supplied with the next footwear combination.

PPP assessment

PPP was measured using the F-Scan system (Software v. 3.42, Tekscan, Boston, MA). The system consists of a 0.18-mm thick sensor with 960 pressure-sensing locations. During the first session, subjects placed their residuum or foot on a new sensor, and the perimeter of the foot was traced on the sensor. The sensor was trimmed to match the plantar surface of the foot and fit inside the shoe. Data from three trials were collected at a sampling rate of 50 Hz for 4 s as the subject walked at their preferred pace on a 6.8-m walkway. Magnitude of PPP on the distal residuum and the contralateral forefoot were obtained using the default size window (4.13 cm^2) of the F-Scan software. The forefoot was chosen because this is the location for most neuropathic ulcers. A mean of the PPP from three steps was used (21). Subjects were allowed to walk with the sensors inside the shoe for several minutes before calibration to repeatedly load the sensor and allow for equilibrium of temperature (22). Data were collected immediately after calibration as recommended by the manufacturer. Reliability for repeated measures using the same equipment and methods has been documented (21). Walking speed was determined by measuring the time to walk a known distance on the walkway during testing.

Statistical analysis

Variables were analyzed using a univariate repeated measure analysis of variance (ANOVA). Individual contrasts were used for post hoc analysis on those variables showing a significant overall F value ($P < 0.05$).

RESULTS — The means and standard deviations for all variables for all combinations are listed in Table 2. The repeated measure ANOVA indicated a significant effect for PPP measured at the distal residuum ($F = 3.22$, $P < 0.01$). Post hoc analysis revealed that all experimental footwear (combinations 2–6) showed lower PPP on the distal residuum compared with the regular shoe with a toe-filler (one-tailed test, $P < 0.05$). There were no differences in PPP on the distal residuum between the experimental footwear combinations 2–6 ($P > 0.05$).

A repeated measure ANOVA also indicated a significant effect for PPP on the forefoot of the contralateral extremity ($F = 2.74$, $P = 0.025$, Table 2). A post hoc analysis revealed combinations 2, 3, and 4 allowed lower PPP ($P < 0.05$) on the forefoot of the contralateral extremity compared with the regular shoe.

A doubly repeated ANOVA was used to determine if there were any differences between the PPP on the distal residuum compared with the contralateral extremity for the six footwear combinations. A significant interaction ($F = 2.56$, $P < 0.05$) indicated that the difference between the PPP on the distal residuum of the TMA and the forefoot of the contralateral extremity varied across combinations. A post hoc analysis indicated PPP was greater on the distal residuum (X = 288 kPa) compared to the forefoot of the contralateral extremity (X = 229 kPa) for the regular shoes with toe-filler only ($F = 4.33$, $P = 0.05$, $n = 20$, pressure values differ slightly from values in Table 2 because the mean was calculated only on subjects who completed data collection in all six combinations). There were no other significant differences.

A secondary purpose was to determine how these shoe components affect walking speed and problems encountered by the patient during wearing time (skin breakdown, cosmesis, function). Patients were able to walk faster wearing the long shoe

Table 2—*Summary of results*

	Footwear combination				PPP		Walking velocity (m/min)
	Length	Insert	RRB	AFO	Residuum (kPa)	Contralateral extremity (kPa)	
1	Full	—	—	—	284 ± 130	239 ± 80	48.9 ± 17.9
2	Full	X	—	X	222 ± 88*	188 ± 79*	49.6 ± 15.3
3	Full	X	X	—	222 ± 110*	197 ± 64*	52.8 ± 14.4*
4	Full	X	X	X	222 ± 83*	196 ± 66*	51.7 ± 16.5
5	Short	X	X	—	236 ± 73*	216 ± 66	53.9 ± 16.7*
6	Short	X	X	X	210 ± 67*	237 ± 109	54.5 ± 16.4*

Data are means ± SD. *Different than combination 1, one-tailed test, $P < 0.05$. kPa, kilopascal; 1 pound per square inch = 6.9 kPa. Repeated measures ANOVA, F and P values: For residuum, $n = 21$, $F = 3.22$, $P < 0.01$; contralateral extremity, $n = 24$, $F = 2.74$, $P = 0.025$; walking velocity, $n = 26$, $F = 3.21$, $P = 0.01$.

Table 3—*Incidence of problems while wearing each footwear combination*

	Footwear combination				Developed skin lesion, blister, or ulcer	Patient refused to wear due to cosmesis	Orthotist, physical therapist, or patient identified problems during walking	Patient completed 1-month wearing time
	Length	Insert	RRB	AFO				
1	Full	—	—	—	2/30 (7)	0/30 (0)	8/30 (27)	13/30 (43)
2	Full	X	—	X	8/29 (28)	1/29 (3)	16/29 (55)	9/29 (31)
3	Full	X	X	—	1/28 (4)	1/28 (4)	3/28 (11)	24/28 (86)
4	Full	X	X	X	1/27 (4)	1/27 (4)	17/27 (63)	9/27 (33)
5	Short	X	X	—	0/27 (0)	5/27 (19)	3/27 (11)	19/27 (70)
6	Short	X	X	X	0/27 (0)	5/27 (19)	16/27 (59)	9/27 (33)

Data are *n* (%).

with the RRB or either of the short shoes (combinations 3, 5, and 6) compared with the regular shoes with a toe filler (combination 1, Table 2). The incidence of problems while wearing the footwear combinations is listed in Table 3. Overall, combination 3 showed the fewest problems, and 24 of 28 (86%) patients were able to complete the full month wearing time.

CONCLUSIONS — All therapeutic footwear reduced PPP on the distal residuum of the TMA compared with a regular shoe. Apparently, the most important factor in reducing the PPP on the residuum was the total-contact, custom-made plastazote insert (Fig. 2). Multiple authors working with patients with peripheral neuropathy have recommended the total-contact insert to increase weight-bearing surface area and to decrease PPP (8,11,15). Combinations 2–6 showed similar PPPs that were, on average, 22% less than the PPP while wearing the regular shoe and toe filler (Table 2).

Footwear combinations 2–4 also showed significantly reduced PPP on the forefoot of the contralateral extremity (Table 2). Reducing PPP on the contralateral extremity is an important consideration to protect this extremity and reduce the high incidence of bilateral amputation after lower extremity amputation (7).

The total contact insert helped to reduce PPP on both feet, but particularly on the distal residuum. In combination 1, when the total contact insert was not used, PPP was greater on the distal residuum than the forefoot of the contralateral extremity (X = 284 vs. X = 239 kPa), consistent with another recent report (23). Only therapeutic full-length shoes (combinations 2–4) reduced PPP on the residuum and the contralateral extremity (Table 2). Patients using the AFO (combinations 2 and 4), however, had problems with skin breakdown and function (Table 3). Sixteen patients (55%) could not complete the 1-month wearing period for the full-length shoe and AFO, because of patient complaints or rejection by the orthotist and physical therapist (combinations 2 and 4, Table 3). Common complaints from patients wearing the AFO were "the brace doesn't allow my ankle to move," and "I don't believe that I can walk as well." Conversely, one subject with a drop foot showed an improved gait wearing the AFO.

The short-shoe combinations allowed increased walking speed and decreased PPP on the residuum but not on the contralateral extremity. Subjects seemed to rely on their contralateral extremity for weight bearing more when wearing the short shoe than when wearing the long shoe. In addition, cosmesis was a negative factor in compliance with the short shoe. Five subjects (19%) refused to wear the short shoe in the community for cosmetic reasons. Since the short shoes used in this study were fabricated from long shoes (Fig. 1), the cosmesis was particularly poor. Two subjects reported, however, that they preferred the short-shoe combination to the long-shoe combination. They reported that they thought they could walk more easily, and the front of the shoe did not interfere with such activities as climbing stairs or getting into a car. Only three subjects (11%) reported problems during walking, and these problems appeared to be due to the RRB.

The footwear combinations using the RRB did not show an additional reduction in PPP, perhaps because the rocker angle was only 20 degrees rather than previous reports of 25 degrees (16,17). We did not use a 25-degree angle, because we have had difficulty with patient compliance. Despite the lack of additional pressure reduction, we believe the RRB is important to use for several reasons. The RRB sole seemed to allow the leg to roll over the distal residuum, helping to substitute for the missing metatarsal phalangeal joints, and minimized movement of the residuum in the shoe. In combination 1, some subjects showed excessive movement of the heel out of the shoe during walking, and the footwear was rejected by patient, orthotist, or physical therapist in 27% of cases (Table 3). In combination 2 (AFO, no RRB), 28% of subjects experienced minor skin breakdown on the anterior surface of their residuum or at their heel. These problems appeared to be due to the residuum slipping inside the shoe. This slippage and subsequent skin breakdown did not appear to occur while wearing the shoes with the RRB sole. Unfortunately, the shear forces, which would arise from the residuum slipping inside the shoe and which could account for the skin breakdown on the anterior and posterior residuum, cannot be measured with current in-shoe pressure systems such as the F-Scan.

Additional evidence to support using the full-length shoe with an RRB sole (combination 3) was that it allowed patients to walk faster (Table 2), and it never was rejected during the checkout period by the orthotist or physical therapist. The three subjects who refused to use this combination complained of instability while using the rocker bottom soles. Twenty-four of 28 subjects (86%) were able to wear this footwear combination for the 1-month adjustment period (Table 3).

Overall, the full-length shoe with a total-contact insert and an RRB sole was the most effective footwear combination in reducing PPP on the distal residuum and the forefoot of the contralateral extremity in patients with diabetes and a TMA. This footwear combi-

nation also allowed patients to walk faster and had a low rejection rate by patients, the orthotist, or the physical therapist. The footwear combination that included an AFO reduced PPP on the residuum significantly, but most patients complained of limited ankle motion during walking. Patients using the short-shoe combination had fewer complaints during walking, but PPP was not lowered on the contralateral extremity and there were many complaints regarding cosmesis. Although there are individual patient characteristics that warrant other prescriptions, based on the results of this study, we recommend the full-length shoe, total contact insert, and RRB sole for most patients with diabetes and TMA (Fig. 2).

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References

1. Sage R, Pinzur MS, Cronin R, Preuss HF, Osterman H: Complications following midfoot amputation in neuropathic and dysvascular feet. *J Am Podiatr Med Assoc* 79:277–280, 1989
2. Hodge MJ, Peters TG, Efird WG: Amputation of the distal portion of the foot. *South Med J* 82:1138–1142, 1989
3. Miller N, Dardik H, Wolodiger F, Pecoraro J, Kahn M, Ibrahim IM, Sussman B: Transmetatarsal amputation: the role of adjunctive revascularization. *J Vasc Surg* 13:705–711, 1991
4. Mueller MJ, Allen BT, Sinacore DR: Incidence of skin breakdown and higher amputation after transmetatarsal amputation: implications for rehabilitation. *Arch Phys Med Rehabil* 76:50–54, 1995
5. McKittrick LS, McKittrick JB, Risley TS: Transmetatarsal amputation for infection or gangrene in patients with diabetes mellitus. *Ann Surg* 130:826–842, 1949
6. Sanders LJ, Dunlap G: Transmetatarsal amputation: a successful approach to limb salvage. *J Am Podiatr Med Assoc* 82:129–113, 1992
7. Pecoraro RE, Reiber GE, Burgess EM: Pathways to diabetic limb amputation: basis for prevention. *Diabetes Care* 13:513–521, 1990
8. Brand PW: The diabetic foot. In *Diabetes Mellitus: Theory and Practice.* 3rd ed. Ellenberg M, Rifkin H, Eds. New Hyde Park, NY, Medical Examination Publishing, 1983, p. 829–849
9. Most RS, Sinnock P: The epidemiology of lower extremity amputation in diabetic individuals. *Diabetes Care* 6:87–91, 1983
10. Boulton AJM, Betts RP, Franks CI, Ward JD, Duckworth T: The natural history of foot pressure abnormalities in neuropathic diabetic subjects. *Diabetes Res* 5:73–77, 1987
11. Cavanagh PR, Ulbrecht JS: Biomechanics of the foot in diabetes mellitus. In *The Diabetic Foot.* 5th ed. Levin ME, O'Neal LW, Bowker JH, Eds. St Louis, MO, Mosby-Year Book, 1993, p. 199–232
12. Durham JR, McCoy DM, Sawchuk AP, Meyer JP, Schwarcz TH, Eldrup-Jorgensen J, Flanigan DP, Schuler JJ: Open transmetatarsal amputation in the treatment of severe foot infections. *Am J Surg* 158:127–130, 1989
13. Sanders GT: *Lower Limb Amputation: A Guide to Rehabilitation.* Philadelphia, Davis, 1986, p. 95–118
14. Shurr DG, Cook TM: *Prosthetics and Orthotics.* Norwalk, CT, Appleton & Lange, 1990, p. 53–56
15. Janisse DJ: Pedorthotic care of the diabetic foot. In *The Diabetic Foot.* 5th ed. Levin ME, O'Neal LW, Bowker JH, Eds. St Louis, MO, Mosby Year Book, 1993, p. 549–576
16. Schaff PS, Cavanagh PR: Shoes for the insensitive foot: the effect of a "rocker bottom" shoe modification on plantar pressure distribution. *Foot Ankle* 11:129–149, 1990
17. Nawoczenski DA, Birke JA, Coleman WC: Effect of rocker sole design on plantar forefoot pressures. *J Am Podiatr Med Assoc* 78:455–460, 1988
18. Bauman JH, Girling JP, Brand PW: Plantar pressures and trophic ulceration: an evaluation of footwear. *J Bone Jt Surg Br Vol* 45(B):652–673, 1963
19. Birke JA, Sims DS: The insensitive foot. In *Physical Therapy of the Foot and Ankle.* Hunt GC, Ed. New York, Churchill Livingstone, 1988, p. 133–168
20. Mueller MJ, Sinacore DR: Rehabilitation factors following transmetatarsal amputation. *Phys Ther* 74:1027–1033, 1994
21. Mueller MJ, Strube MJ: Generalizability of in-shoe peak pressure measures using the F-Scan system. *Clin Biomech* 11:159–164, 1996
22. Koch M: Measuring plantar pressure in conventional shoes with the TEKSCAN sensory system. *Biomed Tech* 38:243–248, 1993 (in German)
23. Garbalosa JC, Cavanagh PR, Wu G, Ulbrect JS, Becker MB, Alexander IJ, Campbell JH: Foot function in diabetic patients after partial amputation. *Foot Ankle Int* 17:43–48, 1996