

Parameters for orthopaedic footbeds

We are all living longer and while this is a welcome development it has, like all things, come at a price, part of which is steadily increasing cost pressures on our healthcare systems caused by an ageing population coupled with a falling number of people paying contributions. One facet of this is a growing need for medical aids such as bandages, orthoses, shoe inlays, footbeds and custom-made orthopaedic footwear.

Germany is one country that has been particularly affected by a rapidly ageing population and the Federal Government has funded the Test and Research Institute Pirmasens (PFI) to

look into ways to reduce costs as regards orthopaedic footwear without sacrificing quality of care. PFI therefore decided to concentrate on the material properties of orthopaedic footbeds to see what might be done as these are so often needed to treat various medical conditions experienced by elderly people.

A well-designed footbed helps to redistribute plantar pressure. This can be optimised by using 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 dictating his choice of

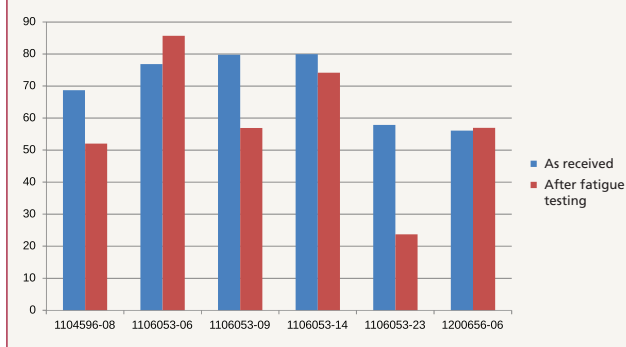
materials and the way in which he combines them in various thicknesses. The sole available criterion for identifying material properties has up to now been the Shore hardness even though the material's structure and other parameters are also of critical importance.

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 now made of synthetic materials whose properties are specifically adapted to the needs of orthopaedic footwear technology. Unfortunately, there is at present a distinct lack of precise definitions of



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Figure 1 – Absorption ratio of 6mm EVA materials as received and after fatigue testing.



properties other than firmer, harder or softer consistencies. Whether a single material or a combination, the optimum choice for a specific application is still very much a subjective interpretation.

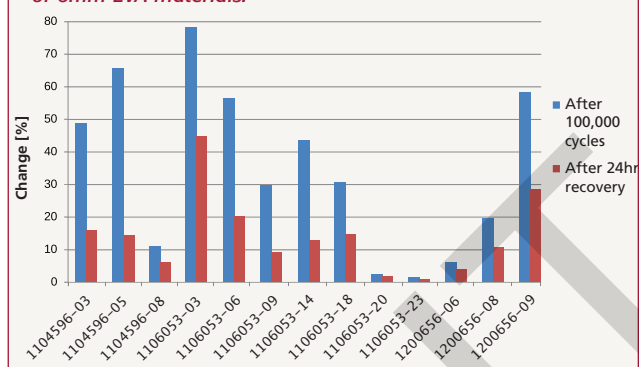
Hygienic aspects such as the behaviour of various materials and products on colonisation by micro-organisms, micro-organism counts, species present and the consequences thereof have also not been addressed. In particular, the increasing incidence of infectious pathogens has considerable practical implications. These micro-organisms not only damage materials and reduce the useful life of orthopaedic aids but can also lead to constant re-infection of the wearer and hence to a major health problem.

PHYSICAL TESTS

As part of its brief, PFI was given the task of developing suitable methods for physical and microbiological tests which would facilitate targeted design of orthopaedic footbeds. More than 70 different materials in various thicknesses were available for testing and of these, 39 cushioning materials were actually tested, including five composites. First of all, the thickness, density, and Shore hardness A and C were measured in order to improve descriptions of the material's properties.

Shock absorption – this test simulates the impact of a heel on the footbed and can also be used in analysing the behaviour of materials on impact of the foot in the ball and toe region and, above all, their damping properties. This test was performed on the material as received and after

Figure 2 – Thickness changes after dynamic fatigue testing of 6mm EVA materials.



testing for dynamic fatigue, the result indicating how much energy the material can absorb (Figure 1).

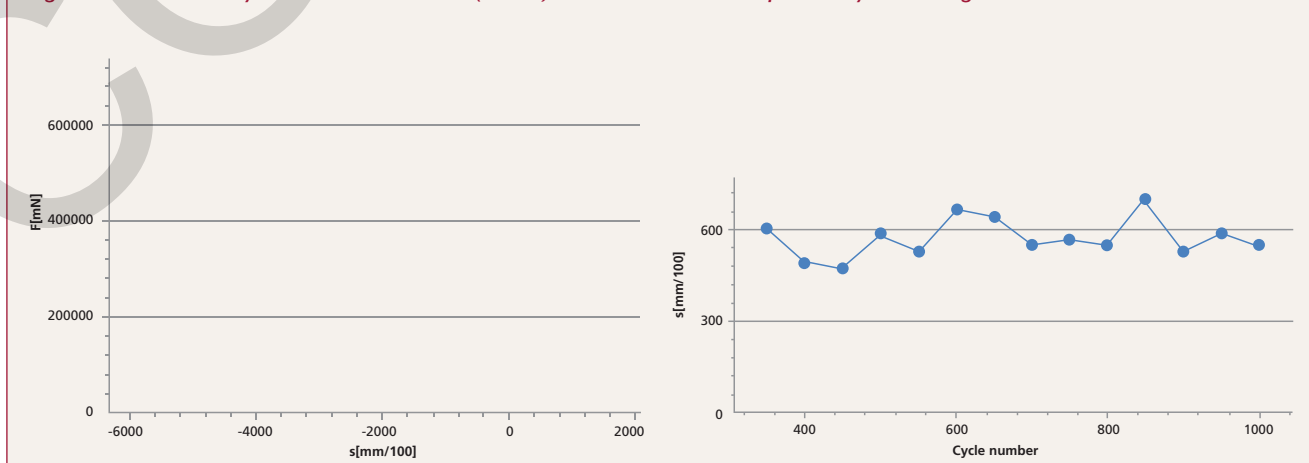
Efficiency of shock absorption was also calculated as this provides additional information about whether a material is suitable as a damping material or for energy storage. Materials having a thickness of less than five millimetres will always break. The thickness of some materials was reduced to such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

Dynamic fatigue – this test measures whether the material can withstand 100,000 load cycles or not. Prior to testing, the starting thickness of the material was measured, again after 100,000 load cycles and, finally, once more after 24 hours' recovery. The percentage change calculated from the three thickness measurements and the mean value from the individual values of the test pieces was then used for further evaluation (Figure 2).

Recovery behaviour – for long-term patient care it is important that the desired effect on the foot is attained during each individual step, particularly as regards damping. This requires the footbed to maintain its specified thickness at the start of every step. The cushioning materials used must therefore 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 showed that material thickness already changed within a comparatively short time. Another experiment was therefore performed to see which material

Figure 3 & 4 – Recovery behaviour of material (lab ref) 1200656-09-00-01_3 prior to dynamic fatigue test.



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 (Figure 3). 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 4).

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

Compression tests – these were performed on a tensile testing machine fitted with a compression die corresponding to that used in dynamic fatigue testing. A force displacement curve was plotted until the test specimen had been compressed to such an extent that the force asymptotically (a line whose distance to a given curve tends to zero) 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 human body weight up to which the materials can be used in the tested thickness.

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

CONCLUSIONS

Materials whose thickness changes during dynamic fatigue testing are particularly suitable for use when adaptation to the shape of the foot is required. Those whose thickness changes only slightly or not at all are particularly suitable for damping. The materials investigated possessed sufficient recovery behaviour provided their thickness changed only slightly or

not at all. The compressive deformation properties of individual materials were revealed by their behaviour in combinations.

In combinations, those materials showing the greatest resistance to deformation appear to dominate the behaviour of the overall combination regardless of which layer they constitute. A large total thickness or number of layers does not necessarily lead to greater resistance to either weight or deformation. Furthermore, Shore hardness A does not in fact provide reliable information as to how materials will perform.

A manufacturer's recommendation regarding use of materials or their combinations for given body weights does indeed seem reasonable, since the materials can behave in very different ways. Experiments performed in connection with this project show the effort involved to have been justified. However, shoes and footbeds do interact with each other, so the former must be included in any consideration of foot care.

MICROBIOLOGY AND HYGIENE

Owing to the long periods for which orthopaedic aids are worn and additional complicating factors such as contamination with infectious wound secretions, knowing the hygienic properties of materials 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 micro-organisms such as bacteria and yeasts, the possible consequences of which include damage to the material and constant re-infection of the wearer.

Various frequently used materials and combinations thereof were evaluated in order to obtain specific information about their microbiological and hygienic properties, and to characterise their behaviour towards bacteria and micro-fungi including yeasts, skin fungi and nail fungi. Two things became apparent. First, a rapid microbial colonisation of the tested medical aid components which remained persistently high even in the absence of nutrients over a period of weeks. Second, problems associated

with the application of microbial reduction methods which often led to extensive material damage. Finding answers to these problems is likely to prove difficult.

In the meantime, 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.

On the basis of its findings, PFI suggests the following test guidelines for hygiene parameters and design. These will serve to improve product quality, minimise the risk of infection and enhance of the quality of life for patients. Tests should cover gram-positive and gram-negative bacteria and also *Candida albicans* as a representative of micro-fungi, dermatophytes where appropriate and should include these parameters:

- Wettability – as well as water uptake and water release where appropriate
- Agar diffusion according to DIN EN ISO 20645 mod. to detect possible leaching substances affecting the skin flora.
- 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.
- Multiple washability (at 40°C and 60°C).
- In addition, studies of microbial colonisation should also be performed in individual cases.

While this investigation and the resulting recommendations by PFI were primarily aimed at footbeds for orthopaedic use, there is also a huge market for their use in everyday footwear both as original equipment and after-sales additions. Details given here should therefore be of value to the industry in general and, while there are some excellent products already available, there is always room for improvement in taking care of peoples' feet. 🦶