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The Physical Characteristics of Materials Used in the Manufacture of Orthoses for Patients with Diabetes

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ABSTRACT

Background: **Neuropathic diabetic foot ulceration may be prevented if the mechanical stress transmitted to the plantar tissues can be modified. Orthotic therapy is one practical method commonly used to maintain tissue integrity. Orthotic design must consider the materials chosen for use in fabrication and profile of the device because both aspects influence the performance and durability of the device. Published research evaluating the physical properties of materials commonly used in the manufacture of orthoses for patients with diabetes is limited. This study investigated the physical properties of materials used to fabricate orthoses designed for the prevention of neuropathic diabetic foot ulcers.** ***Methods:*** **Fifteen commonly used orthotic materials were selected for testing: four specifications of 6.4-mm Poron® (Rogers Corp., Gent, Belgium), 3.2-mm Poron®, three densities of 12-mm Ethylene Vinyl Acetate (EVA), 12-mm low-density plastazote, two depths (6.4-mm, 3.2-mm) of Cleron*TM* (Algeo Ltd., Liverpool, UK), Professional Protective Technology (PPT), and MaxaCane (Algeo Ltd, Liverpool, UK). The density, resilience, stiffness, static coefficient of friction, durability, and compression set of each material were tested, ranked, and allocated a performance indicator score.** ***Results:*** **The most clinically desirable dampening materials tested were Poron® 96 (6-mm) and Poron® 4000 (6-mm). High density EVA (Algeo Ltd., Liverpool, UK) and Lunacell Nora® EVA (Freudenberg, Weinhein, Germany) possessed the properties most suitable to achieve motion control. The data present a simple and useful comparison and classification of the selected materials.** ***Conclusions:*** **Although this information should not be used as a single indicator for assessing the suitability of an orthotic material, the results provide clinically relevant information relating to the physical properties of orthotic materials commonly used in the prevention of neuropathic diabetic foot ulcers.**

Key Words: Diabetes; Materials; Orthoses; Physical Characteristics

INTRODUCTION

The use of insoles can instantly modify the kinematics and kinetics of locomotion, often with profound symptom outcome. Insole design begins with a determination of required treatment objectives. In the management of diabetic neuropathic feet, the primary treatment objective is to prevent plantar ulceration. The causal pathway of ulceration is complex, but strong associations have been identified between diabetic peripheral neuropathy, repetitive mechanical tissue stress, and ulceration; 82% of diabetic patients presenting with foot ulcerations also have clinical signs and symptoms of diabetic neuropathy.[1,8,13,18,20] Loss of sensation represents one aspect of neuropathic feet that predisposes to the occurrence of plantar foot ulcerations. Of equal importance is increased plantar pressure, particularly forefoot pressures.[2,4,5,8,15,25,27] Studies have indicated that plantar foot ulcerations repeatedly occur at sites of high or peak pressure.[10,15]

Neuropathic ulceration may be prevented if mechanical stress transmitted to the plantar tissue can be modified. One cost-effective and practical method of ulcer prevention is the use of foot orthotic therapy. To ensure successful treatment outcome, foot orthoses for preventative management of the diabetic foot must attain several performance objectives.[12,26]

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1. Relieve areas of excessive plantar pressure
2. Reduce shock to the musculoskeletal system
3. Reduce shear within the plantar tissues
4. Accommodate fixed foot deformities
5. Stabilize and support flexible foot deformities
6. Improve weight transfer through the static foot in gait

Attainment of these objectives is affected by the materials chosen for fabrication and the profile of the device. Both aspects influence the performance and durability of the device, but published research evaluating the properties of materials used for the manufacture of foot orthoses for patients with diabetes is outdated.[6,7,9,11,14,16,17,19,21,23,24]

This study aimed to provide practitioners with information that will allow choice of material in insole manufacture for the successful management of neuropathic diabetic feet. In particular, it investigated the physical properties of materials used in the fabrication of foot orthoses designed for the prevention of neuropathic diabetic foot ulceration.

Definition of Terms

Six physical properties have been identified as pertinent to insole design: 1) density, 2) resilience, 3) compressive stiffness, 4) static coefficient of friction and shear, 5) durability and 6) compression set.

Density

Density is a measure of the amount of matter contained within a given space. Light materials have a low density and heavy materials a high density. While a light material may be preferable within insole design to maintain gait efficiency, a low-density material may compress prematurely or 'bottom out,' reducing shock attenuation. Conversely, a material of high density will not compress, rendering it unsuitable as a shock attenuator.

Resilience

Resilience is defined as the amount of energy returned during unloading as a percentage of the amount of energy absorbed during loading.[28] The lower the resilience the greater the damping or shock attenuation capacity of the material.[28] In the prevention of diabetic foot ulceration, the aim of the orthosis is to minimize energy return. The most appropriate material would be one displaying low resilience and high dampening, absorbing the greatest magnitude of kinetic energy transmitted from the musculoskeletal system after its transformation to strain energy.

Compressive Stiffness

The stiffness of a material, defined as the resistance of a material to deformation, is expressed as stress per unit strain[28] and can be measured by applying compressive or tensile stress. When studying orthotic materials, compressive stress is more applicable than tensional stress because it more closely represents the form of stress transmitted during the materials application within shoe. It has been established that low density plastazote is a highly deformable material;[6,22,23] materials defined as stiff, include pelite and firm plastazote.[7,23] Lack of standardized classification systems has led to ambiguity, particularly for materials falling within the midrange; rubber foam is reported to be highly deformable by some,[22,23] but, conversely, is considered as moderately deformable by others.[7]

In clinical practice, in the management of diabetic foot pathologies, a laminate of several materials of varying stiffness maybe preferred in the manufacture of foot orthoses to produce a device capable of performing a number of desirable tasks. Stiff material may be required to achieve motion control, support, and stability; a moderately stiff material also may be necessary to extend time to force peak impact and, thus, reduce loading. A material of low stiffness and rapid deformation may be necessary to ensure the insole is able to mold sufficiently to the contours of the foot and, thus, redistribute pressure away from bony prominences.

Coefficient of Friction and Shear

In foot orthotic design, the role of coefficient of friction requires definition. Friction is defined as the force between the surfaces of two objects, which act parallel to the surfaces and prevent or resist them sliding or slipping.[3] An increase in the coefficient of friction will result in an increase in the frictional force. Shear is defined as a load composed of two equal opposite parallel forces that tend to displace one part of an object with respect to an adjacent part along a plane parallel to and between the lines of force.[28] The important difference between friction and shear is that shear occurs within an object. Within the foot, shear force occurring within the plantar tissue is potentially destructive to the tissue. Shear force could cause the displacement of one layer of plantar tissue with respect to another, leading to the development of plantar ulceration especially in the presence of diabetic neuropathy. When applied to the prevention of ulceration in diabetic neuropathy, if the coefficient of friction between the sock and the orthosis interface is reduced to below the shear force required to displace and damage the tissue, slippage may occur at the sock-orthosis interface first and redistribute the shear force away from the plantar tissues. The preferred top cover of the orthotic device for the management of the diabetic neuropathic foot should be designed to minimize shear injury, with a relatively low static coefficient of friction.

Durability

The durability of a material is commonly assessed through fatigue testing. In orthotic therapy, durability is more appropriately determined by the number of cycles to loss of performance, a state that may occur prior to complete material failure. This may explain the limited research to date incorporating S-N curves (where S equals cyclical stress amd N equals the logarithmic scale of cycles to failure) to test durability within the field of orthotic material testing.

Compression Set

Compression set is defined as the residual contraction in the test piece after it has been compressed either to a given compression strain or under a given compression stress for a given time and then allowed to recover for another given time.[22] A controlling material should ideally possess a high compression set, reducing in thickness very little over the test period. A cushioning material would be expected to reduce in thickness by less than 50% to preserve an acceptable degree of performance. In comparison, a moldable material would be expected to reduce considerably over a short period of applied compressive stress.

MATERIALS AND METHODS

Fifteen commonly used orthotic materials were selected for testing (Table 1).

Density

To measure density a sample disc of uniform dimension was cut from the test material using a standard manual pressing. Each disc mass was calculated using a digital balance to the nearest 0.1 mg. Volume was calculated using a micrometer measuring to the nearest 0.001 mm. Each measurement was repeated three times and a mean used to compute the density of each material.

Resilience

Using a specifically designed rig, a 25-mm ball bearing at a height of 1.0 m was released onto the prepared material and recorded on digital video (Figure 1). Using slow motion/paused playback techniques the height of the rebound was measured by a vertical scale. Resilience was calculated as the rebound height as a percentage of the original height.

Table 1: Orthotic materials selected for testing

Material Sample	Thickness
Poron 92	6 mm
Poron 94	6 mm
Poron 96	6 mm
Poron 4000	6 mm, 3 mm
EVA High Density	12 mm
EVA Medium Density	12 mm
Lunacell Nore EVA	12 mm
Cleron	6 mm, 3 mm
Low-Density Plastazote	6 mm
MaxaCane	6 mm, 3 mm
PPT	6 mm, 3 mm

PPT = professional protective technology; EVA = ethylene vinyl acetate.

Fig. 1: Purpose-built resilience measurement rig.

Stiffness

Using the rig, a rubber weight (800 g) was dropped three times from a height of 0.75 m onto the test material, with the F-Scan in-shoe pressure analysis system positioned underneath the test material. Stiffness was determined by measuring the time to offloading (weight unloaded from the material after the first bounce captured by the F-Scan in-shoe pressure analysis system); a mean of the three tests was taken.

Static Coefficient of Friction

Friction was measured using a friction measurement rig cloaked within a sock to replicate the sock interface. The test material was adhered to a weighted block and positioned on the rig. A series of weights were added to a pulley system attached to the block, corresponding to the instant at which the block began to slide. The static coefficient of friction of the material was computed:

$$\begin{array}{c}\text{Static Coefficient}\\ \text{of Friction}\end{array} = \frac{\begin{array}{c}\text{Mass of the block +}\\ \text{mass of the material}\end{array}}{\begin{array}{c}\text{Weight required to}\\ \text{produce movement}\end{array}}$$

The process was repeated three times and the average determined for each material.

Durability

Durability, measured by loss of performance, was computed using a comparison measure of resilience after cyclic loading as a percentage of the respective results before cyclic loading. A purpose-built bench top cyclic loader was used to fatigue the test material loaded using a plunger for 25,000 cycles at a force of 350 Kpa at a frequency of 1 Hz (Figure 2). Previous research established this baseline from a person taking 45 steps a minute for 20 minutes a day, 30 days a month over a 4-month period.[11]

Compression Set

The thickness of the material was measured by a micrometer. Cyclic loading was introduced for the duration and magnitude previously described. The thickness of the material sample was then measured again 24 hours after cyclic loading had ceased.

RESULTS

Density

Of the materials tested, Plastazote 6 mm had the lowest density (0.0399 g/cm^3), while MaxaCane (Algeo Ltd., Liverpool, UK) 6 mm had the greatest (0.08793 g/cm^3).

Resilience

Three Poron® (Rogers Corp., Gent, Belgium) samples (92, 94, 96) (6 mm) all displayed low resilience (less than 10%). In contrast plastazote (6 mm) was most resilient closely followed by MaxaCane (6 mm), 37.4% and 35.6%, respectively).

Stiffness

There was little recorded difference in the time to offloading between the materials tested (0.008 seconds), consequently meaningful interpretation of material stiffness was difficult. However, a trend was established, confirming Poron® and Cleron^{TM} (Algeo Ltd., Liverpool, UK) to be of low stiffness, while EVA (Algeo Ltd., Liverpool, UK) could be considered stiff. The brief offloading time exhibited by PPT (Algeo Ltd., Liverpool, UK) might potentially be an example of the material 'bottoming out' during testing.

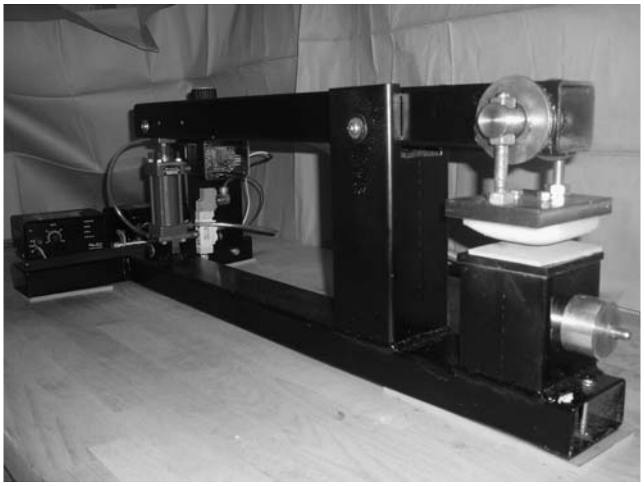

Fig. 2: Purpose-built cyclic loading rig.

Static Coefficient of Friction

Of the materials tested, Lunacell (or EVA) displayed the highest static coefficient of friction followed by medium density EVA, while Poron® 96 (6 mm) displayed the lowest.

Durability

MaxaCane (3 and 6 mm) demonstrated a large reduction in resilience after fatigue compared to new; therefore, MaxaCane was considered the least durable of the materials tested. Interestingly, plastazote appeared to become more resilient after repetitive loading.

Compression Set

MaxaCane (6 and 3 mm) along with plastazote displayed 50% reduction in thickness after repetitive loading. All the other materials tested remained within 97% of the original thickness after repetitive loading. However, Poron® 4000, Cleron^{TM}, and the three densities of EVA were the only materials tested that did not sustain visual damage after repetitive loading.

Performance Indicator Score

None of the material tests can be used as a single indicator for assessing the suitability of an orthotic material. However, used in combination they provide criteria to form a performance indicator score designed to portray important information relating to the physical properties of each material. The performance indicator score for each material was calculated, using the findings of the study and the performance indicator matrix (Table 2). The performance indicator matrix was a tool designed to translate the results from each test into a score. For each physical property analyzed, the materials tested were divided equally into two groups, one group of materials obtaining higher results and the other lower results. Density was divided into three groups to include a medium density group to better-fit clinical requirements. The performance indicator matrix contained three broad categories, matching the general functional purpose required of materials used in the design of orthoses for the management of the neuropathic diabetic foot: 1) control, 2) dampening, 3) moldability. For each material, three scores were calculated corresponding to the material's apparent ability to perform each function. The higher the score the more suitable the material was for that task; the maximum score of 6 indicated a high suitability. For example Poron® 96 was found to have a low resilience; therefore, using the matrix (Table 2) Poron® 96, scored 0 for control but was given a 1 for both dampening and moldability (Table 3). The scoring process was continued for each property tested until Poron® received a final score reflecting its ability to control, dampen, or mold. Poron® scored a maximum of 6 for dampening, suggesting it would be an appropriate orthotic

Table 2: Performance Indicator Matrix

	Control		Dampening		Moldable	
Density	High	1	Medium	1	Low	1
Resilience	High	1	Low	1	Low	1
Force attenuation	Low	1	High	1	Low	1
Coefficient of friction	High	1	Low	1	Low	1
Compression set	High	1	High	1	Low	1
Durability	High	1	High	1	Low	1
Performance index	Optimal Score	6	Optimal Score	6	Optimal score	6

Table 3: Results matrix for Poron® 96

Property	Control	Dampening	Moldability
Density	0	1	0
Resilience	0	1	1
Force attenuation	0	1	0
Coefficient of Friction	0	1	1
Compression set	1	1	0
Durability	1	1	0
Total Score	2	6	2

Table 4: Performance index results (maximum suitability 6)

Material	Control	Dampening	Mouldability
Plastazote 12 mm	2	2	2
Poron® 92 6 mm	1	3	3
Poron® 96 6 mm	2	6	2
Poron® 4000 6 mm	2	6	2
Poron® 94 6 mm	3	5	3
PPT 6 mm	3	3	3
Cleron 6 mm	4	4	1
MaxaCane 6 mm	3	1	2
Poron® 4000 3 mm	1	5	3
PPT 3 mm	3	3	3
Cleron 3 mm	4	4	1
MaxaCane 3mm	3	1	2
High Density EVA 12 mm	6	2	1
Medium Density EVA 12 mm	5	3	1
Lunacell 12 mm	6	2	1

EVA = ethylene vinyl acetate; PPT = professional protective technology.

material choice to achieve its treatment objective. However, a score of 2 for control and moldability indicated that Poron® was a poor choice if control or moldability were required. Table 4 summarizes the performance indicator score for all the materials tested.

DISCUSSION

Anecdotal evidence suggests that the most promising orthotic design would incorporate a laminate of several materials to extract the desired properties from each material.[22] For example, for ulcer prevention of a diabetic foot it has been suggested that a tri-laminate, consisting of a moldable top layer, a middle layer offering long lasting shock absorption, and bottom layer for control would achieve the best results.[12]

Based on the materials considered for investigation within the confines of this study, the performance indicator score can be used to suggest the most appropriate material (Table 4). Materials possessing the physical properties most suitable to achieve control are high-density EVA and Lunacell. Materials demonstrating the physical properties offering good dampening characteristics are Poron® 96 (6 mm) and Poron 4000 (6 mm). It appeared from the performance indicator score that none of the materials tested contained all the desired physical properties of a moldable material; however, five materials sharing the highest score for moldability (3) could be considered most appropriate from the selection of materials tested and included Poron® 92 (6 mm), Poron® 94 (6 mm), PPT (6 mm and 3 mm), and Poron® 4000 (3 mm). This scoring system needs to be used in conjunction with clinical expertise but could be a useful addition when assessing material selection, thickness, and application in relation to the diabetic foot.

There were limitations in investigating the physical properties of the orthotic materials. Errors may have occurred because of movement of the camera, or the point at which the tape was paused may not have corresponded perfectly with the maximum rebound height of the ball if it occurred between recorded frames. However, the potential error is not considered to be of a magnitude to invalidate the results.

Limited conclusions were drawn from the experiment analyzing material stiffness. Variation in off-loading time within a material sample on repeated testing was greater in some cases than the variation between the samples, suggesting insufficient precision of the experimental methods. Potential error could have originated from the limitations of the system used to gather data or the methods used to test the material. Although the release mechanism of the weight was controlled, the orientation at which the weight contacted the test sample varied, potentially altering the data recorded. This aspect of the experiment may have been improved if the orientation of the weight at impact could have been controlled or if the weight was of more uniform dimension. Furthermore, the velocity at which the weight impacted the sample surface was not representative of the velocity of heel strike; this discrepancy may have affected the behavior of the material to impact or the response of the system collecting the data.

When calculating the static coefficient of friction a digital balance accurate to 0.01 g was used. In contrast, the minimum size of the weight added to generate the eventual movement of the test sample on the measurement rig was 2.0 g, and this may have affected the rank positioning of similar materials.

The purpose-built repetitive loading device was designed and fabricated to replicate the force applied to the material in-shoe. However, unlike the within shoe environment, in which the foot orthotic material is required to function, the repetitive load applied was vertical in nature. It is highly possible that the introduction of forces that are no longer perpendicular to the material surface and the addition of shear stress will act to accelerate and amplify the effects of wear and tear. Although not truly representative of the forces occurring within the shoe, the advantages of using a bench top device to fatigue the test samples are that both the environment and load application are repeatable enabling a true comparison of a materials' responses to the applied load.

It is recognized that none of the experiments conducted were able to fully replicate the environment within shoe, and bench-top testing was not predictive of clinical performance. Therefore, longitudinal research is required to investigate the response of orthotic materials' response to within shoe environment under conditions of increased heat and humidity.

REFERENCES

1. **Abbott, C; Vileikyte, L; Williamson, S; Carrington, A; Boulton, A:** Multicenter study of the incidence of and predictive risk factors for diabetic neuropathic foot ulceration. Diabetes Care **21**:1071–1075, 1998.
2. **Armstrong, D; Peters, E; Athanasiou, K; Lavery, L:** Is there a critical level of plantar foot pressure to identify patients at risk for neuropathic foot ulceration? J. Foot Ankle Surg. **37**:303–307, 1998.
3. **Avison, J:** *The World of Physics,* Thomas Nelson and Sons Limited. Surry. London, 1984.
4. **Bennett, P; Stocks, A; Whittam, D:** Analysis of risk factors for neuropathic foot ulceration in diabetes mellitus. J. Am. Podiatr. Med. Assoc. **86**:112–116, 1996.
5. **Boulton, A; Betts, R; Franks, C; et al.:** Abnormalities of foot pressure in early diabetic neuropathy. Diabet. Med. **4**:225–228, 1987.
6. **Brodsky, J; Kourosh, S; Stills, M; Mooney, V:** Objective evaluation of insert material for diabetic and athletic footwear. Foot Ankle Int. **9**:111–116, 1988.
7. **Campbell, G; Newell, E; McLure, M:** Compression testing of foamed plastics and rubbers for use as orthotic shoe insoles. Prosthet. Orthot. Int. **6**:48–52, 1982.
8. **Caselli, A; Pham, H; Giurini, J; Armstrong, D; Veves, A:** The forefoot to rearfoot plantar pressure ratio is increased in severe diabetic neuropathy and can predict foot ulceration. Diabetes Care **25**:1066–1071, 2002.
9. **Cinats, J; Reid, DC; Haddow, JB:** A biomechanical evaluation of sorbothane. Clin. Orthop. **222**:281–288, 1987.

10. **Ctercteko, G; Dhanendran, M; Hutton, W; Quesne, LP:** Vertical forces acting on the feet of diabetic patients with neuropathic ulceration. Br. J. Surg. **68**:608–614, 1981.
11. **Foto, J; Birke, J:** Evaluation of multidensity orthotic materials used in footwear for patients with diabetes. Foot Ankle Int. **19**:836–838, 1998.
12. **Janisse, D:** A scientific approach to insole design for the diabetic foot. The Foot. **3**:105–108, 1993.
13. **Kastenbauer, T; Sauseng, S; Sokol, G; Auinger, M; Irsigler, K:** A prospective study of predictors for foot ulceration in type 2 diabetes. J. Am. Podiatr. Asso. **91**:343–350, 2001.
14. **Kuncir, E; Wirta, R; Golbranson, F:** Load-bearing characteristics of polyethylene foam: an examination of structural and compression properties. J. Rehabil. Res. Dev. **27**:229–238, 1990.
15. **Lavery, L; Armstrong, D; Wunderlich, R; Tredwel, J; Boulton,A:** Predictive value of foot pressure assessment as part of a population based diabetes disease management program. Diabetes Care **26**:1069–1073, 2003.
16. **Lavery, L; Vela, S; Ashry, H; Lanctot, D; Athanasiou, K:** Novel methodology to obtain salient biomechanical characteristics of insole materials. J. Am. Podiatr. Assoc. **87**:266–271, 1997.
17. **Lewis, G; Tan, T; Shiue,Y:** Characterization of the performance of shoe insert materials. J. Am. Podiatr. Assoc. **81(8)**:418–424, 1991.
18. **Macfarlane, R; Jeffcoate,W:** Factors contributing to the presentation of diabetic foot ulcers. Diabet. Med. **14**:867–870, 1997.
19. **Ogrodnik, P:** *Fundamental engineering mechanics,* Addison Wesley Longman Limited, Essex, 1997.
20. **Peters, EJ; Lavery L:** Effectiveness of the diabetic foot risk classification system of the international working group on diabetic foot. Diabetes Care **24**:442–1447, 2001.
21. **Pratt, D; Rees, P; Rodgers,C:** Assessment of some shock absorbing insoles. Prosthet. Ortho. Int. **10**:43–45, 1986.
22. **Rome, K:** A study of the properties of materials used in podiatry. J. Am. Podiatr. Med. Assoc. **81**:73–83, 1991.
23. **Sanders, J; Greve, J; Mitchell, S; Zachariah, S:** Material properties of commonly-used interface materials and their static coefficients of friction with skin and socks. J. Rehabil. Res. Dev. **35**:161–176, 1998.
24. **Shiba, N: Kitaoka, HB; Cahalan, TD; Chao,EY:** Shock-absorbing effect of shoe insert materials commonly used in management of lower extremity disorders. Clin. Orthop. **310**:130–136, 1995.
25. **Stess, R; Jensen, S; Mirmiran, R:** The role of dynamic plantar pressures in diabetic foot ulcers. Diabetes Care **20**:855–858, 1997.
26. **Tyrsell, W:** Orthotic intervention in patients with diabetic foot ulceration. Wound Care **8**:530–532, 1999.
27. **Veves, A; Murray, H; Young, M; Boulton, A:** The risk of foot ulceration in diabetic patients with high foot pressure: a prospective study. Diabetologia. **35**:660–663, 1992.
28. **Watkins, J:** *Structure and function of the musculoskeletal system,* Human Kinetics, United States, 1999.