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PUT TO THE TEST

Data support use of P-Cell in diabetic footwear

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According to the National Institute of Diabetes and Digestive and Kidney Diseases, diabetes affects 17 million Americans (6.2% of the population). In addition, 60% to 70% of people with diabetes have nervous system damage.¹ Peripheral neuropathy is one aspect of this nerve damage and may be in the form of impaired sensation, numbness, or pain in the feet. Foot problems, including foot ulcers, can be a serious complication that may result in amputation. More than 60% of nontraumatic lower limb amputations in the U.S. occur among people with diabetes.¹

According to G. James Sammarco's *The Foot in Diabetes*, most diabetic foot problems can be managed with some combination of foot orthoses (insoles) and properly fitting shoes.² Shoe insoles are important for people with diabetes because they protect the skin and foot and act as a supplement to the fat pad on the bottom of the foot. Cushioning insoles are often prescribed to protect and cushion the sole and distribute weight-bearing force, which will reduce the pressure concentration on plantar skin and under bony prominences.³ An insole should provide shock absorption and reduce shear stress.⁴

Although LD45 pink Plastazote is the current industry standard soft tissue supplement used in shoe insoles for people with diabetes, it has limitations. A concern noted by practitioners in the diabetic footwear industry is that Plastazote "bottoms out" quickly, displaying a rapid and extreme loss of thickness.³ Another study stated that Plastazote should not be used as a shock-absorbing material.⁵

These concerns about Plastazote led to the development of a new product, P-Cell, which may be used as an alternative to Plastazote.

Methods

A study was commissioned by P-Cell manufacturer Acor to compare P-Cell to Plastazote.

Plastazote is an expanded closed-cell polyethylene foam produced by a proprietary manufacturing process. P-Cell is a closed-cell ethyl vinyl acetate (EVA), also produced by a proprietary manufacturing process. Independent tests have shown that P-Cell is noncytotoxic,⁶ and is not considered to be a primary skin irritant.⁷ Additional testing concluded that P-Cell is not a skin-sensitizing agent.¹⁰

Material qualities tested were shock absorption, cushioning factor, durability, compression set (bottoming out), abrasion, odor absorption, coefficient of friction, tensile strength, and liquid absorption/moisture deflection. Six-mm thick samples of each material were used in the tests. The testing was performed at two independent testing facilities, SATRA and Artech.

SATRA Technology Centre is an international nonprofit membership organization for researching and testing consumer products located in Northamptonshire, U.K. SATRA's laboratories are accredited for a wide range of tests and procedures including footwear testing.

Artech Testing is an independent materials and product testing laboratory located in Chantilly, VA. Artech acquired the Footwear Industries of America (FIA) Testing Laboratory in 1989 and has continued to expand its capabilities.

Tests performed

Nine tests were performed.

Shock absorption test-SATRA Test Method 142 (1992).⁸ Falling weight test in which an 8.5-kg mass is dropped from a height of 50 mm onto the material. These conditions are designed to simulate the heel strike for a man running. The impact striker is circular (45 mm diameter) with a semidomed face (37.5 mm radius of curvature). An accelerometer and a displacement transducer are attached to the mass and produce the following information:

- Maximum deceleration (m/s/s) of the mass on impact with the sample. The lower the maximum deceleration, the better the shock absorption.
- Energy return (%). The proportion of the energy returned after impact from the rebound height of the mass.
- Maximum penetration (mm). The maximum dynamic compression of the sample at impact.

The test was first carried out on a standard block material (din rubber), which represents hard-heeled everyday footwear, and then on the test samples combined with the standard block material. The effect of each sample on the shock absorption of the standard material was then assessed.

Cushioning-SATRA TM 159 (1992).⁸ Two parameters are determined from compression testing:

- The cushion energy of the component. The higher the CE value, the greater the cushioning effect of the component. CE is dependent on thickness.

- The cushion factor of the material. The CF is an intrinsic material property indicating the inherent cushioning ability of the material the component is made from. A low CF value indicates an effective cushioning material.

This test measures the total amount of energy required to completely compress the materials. When assessing CE, samples of foam are placed in a compression cage on a tensile tester. The work done in compressing the sample is measured and expressed in millijoules (mJ). This gives an indication of the cushioning properties of the sample/component. When assessing the CF, the sample thickness is built up to at least 16 mm. This prevents the test piece from bottoming out (reaching full compression) during the test, which provides an indication of the cushioning properties of the foam.

Both CE and CF values are obtained at two applied loads during the test. The first test is equivalent to a typical walking pressure (360 kPa); CE_w and CF_w values are relevant to everyday footwear. The other simulates typical running pressure (688 kPa); CE_r and CF_r values are relevant to sports footwear.

Durability (dynamic compression test)-included in SATRA TM 159 (1992).⁸ The durability of the cushioning properties of insole materials is assessed by repeated loading using the SATRA dynamic compression machine, which incorporates an element of shear in the loading. The reduction in CE is measured after 10,800 cycles.

Compression set-(24-hour compression set) Artech AT-304.⁹ Samples of the materials are compressed under 300 pounds for 24 hours. The rebound of the material is then measured after a 60-minute rest period.

Abrasion-(Martindale abrasion) Artech AT-1 (modified).⁹ A 2-inch specimen of the material is rubbed against a worsted wool fabric under dry and wet conditions. The total weight loss is calculated after 3200 dry cycles and after 1600 wet cycles.

Qualitative odor (bottle incubation test)-SATRA TM 351 (1996).⁸ In this test, specimens from the test insoles and two commercially available materials are placed in bottles with three drops of isobutyric acid (IBA), a strong smelling, volatile substance reminiscent of foot odor. The bottles are left for 24 hours and then subjectively assessed by a panel of assessors. The panel grades the materials on a scale of 0 to 5 as follows:

- Negligible / no odor (empty container)
- Very slight odor
- Slight odor
- Moderate odor
- Strong odor
- Very strong odor

Several control bottles are also assessed at the same time. One contains only IBA and acts as the "very strong odor" (grade 5) control. Another bottle is empty and is used as the "no odor" (grade 0) benchmark. A third contains only the test sample so that inherent odors in the material are not confused with the IBA odor.

Friction of insoles (coefficient of friction)-SATRA TM 184 (2000).⁸ A hose- (sock) covered contactor is brought into contact with the insole material, which is mounted on a horizontal surface, under a specified vertical force. After a short period of static contact, the contactor is moved relative to the insole at a specified speed. The force required to move the surfaces over each other is recorded. The horizontal force is then divided by the vertical force to give the coefficient of friction ($CoF = hf/vf$). The test can be carried out under dry and damp conditions. The higher the CoF, the higher the friction.

Tensile strength-Artech AT-329.⁹ Tensile strength is the force per unit of the original cross sectional area applied at the time of rupture. This is calculated by dividing the force required to tear the material by the cross sectional area of the unstressed specimen, and is reported in pounds per square inch or, in this case, kilograms of force per square centimeter. This test was completed on an Instron machine.

Liquid absorption-(Sears Modified absorption procedure) Artech.⁹ A 2 x 2-inch sample of each material was submerged for six minutes in a container of artificial perspiration, of which three minutes involved a vacuum process. The material was allowed to drain for 10 minutes. The increase in weight to the material was calculated.

Results

Results of all tests generally favored P-Cell.

Shock absorption.⁸ The din rubber material exhibited a maximum deceleration of 390 m/s/s. When combined with P-Cell, the maximum deceleration was reported at 270 m/s/s. When combined with Plastazote, the maximum deceleration was 305 m/s/s. P-Cell was able to slow the striker in the shock absorption test 31% more than the din rubber standard material, while Plastazote bested the control number by only 22%.

Cushioning.⁸ P-Cell's CE before dynamic compression under walking conditions tests were at 165 mJ, and at 256 mJ under running pressure. Plastazote's CE values were 131 mJ and 204 mJ respectively. Therefore, P-Cell's CE_w is 25% greater and CE_r is 25% greater than Plastazote's.

P-Cell's CF is 4.8 under walking conditions and 5.8 under running conditions. Plastazote exhibits CF of 5.4 and 6.5 respectively. Therefore, P-Cell's CF_w is 11% more effective and its CF_r is 11% more effective than the corresponding cushion factors for Plastazote.

Durability.⁸ After dynamic compression with shear, P-Cell's CE (CE_w = 149 mJ, CE_r = 239 mJ) remains 27% better than the CE of Plastazote (CE_w = 117 mJ, CE_r = 187 mJ).

Compression set.⁹ P-Cell rebounded 71.6% after the 24-hour compression test. Plastazote rebounded 73.6%. There is only a slight difference between the two materials.

Abrasion.⁹ In dry tests, P-Cell reported average losses of 0.22 grams after 3200 dry cycles. This represents a loss of 29% of its total weight. In dry tests, Plastazote lost an average of 0.15 grams, equaling 39% of its total weight. In wet tests, P-Cell lost 0.03 grams, or 4.4% of its total weight after 1600 wet cycles, while Plastazote lost 0.04 grams or 9.1% of its total weight.

Qualitative odor.⁸ In its appraisal by a panel of four assessors, P-Cell received a qualitative ranking between 4 and 5 out of 5. Plastazote received a ranking of 5 out of 5. There is only a slight difference between the two materials, with P-Cell performing slightly better.

Coefficient of friction (CoF).⁸ Dry P-Cell has a CoF of 0.69, while damp P-Cell's CoF is 0.55. Dry Plastazote's CoF is 0.5, while damp Plastazote has a CoF of 0.48.

Tensile strength.⁹ Testing showed that 13.3 kg/cm² of force is required to tear P-Cell. Plastazote tore at 6.2 kg/cm² of force. Therefore, 114% more force was required to tear P-Cell.

Liquid absorption (moisture deflection).⁹ Liquid absorption percentage was calculated by dividing the change in weight of the material by the original weight of the material. A higher number indicates more liquid absorption. Liquid absorption for P-Cell was 17.3% (therefore deflection was 82.7%). Liquid absorption percentage for Plastazote was 58.6% (therefore deflection was 41.4%).

Discussion

After reviewing the data, we conclude that P-Cell performed more favorably than Plastazote in the areas of shock absorption, cushioning, durability, abrasion, friction, tensile strength, and moisture deflection. All of these areas represent important insole features for all types of feet, especially diabetic feet.

Shock absorption and cushioning. Because the diabetic foot can be insensate, it is prone to injury and irritation. The ability of the footwear to disperse and absorb the shock that occurs with every step is essential. P-Cell's superior performance in the areas of cushioning and shock absorption are desirable to protect the diabetic foot from potential injury.

Abrasion. Rough or abrasive materials may lead to foot soreness. A less abrasive insole can help protect the foot, especially a diabetic foot. The more abrasive the surface of the insole, the more likely the foot will become irritated, which may result in blistering. In a person with diabetes this could result in ulceration. P-Cell is less abrasive than Plastazote.

Coefficient of friction. The surface friction properties of insoles affect foot comfort. A secure grip inside a shoe prevents shear on the foot by keeping it from slipping inside the shoe. Excessive movement in the shoe can allow areas of the foot to rub against the upper, resulting in soreness. A higher coefficient of friction keeps the foot from moving and rubbing inside the shoe. P-Cell has a higher coefficient of friction than Plastazote. As the insole is worn, it will typically absorb moisture. So it is significant that the relative difference in coefficient of friction was consistent during both damp and dry conditions.

Moisture deflection. Insoles that absorb body fluids are harder to keep clean and allow bacteria to grow near the foot. Bacteria on a diabetic foot could allow complications such as infections to develop. P-Cell displayed higher moisture deflection than Plastazote.

Durability and tensile strength. P-Cell's higher durability and tensile strength allow for longer wearability and life of insoles than Plastazote.

It is evident from this investigation that P-Cell is not only more durable, but also a more clinically appropriate soft tissue supplement than the current standard for use in diabetic footwear, Plastazote. P-Cell has been qualified as noncytotoxic,⁶ and is not considered to be a primary skin irritant.⁷ Additional studies will be performed in the future, to determine other uses for P-Cell.

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Additional resources

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