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for orthopaedic products

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Summary

The objective of this project was to carry out a series of tests to evaluate the NORA EVA system for use in orthopaedic footwear and other products. The NORA system has been widely used in continental Europe and this study was intended to provide test data which could be used as part of a marketing package for selling the concept to the Department of Health and the UK orthopaedic industry.

The work programme involved measurements of the shock absorption properties of the materials, the cushioning properties and the retention of these properties after simulated wear. Compression set and spread properties were also evaluated.

The work has shown that a wide range of shock and cushioning properties have been built into the various materials within the package and, by correct combination of materials, a wide range of properties could be engineered into various products. The properties are such that the NORA system should be very satisfactory for orthopaedic footwear.

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Main conclusions

- 2.1. The density measurements made confirm those quoted in the trade literature indicating that the properties of the materials can be consistently achieved.
- 2.2. The range of materials offers a wide range of shock absorption values. Those materials intended for use as cushioning materials have given results ranging from 'g' values of 9.0 to 17.0. The lower levels achieved are typical of the best materials tested thus reducing shock to the foot and lower leg.
- 2.3. With the exception of the very low density material "LUNAIRMED", the compression set properties are good and indicate good retention of shape in wear. LUNAIRMED has been designed to have a very low density for use in combination with other materials or as inserts where high degrees of cushioning are required. All materials tested recovered well when left for extended times after compression.
- 2.4. All materials exhibited good cushioning properties, the cushion factor tests showing that the basic material has intrinsically good cushioning properties which should effectively distribute pressure between the foot and the inserts in wear. The level of cushioning is obviously dependent upon the thickness and specific material selected.
- 2.5. Changes in test results after repeated compression were small indicating a high degree of stability in the material. Also, minimal changes were seen after a washing test.
- 2.6. Whilst more work is needed, the limited abrasion testing suggests that good durability will be achieved in wear.

OVERALL CONCLUSION

The results of these tests have shown that the NORA EVA system has the potential to provide many of the properties required for the materials used in orthopaedic products. The properties of the material are stable after simulated wear and the results suggest a good level of durability.

3.1. MATERIALS SUBMITTED FOR TESTING

A total of 8 materials each in two thicknesses, 6mm and 12mm, were submitted for test. These were :

1 & 2 Lunalight A) Normally used for lifting sheets and footbeds combined
3 & 4 Lunacell A) with Lunairflex and the various grades of Lunasoft.

5 & 6 Lunasoft SLW)
7 & 8 Lunasoft SL) Lifting sheets and cushioning materials.
9 & 10 Lunasoft A)

11 & 12 Lunairflex) Cushioning materials for beddings and shock
13 & 14 Lunairmed) absorption.

15 & 16 Luna-ortho

3.2. TESTS AND TEST METHODS

The following range of tests was carried out :

a. Density

Density was measured from the mass and dimensions of a rectangular sample.

b. Shock absorption

Tests were carried out using the SATRA Method PM 142P. In this test a 100mm diameter disc of the material is subjected to an impact force by a 8.5kg mass falling from a drop height of 50mm. The striker is domed with a diameter of 45mm and a radius of 37.5mm. These conditions represent the forces applied to a normal shoe by the heel bone (calcaneum) at heel strike. The degree of abruptness with which the weights are brought to rest measured by an accelerometer 'g' value gives a measure of the shock absorption properties of the material – a low 'g' value is good. The depth of penetration of the striker and the rebound of the striker quoted as energy return are also measured. Highly elastic materials give a high rebound while dead materials give little bounce.

Two sets of tests were carried out :

- i. Each of the 8 materials supplied were tested with two layers of the 12mm material being plied to give 24mm thickness.
- ii. Samples of 12mm Lunelight A and Lunacell A laminated to 6mm layers of Lunasoft SLW, SL and A, Lunairflex and Lunairmed.

c. Compression set

Compression set measurements were made using the ASTM D395 test. In this test, 25mm discs of foam were subjected to 50% compression for a period of 22 hours at 22°C. Again, each material was tested with 12mm materials plied together. The thickness of the test pieces was measured before compression, 1 hour after removal of the compression force, and several weeks after removal of the compression force. The compression set was calculated as the difference between the initial and final thickness divided by initial thickness x 100.

The tests were confined to those materials normally used as cushioning materials

d. Cushioning properties

Tests were carried out using the SATRA Cushioning Assessment Test (SATRA PM 159D : 1991).

- i. The Cushion Energy (CE) of the component. The higher the CE value, the greater the cushioning effect of the component. CE is dependent upon thickness. This was measured on both 6mm and 12mm materials.
- ii. The Cushion Factor (CF) 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 indicates an effective cushioning material. The Cushion Factor was measured at a nominal thickness of 24mm.

Both CE and CF are obtained at two applied loads during the Cushioning Assessment Test, one equivalent to a typical walking pressure (3.7 kgf/sq.cm), the other equivalent to a typical running pressure (7.0 kgf/sq.cm).

In addition to the tests on the materials as received, the Cushion Energy measurement was made on the materials after repeated compression to simulate wear. This was reproduced using the SATRA dynamic compression machine. In this test a sample of material is attached to a stiff beam and a roller is cycled against the test piece to represent the rolling interaction of a shoe with the ground. The test piece is positioned such that the movement of a 10kg weight placed at the end of the beam produces a typical walking load. After approximately 11,000 cycles, the test pieces were removed for re-testing. Measurements of the thickness and area of the test pieces before and after testing also give measures of the compression set and spread of the material. This treatment also identifies those materials which are prone to breakdown in wear.

Measurements were also carried out on the lowest density material "LUNAIRMED" after a low temperature (40°C) washing test to establish whether or not washing changed the cushioning properties of the material.

e. Abrasion resistance of surface

In order to assess the abrasion resistance of the NORA EVA material, abrasion tests to European Method prEN344 and SATRA method PM 14 were carried out.

Results and discussion of results

4.1. DENSITY MEASUREMENTS

Table 1. Comparison between measured values of density and nominal values

Material	Density g/cm ³	
	Measured	Quoted in literature
Lunalight A	0.33) 0.35
Lunacell A (6mm)	0.38)
Lunacell A (12mm)	0.36) 0.35
Lunasoft SLW (6mm)	0.20)
Lunasoft SLW (12mm)	0.20) 0.22
Lunasoft SL (6mm)	0.22)
Lunasoft SL (12mm)	0.19) 0.20
Lunasoft A (6mm)	0.43)
Lunasoft A (12mm)	0.39) 0.40
Lunaflex (6mm)	0.11)
Lunaflex (12mm)	0.12) 0.12
Lunairmed (6mm)	0.07)
Lunairmed (12mm)	0.07) 0.07
Luna-ortho (6mm)	0.30) -

Table 1 shows the results of the density measurements compared with the nominal density recorded in the literature. The results show a high degree of consistency between the 6mm and 12mm materials and in general terms, the measured values are very close to the values quoted in the literature.

4.2. SHOCK ABSORPTION MEASUREMENTS

Table 2. Shock absorption test results on individual materials

Material (all 24mm thick)	'g' value	Maximum penetration (%)	Energy return (%)
Lunalight	19.5	4.5	32.0
Lunacell A	28.5	2.5	25.0
Lunasoft SLW	10.5	8.0	37.5
Lunasoft SL	11.5	7.5	34.0
Lunasoft A	17.0	6.0	39.0
Lunairflex	9.0	9.5	36.0
Lunairmed	9.0	10.5	40.5
Luna-ortho	14.0	6.0	36.0

There is a substantial amount of experience linking health problems such as osteo-arthritis, lower back pain and joint disorders to repeated impacts in walking. Whilst leg shock may not cause injury per se, it may exacerbate deterioration of diseased or damaged joints. Clinical trials have shown that the use of shock-absorbing materials can help prevent and aid recovery from injury. A low value of 'g' is desirable, and values of 9, achieved by Lunairflex and Lunairmed, are as low as any measured on the best materials. Typically, values on foam materials range from 9-20. The NORA EVA materials can clearly be engineered to give a range of properties for different applications. Workers claim that high energy return is of benefit to wearers and everyone knows that walking on soft sand (zero energy returns) is very tiring. The benefit of high energy return does, however, still have to be quantified.

Table 3. Shock absorption test results on combinations of materials

Material	'g' value	Maximum penetration	Energy return (%)
<i>12mm Lunelight A laminated to 6mm :</i>			
5 Lunasoft SLW	19.0	6.0	35.0
7 Lunasoft SL	19.0	5.0	32.0
9 Lunasoft A	19.5	4.5	33.5
11 Lunairflex	19.5	5.0	37.0
14 Lunairmed	19.0	5.0	40.0
<i>12mm Lunacell A laminated to 6mm :</i>			
5 Lunasoft SLW	25.0	4.5	33.0
7 Lunasoft SL	25.0	4.0	29.5
9 Lunasoft A	25.0	3.5	32.0
11 Lunairflex	25.0	4.0	34.5
14 Lunairmed	26.0	4.0	38.0

Table 3 shows the results of the two materials mainly used as lifts (Lunalight A and Lunacell A) combined with the softer cushioning material. They show very clearly that the thicker "soling" materials dominate the performance. The results obtained on Lunelight A, 'g' value 19 to 19.5, are typical of the values obtained by many trainers and casual shoes. The results on Lunacell A are more typical of the best results obtained on more structured footwear. Again, very good energy return results were achieved on all material combinations.

4.3. COMPRESSION SET

The results of the compression set results are shown in Table 4.

Table 4. Compression set results (ASTM D395 test)

Material	Compression set (%)	
	Measured 1 hour after release	Measured several weeks after release
Lunasoft SLW	11.9	1.8
Lunasoft SL	13.0	2.5
Lunasoft A	8.0	2.2
Lunairflex	20.5	2.1
Lunairmed	31.5	3.5

Other than for the low density Lunairflex and Lunairmed materials, the compression set results are good. Results of up to 20% would be expected. Although the two low density materials have given high values when measured 1 hour after release, relatively little of the set is retained after a long recovery period.

4.4. CUSHIONING PROPERTIES

Table 5. Results of cushion energy tests

Material	Thickness (mm)	Initial cushion energy (kgf/mm)		Cushion energy after dynamic compression		Compression set (%)	Area spread (%)
		Walking	Running	Walking	Running		
Lunasoft SLW	6mm	17.2	28.2	15.6	25.7	4.8	2.2
Lunasoft SLW	12mm	32.1	52.2	29.1	48.0	5.0	4.0
Lunasoft SL	6mm	16.0	28.6	13.1	22.4	6.6	3.4
Lunasoft SL	12mm	32.2	54.3	26.5	44.0	6.3	3.3
Lunasoft A	6mm	3.7	18.5	4.3	18.0	1.4	0.2
Lunasoft A	12mm	12.5	46.9	14.4	44.9	1.9	0.6
Lunairflex	6mm	15.2	23.7	14.1	22.3	3.8	2.4
Lunairflex	12mm	30.9	48.3	27.2	42.5	6.3	3.5
Lunairmed	6mm	16.2	25.0	14.6	22.9	8.4	4.1
Lunairmed	12mm	26.9	42.0	24.1	37.9	10.9	4.5

Table 5a. Cushion energy tests after low temperature washing

Lunairmed	12mm	28.0	43.3	-	-	-	-
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Table 5 and Table 5a show the results of Cushion Energy tests on the cushioning materials before and after repeated compression. The higher the cushion energy, the greater the cushioning effect is likely to be in wear. Rigid materials and very weak soft foams both give low results since the former are incompressible and the latter "bottom out".

Typical values for a wide range of commercial insocks are from 3 to 13kgf/mm and results depend on insock thickness. From experience so far, we can say that insocks giving values greater than 7kgf/mm would be expected to reduce under-foot peak pressures in walking considerably.

On this basis, most of these materials have given exceptionally good results even when used at 6mm thickness. Furthermore, the reduction in Cushion Energy after dynamic compression is minimal. Also the compression set and area spread results are good. For example, polyethylene foam, often used in orthopaedic applications, gives compression set values in the order of 20%. The better polyurethane foams do, however, give results well below 1%.

The change in Cushion Energy after washing was not changed by a significant amount. There was no evidence of any breakdown of any of the materials after the dynamic compression treatment.

The results of Cushion Factor tests, which is a fundamental property of the material independent of thickness, are shown in Table 6. Results which have typically been obtained on materials range from 7 when measured under conditions equating to walking, and from 4.5 to 9.7 for materials measured under conditions equating to running. On this basis most of these materials perform to the best standard and these properties are retained after repeated compression. A high result was obtained on the Lunasoft A material under walking conditions which should be investigated further.

Table 7 show typical results of materials previously tested for compression purposes.

Table 6. Results of cushion factor tests

Material	Density* (g/cm ³)	Cushion factor (measured on nominal thickness of 24mm)	
		Walking	Running
Lunasoft SLW	0.20	4.3	5.0
Lunasoft SL	0.21	4.6	5.2
Lunasoft A	0.41	10.6	5.7
Lunairflex	0.12	4.6	5.7
Lunairmed	0.07	4.9	6.0

* Average value for 6mm and 12mm materials.

Table 6a Cushion factor tests after low temperature washing

Lunairmed	0.07	5.1	6.2
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Table 7. Typical cushioning properties of insock materials

Sample ref	Material type	Density (g/cm ³)	Cushion factor	Thickness (mm)	Cushion energy (kgf/mm)	Cushion energy after dynamic compression (kgf/mm)	Compression set (%)
1	PVC	0.26	6.2	4.9	8.8	7.4	3.2
2	PVC	0.41	7.8	2.9	3.9	3.7	0.7
3	PU	0.30	4.0	3.0	8.2	7.7	0.3
4	PU	0.48	4.3	3.1	6.8	6.5	0.4
5	Viscoelastic PU	1.27	6.8	3.3	3.0	2.8	0.3
6	PE	0.03	6.8	4.3	9.3	2.2	21.9
7	Rubber	0.13	4.8	3.9	9.5	8.1	6.1
8	Neoprene	0.53	6.3	5.2	9.6	9.1	0.2

4.5 ABRASION RESISTANCE OF SURFACE OF NORA EVA

Initially, the Veslic Test (prEN 344 test) was carried out but unsatisfactory test results due to high friction between standard abrasive fabric and test material causing excessive movement of the abrasive fabric. It was therefore decided to carry out a modified SATRA PM 14 test. In this test, the loss of thickness measured after 1024 cycles with a wet fabric pad was measured at 1.0%. This suggests that the materials have a very high resistance to abrasion damage.