# Advanced Material Parameters for Orthopaedic Footbeds

***Cost pressures in the healthcare system are compelling companies in the orthopaedic footwear technology sector to seek effective solutions enabling them to offer patients at least the same quality of care at less cost. Particularly in the case of orthopaedic footbeds, more information about the material properties would make work easier. This was the topic of a PFI research project. Read on …***

Cost pressures in the healthcare system have been steadily increasing in recent years and this trend is set to continue. The reason is seen in an ageing population coupled with a falling number of people paying contributions to the health insurance system. The increasing percentage of older persons in the total population is leading to an increasing supply need for medical aids such as bandages, ortheses, shoe inlays, footbeds, and custom-made orthopaedic shoes /1/. Health insurance providers are attempting to drive down the cost of providing orthopaedic footwear /2/. Hence companies in the orthopaedic footwear technology sector face the challenge of developing effective approaches permitting them to provide at least the same quality of care at less cost.

Provision of a footbed for a patient will serve to redistribute the plantar pressure. The pressure distribution can be optimised through use of an appropriate combination of materials of different hardnesses. Hitherto, footbeds and inlays have been produced on an empirical basis. The subjective experience of the orthopaedic shoemaker dictates his choice of materials and the way in which he combines them in various thicknesses. The sole available criterion for description of the material properties has so far been the Shore hardness, although the material structure and other parameters are also of critical importance.

Recent years have seen a substantial increase in the range of materials used. Whereas inlays and footbeds were formerly made mainly of cork and leather, increasing use is nowadays made of synthetic materials whose properties are specifically adapted to the needs of orthopaedic footwear technology. The demands of certain medical conditions on hygiene are also attracting increasing attention. The relevant literature, for example /3/, only makes mention of firmer, harder, or softer consistency. There is a lack of more precise definitions of properties. The reader has to resort to a subjective interpretation of which material is harder or softer and whether it is the optimum choice for a specific application.

Hygienic aspects such as the behaviour of various materials and products on colonisation by microorganisms, microoganism counts and species present, and the consequences thereof have not yet been addressed. In particular, the increasing incidence of infectious pathogens has considerable practical implications. These microorganisms  not only damage the materials, thus reducing the useful lifetime of orthopaedic aids, but can also leads to constant re-infection of the wearer and hence to a massive health problem.

Within AiF Research Project 16994 it was the task of PFI to develop suitable methods both for physical and for microbiological tests which would facilitate targeted design of orthopaedic footbeds.

More than 70 different materials in various thicknesses were available for testing. Of these, 39 cushioning materials were actually tested, including five composite materials.

## Physical Tests

First of all, the thickness, the density, and the Shore hardness A and C were measured for all tested materials.

The following test methods were selected for improved description of the material properties:

1. Shock absorption

This test simulates the impact of the heel on the footbed. However, these results are also of use in analysing the behaviour of materials on impact of the foot in the ball and toe region. Above all, the damping properties of the materials should be investigated here. Load is applied to the test specimen by a mechanical device with a free falling mass. During load application, appropriate sensors record the reactive forces (acceleration sensor) on the base plate of the measuring instrument and the resulting deformation of the test specimen (displacement sensor). This test was performed on the material both as received and also on conclusion of dynamic fatigue testing.

One of the results obtained was the shock absorption ratio, which is calculated as follows:

Measured depth of penetration/initial thickness × 100% = Shock absorption ratio in %

The result indicated how much energy the material can absorb. By way of illustration, Figure 1 shows the results obtained for a number of EVA materials of different thicknesses. Various combinations of materials were tested by this method.

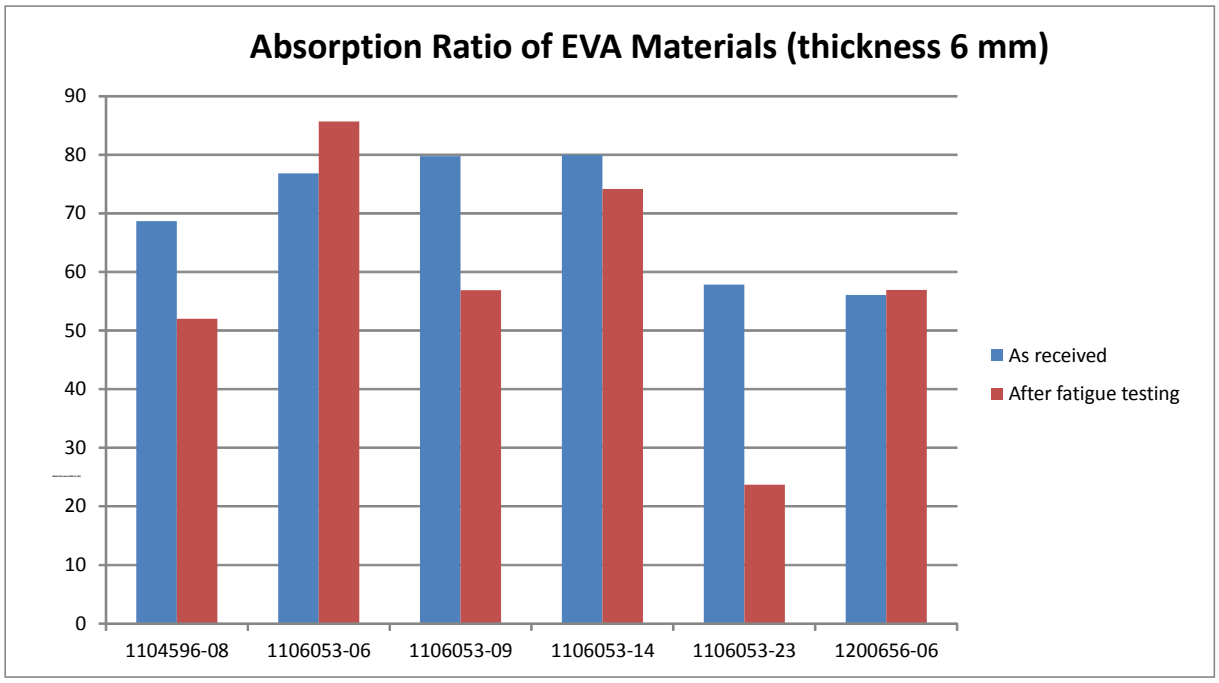


***Figure 1: Absorption ratio of EVA materials (thickness 6 mm) as received and after fatigue testing***

The shock absorption efficiency was also calculated and provides additional information about whether a material is suitable as a damping material or for energy storage. Materials having a thickness of less than five millimetres will always break. The thickness of some materials was reduced to such an extent after dynamic fatigue testing that they also broke.

2. Dynamic fatigue test

This test shows whether the investigated material can withstand 100,000 load cycles or not. The samples had a diameter of 70 mm. The contact area of the test striker was 15 cm². The striker applied a load of 600 N on the test specimen, corresponding to a pressure of 40 N/cm². Prior to testing, the starting thickness of the material was measured and the measurement repeated after 100,000 load cycles and again after 24 hours' recovery. The percentage change was calculated from the various thickness measurements. The mean value was calculated from the individual values of the specimens and used for further evaluation.

Figure 2 shows typical results obtained in these studies, which were also performed on various combinations of materials.

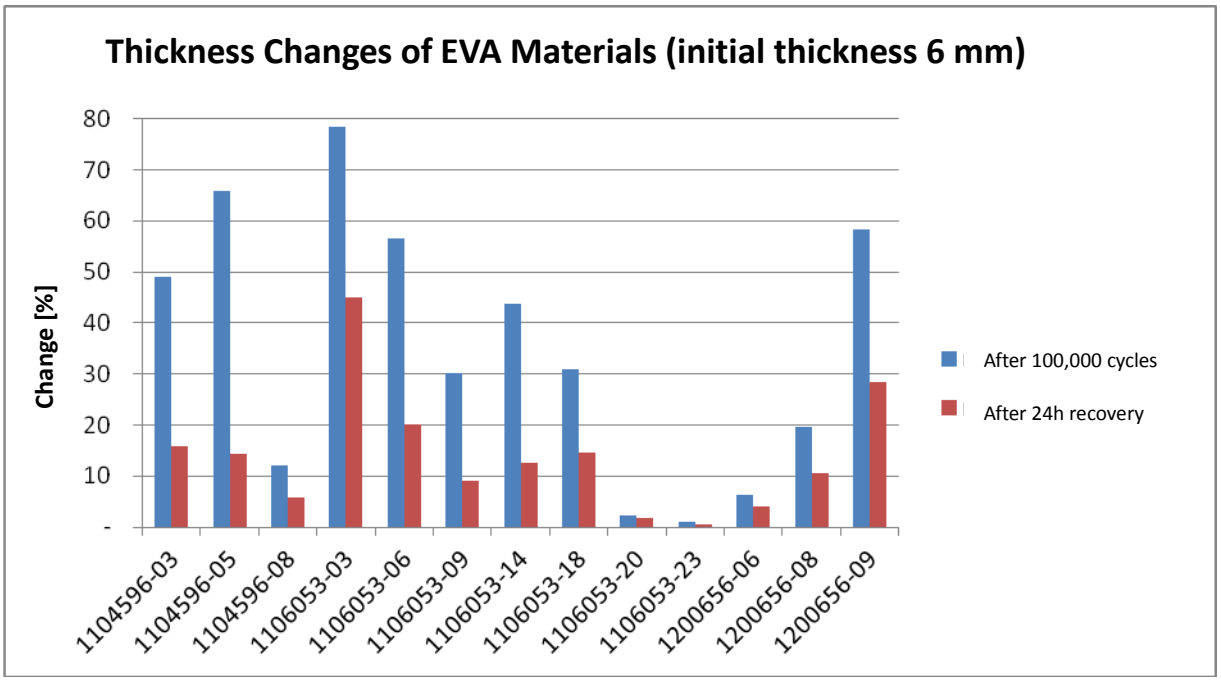


***Figure 2: Thickness changes after dynamic fatigue testing of EVA materials having a starting thickness of 6 mm***

## 3. Recovery behaviour

For long-term patient care it is important that the desired effect is attained during each individual step, particularly in the case of damping. This requires that the footbed presents its specified thickness at the start of every step. The cushioning materials used must immediately return to their original geometry after being compressed when a step is taken, faster than it takes to complete the next step. Studies on the behaviour of the materials during dynamic fatigue testing have shown that the material thicknesses already change within a comparatively short time. Another experiment was therefore performed to examine which material thickness is actually available for each step. The speed with which the materials return to their original thickness after compression and the forces acting in the recovery process were determined. A supplementary measuring device was added to the dynamic test instrument which recorded this thickness on each contact (next step) and plotted the value at predetermined intervals (Figure 3).

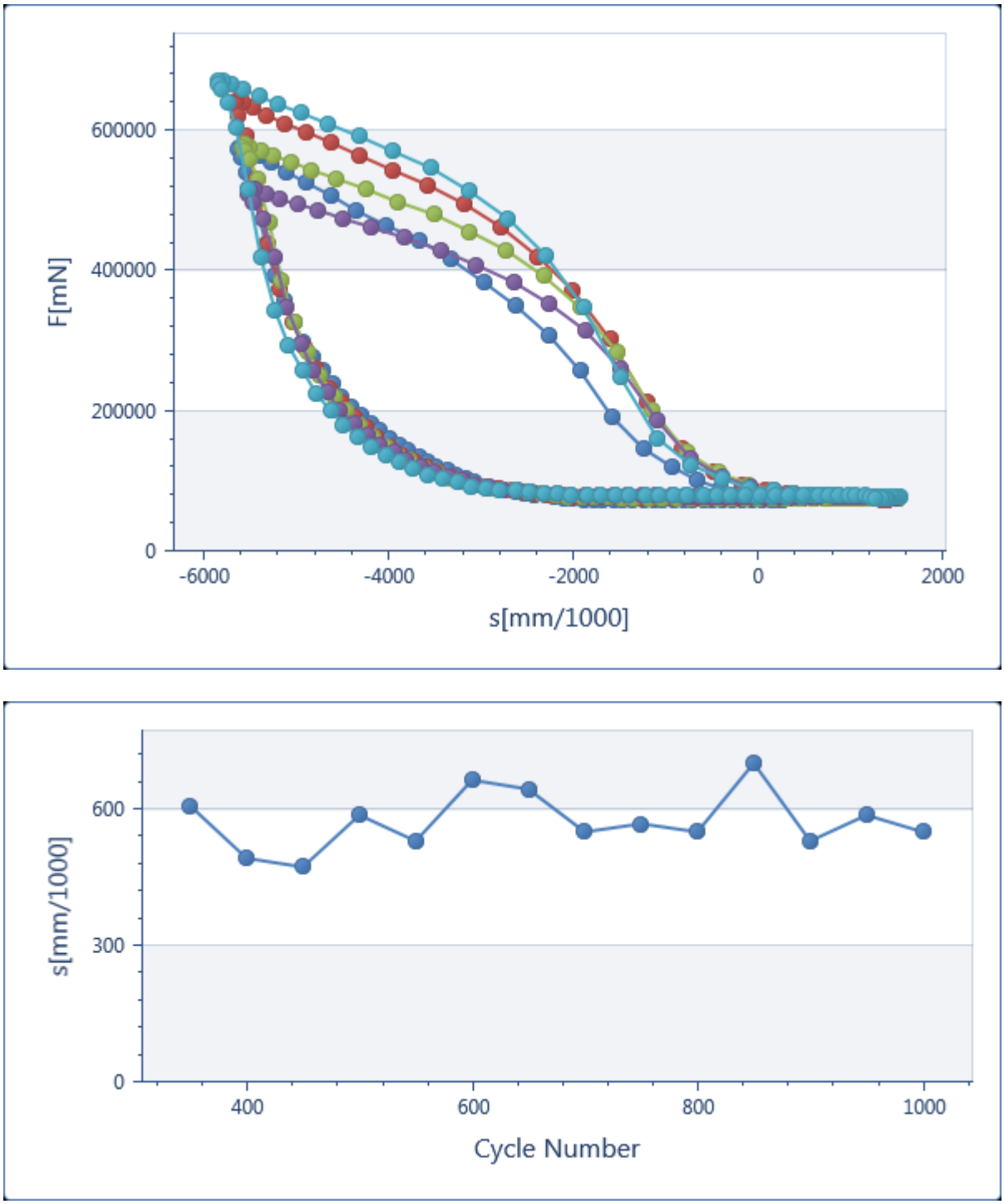


***Figure 3: Recovery behaviour of Material 1200656-09-00-01_3 prior to dynamic fatigue test***

This experimental set-up did not offer any additional information beyond that obtained in the dynamic fatigue test. The materials do indeed recover; however, the decisive factor is the general alteration of the materials, i.e. reduction of their thickness, induced by the loading cycles.

## 4. Compression tests

The experiments were performed with a tensile testing machine fitted with a compression die corresponding to that used in dynamic fatigue testing. The compression die was then lowered at a speed

of 25 mm/min. A force-displacement curve was plotted until the test specimen had been compressed to such an extent that the force asymptotically approached an infinite value. The necessary force was measured shortly before this point was reached. On conversion to weight, this value provides an indication of the body weight up to which the materials can be used in the tested thickness.

Appropriate tests permit far better description of the properties of materials. Above all, the dynamic fatigue test affords the properties of the materials relevant to the changes they undergo during walking. Additional important information concerning the damping behaviour of the materials can be obtained by shock absorption testing. Testing of the recovery behaviour did not yield any important information.

In summary, it can be stated:

- Materials whose thickness changes during the dynamic fatigue test are particularly suitable for use when adaptation of their shape to that of the foot is desired.
- Materials whose thickness changes only slightly or not at all on loading are particularly suitable for damping.
- The materials investigated possess sufficient recovery behaviour if their thickness changes only slightly or not at all on dynamic fatigue testing.
- The compressive deformation properties of the individual materials are manifested in the behaviour of material combinations.
- A manufacturer's recommendation regarding use of materials or their combinations for given body weights does indeed seem reasonable, since the materials behave in very different ways. Experiments performed in connection with this project show the effort involved to be justified.
- In combinations of materials, those materials which exhibit the greatest resistance to deformation appear to dominate the deformation behaviour of the overall combination – regardless of which layer they constitute.
- Large total thickness or large number of layers does not lead to greater weight resistance or greater resistance to deformation.
- The Shore hardness A does not provide reliable information about the effects of the various materials.
- Shoes and footbeds interact with each other. Thus shoes must be included in any consideration of foot care.

## Microbiology and Hygiene

Owing to the long periods for which the orthopaedic aids are worn and additional complicating factors such as contamination with infectious wound secretions, a knowledge of hygienic aspects of the materials used and their combinations is of cardinal importance. Yet these factors have hitherto received little attention. There is a high risk of contamination of orthopaedic aids with microorganisms, i.e. with

bacteria and yeasts. The possible consequences include damage to the material and constant re-infection of the wearer.

A series of test methods suitable for examining relevant hygiene parameters was initially selected for this project. Various frequently used materials and combinations thereof were then examined and evaluated in order to obtain specific information about their microbiological and hygienic properties and to characterise their behaviour towards bacteria and microfungi (yeasts, skin fungi and nail fungi).

Particular attention is drawn, on the one hand, to the rapid microbial colonisation of the tested medical aid components, which remained persistently high even in the absence of nutrients over a period of weeks, and, on the other hand, to the problems associated with the application of microbial reduction methods, which often led to extensive material damage. The provision of appropriate solutions will long remain a challenge for material manufacturers and orthopaedic shoemakers.

On the basis of the results obtained, a test guideline was developed for hygiene parameters, as were design guidelines paying due attention to hygienic aspects. These serve to improve product quality, minimise the risk of infection, and thus enhance of the quality of life of patients.

The range of tests should cover gram-positive and gram-negative bacteria and also *Candida albicans* as a representative of microfungi as well as dermatophytes where appropriate, and should include the following parameters: Wettability as well as water uptake and water release where appropriate, agar diffusion test according to DIN EN ISO 20645 mod. to detect possible leaching substances affecting the skin flora, testing of the antimicrobial efficacy of materials for which corresponding claims have been made in challenge tests according to ASTM E 2149 mod. or DIN EN ISO 16187, applicability of hygienisation procedures, especially UV irradiation at 254 nm for surface microbial reduction, and testing for multiple washability (at 40 °C and 60 °C). In addition, studies of microbial colonisation should also be performed in individual cases.

It is essential to consider hygienic properties in the choice of materials and in the design of orthopaedic aids, especially with regard to inhibition zones, use of antimicrobial finishes, and – in view of the high survival rates of microbes – the applicability of hygienisation measures.

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The final report containing all the results is available from PFI.

References:

/1/ Hilfsmittelversorgung: Eurocom fordert Festzuschusssystem
Orthopädie Schuhtechnik 7/8/2009, p. 13

/2/ Prozesskostenrechnung: Ausgaben und Arbeitsabläufe im Griff
Orthopädieschuhtechnik 7/8/2008, p. 39
C. Maurer Druck und Verlag

/3/ Carl R. H. Rabl and Werner Nyga
Orthopädie des Fußes (7th Edition)

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