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Braille dot height research: Investigation of Braille Dot Elevation on Pharmaceutical Products

FINAL REPORT

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Authors:

Dr Graeme Douglas

Annette Weston

Jennifer Whittaker

Visual Impairment Centre for Teaching and Research (VICTAR)
School of Education
University of Birmingham
Birmingham, B15 2TT, UK

Dr. Sarah Morley Wilkins

RNIB
Centre for Accessible Information (CAI)
58-72 John Bright Street
Birmingham, B1 1BN, UK

Duncan Robinson

Field Boxmore
Millennium Way West
Phoenix Centre
Nottingham, NG8 6AW, UK

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EXECUTIVE SUMMARY

Report overview and structure

The final report outlines research which was undertaken **to provide empirical evidence** to answer the following research questions:

1. Establish the minimum height of embossed braille for product identification by braille users;
2. Establish the legibility of screen-printed braille - by making a recommendation based on collating findings of testing one height on two different label substrates with the embossed data;
3. Set a tolerance value for intra-cell dot height of embossed braille alongside the minimum height specification to maintain product identification by braille users;
4. Determine which type of measuring tool is most appropriate according to the sensitivity of measurement required;
5. Investigate the impact of embossed braille on underlying print legibility.

The report can be thought of as being in three broad areas – work related to the preparation and measurement of braille, work related to users trials of the braille, and finally the visual inspection of the braille material and the underlying print.

Firstly, the sections entitled “Phase 1: Braille production and measurement” and “Phase 2: Further investigation of the measurement of braille height” outline the method of production of the embossed braille cartons and screen-printed braille labels used in the study and presents details of the procedure and outcomes of the measurement of this braille.

Secondly, the section “Phase 1: User trials – method” outlines the carefully controlled and balanced methods adopted in a user trial of the braille material. The trial involved 45 representative braille-using participants carrying out a series of reading tasks in order to establish the suitability of the braille materials for labelling of medicine. This is followed by sections which present the results of the user trial in relation to embossed braille cartons, screen-printed braille labels, and follow-up analysis of reading errors made.

Thirdly, the final substantive section (‘Phase 2: Visual inspection of embossed braille’) considers the impact of embossed braille upon legibility of underlying print.

A Glossary of statistical terms is given in Appendix 2.

Aim 1

Establish the minimum height of embossed braille on cartons for product identification by braille users

Forty-five braille reading participants took part in user trials of embossed braille of six different heights. The height conditions used in these user trials are typical of the height of commercially-produced embossed braille on pharmaceutical packages. Performance in the identification of the products across the six height conditions and

levels of subjective confidence was as follows (when 'baseline performance' is performance when reading from standard Braille). The carton embossed braille heights in each of the six height conditions (as measured by a micrometer of 0.55N pressure) is also given (giving actual values recorded).

Height condition 1:

- 33% of participants matched their baseline performance, with 31% feeling confident that they could definitely or probably identify the product.
- Mean dot height of 0.06mm and dot heights ranged from 0.02mm to 0.11mm.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height condition 2:

- 71% of participants matched their baseline performance, with 78% feeling confident that they could definitely or probably identify the product.
- Mean dot height of 0.14mm and dot heights ranged from 0.09mm to 0.20mm.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height condition 3:

- 84% of participants matched their baseline performance, with 89% feeling confident that they could definitely or probably identify the product.
- Mean dot height of 0.15mm and dot heights ranged from 0.09mm to 0.20mm.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height Condition 4:

- 93% of participants matched their baseline performance, with 93% feeling confident that they could definitely or probably identify the product.
- Mean dot height of 0.18mm and dot heights ranged from 0.12mm to 0.24mm.
- No significant difference between performance and baseline ($p > 0.05$).

Height Condition 5:

- 93% of participants matched their baseline performance, with 98% feeling confident that they could definitely or probably identify the product.
- Mean dot height of 0.19mm and dot heights ranged from 0.13mm to 0.24mm.
- No significant difference between performance and baseline ($p > 0.05$).

Height Condition 6:

- 97% of participants matched their baseline performance, with 98% feeling confident that they could definitely or probably identify the product.
- Mean dot height of 0.23mm and dot heights ranged from 0.15mm to 0.29mm.
- No significant difference between performance and baseline ($p > 0.05$).

Aim 2

Establish the legibility of screen-printed braille labels - by making a recommendation based on collating findings of testing one height on two different label substrates with the embossed data

The following presents reading performance (compared with baseline) against each of the four screen printed braille label conditions (glossy label on a bottle; glossy label on a box; matt label on a bottle, and matt label on a box):

Glossy label on bottle:

- 78% of participants matched their baseline performance, with 87% feeling confident that they could definitely or probably identify the product.
- Performance was significantly poorer than baseline ($p < 0.05$).

Glossy label on box:

- 93% of participants matched their baseline performance, with 91% feeling confident that they could definitely or probably identify the product.
- Performance not significantly different from baseline ($p > 0.05$).

Matt label on bottle:

- 87% of participants matched their baseline performance, with 91% feeling confident that they could definitely or probably identify the product.
- Performance was significantly poorer than baseline ($p < 0.05$).

Matt label on box:

- 96% of participants matched their baseline performance, with 98% feeling confident that they could definitely or probably identify the product.
- Performance not significantly different from baseline ($p > 0.05$).

The braille heights of the two types of screen printed labels relate to (as measured by a micrometer of 0.55N pressure):

- Glossy label: high-gloss synthetic labels, mean dot height of 0.21mm and dot heights ranged from 0.19mm to 0.22mm.
- Matt label: LW60 coated paper labels, mean dot height of 0.19mm and dot heights ranged from 0.16mm to 0.20mm.

Aim 3

Set a tolerance value for intra-cell dot height of embossed braille alongside the minimum height specification to maintain product identification by braille users;

For the embossed braille samples used (described above), the research revealed little evidence to support the hypothesis that inconsistent dot heights within a given cell may lead to reading errors (within the ranges of measurements in each of these conditions). Therefore standards for embossed braille height on pharmaceutical packaging should incorporate the tolerance values based upon the height ranges in the user trial samples.

Aim 4

Determine which type of measuring tool is most appropriate according to the sensitivity of measurement required:

Three methods of measuring braille dot height were explored in this study: Micrometer, Microscope, and Optical Comparator. The micrometer was found to be most practical, and procedure followed in the study was as follows:

- Using a spring loaded dial micrometer: model Mitutoyo 547-320 dial micrometer anvil pressure of 0.55N; Model numbers: Dial and anvil – Mitutoyo No 2046F; Handle – Mitutoyo No. 7321)
- Anvil measuring height of whole braille cell (i.e. not measuring individual dots within a cell);
- Taking a cell at beginning, end, and middle of each line of braille text (to assess consistency across rows and columns);
- The **average braille dot height** for a line of braille is established by calculating the average of the three measurements.
- The **minimum braille dot height** for a line of braille is the minimum of the three measurements.

Further analysis revealed to other important factors when measuring braille height. Firstly, micrometers exert a downward pressure and this pressure distorts the braille and reduces its height during measuring. The heights quoted in this study (unless stated otherwise) are based upon using a micrometer of pressure 0.55N. However, micrometers of higher pressure (e.g. model Mitutoyo 547-320, 1.47N trialled in the study) will measure the same braille lower. Additionally the level of distortion is also linked to the number of dots in the braille cell being measured – a single dot cell is particularly (though not exclusively) prone to distortion.

Secondly, embossed braille height for the materials tested consistently and significantly dropped ('settled') in the six and half months between measurements. The average drop in height was 0.02mm (from 0.18mm to 0.16mm). This highlights that when implementing any braille height standard, producers of embossed braille must account for when they measure the braille height and the likely drop in the braille height in the time period between manufacture and eventual purchase.

Aim 5

Investigate the impact of embossed braille on underlying print legibility

Two studies were carried out to investigate the impact of embossed braille on underlying print legibility. The first study involved gaining the subjective views of a 55 industry experts as to relative impact of the braille of different heights upon the 'readability and aesthetics' of the underlying print. The second study involved systematically analysing the impact of embossed braille of different heights upon the cracking of the packaging surface.

Results demonstrated that there is a link between embossed braille height and subjectively judged impact upon the readability and aesthetics of the underlying print – the higher the braille the greater the impact. This is due the greater amount (and

greater extent) of the cracking of the card surface at greater braille heights. It is important to highlight that these results should only be limited to the method of braille production and substrate used in this study (medium weight calliper coated 400 micron board GC2 with standard water-based varnish) – for example, other substrates may crack to a greater or lesser extent at these braille heights. It should also be noted that cracking to card surface is also more visible on card with a darker surface.

INTRODUCTION AND OVERVIEW

The European Standards Organisation (CEN) Technical Committee is developing a European Standard to provide voluntary requirements and guidance to the pharmaceutical and packaging industries on incorporating legible braille onto pharmaceutical packaging. As part of this process a CEN Task Force is required to establish the minimum height of embossed braille for product identification by braille users.

The reason this is seen as important is that dot elevation currently achieved in embossed braille is variable, and often less than 0.3mm, and in some cases it is significantly lower than this (lower than 0.15mm). These dot heights are in some cases considerably lower than dot heights in standard braille production in most countries in the EU (e.g. in the UK 0.46mm, and the European Blind Union (EBU) agreed figure is 0.5mm). In addition, there is a concern from some stakeholders that braille may affect the legibility of print beneath the braille.

In order to meet the needs of people with a visual impairment who use braille to identify their medicine, and to answer these specific questions, the Royal National Institute of the Blind (RNIB) and the University of Birmingham were invited by the CEN task force to develop a research protocol, and to conduct a systematic review of previous research evidence/literature (a review which was previously circulated to the Task Force and revealed a significant lack of appropriate and robust evidence, hence the need for this research).

The brief for the protocol was for it to be acceptable, robust, replicable and representative and be able to provide empirical evidence to establish the minimum dot height for product identification by braille users. In addition, it needed to be deliverable within the CEN timetable, and be achievable with minimal cost without compromising scientific rigour.

A final protocol was the outcome of extensive industry and expert liaison. The research design had the following aims; to provide empirical evidence to:

1. Establish the minimum height of embossed braille for product identification by braille users;
2. Establish the legibility of screen-printed braille - by making a recommendation based on collating findings of testing one height on two different label substrates with the embossed data;
3. Set a tolerance value for intra-cell dot height of embossed braille alongside the minimum height specification to maintain product identification by braille users;
4. Determine which type of measuring tool is most appropriate according to the sensitivity of measurement required.

Alongside these key areas under investigation, the impact of braille on underlying print legibility will also be considered for the materials produced.

This Final Report presents findings collected over two phases of data collection between April and December 2007. The research was carried out by the Visual Impairment Centre for Teaching and Research (VICTAR), with support from RNIB, Field Boxmore, and Kenilworth Products.

PHASE 1: BRAILLE PRODUCTION AND MEASUREMENT

Introduction

The study based its conditions on the most common packaging and labelling materials used in the industry and typical of current production capabilities across Europe as agreed by the Task Force.

After consideration, it was agreed to use custom-made samples in order to control for the variance in existing cartons/labels which would not have allowed a fully controlled study to be undertaken, and the carton manufacturer confirmed their ability to produce reliably to the heights specified. In addition, it was agreed that there was no efficiency saving (either time or cost) by using real cartons/labels

Embossed cartons

It was intended that six different heights of embossed braille would be tested on one standard weight and finish of carton: medium weight calliper coated 400 micron board GC2 with standard water-based varnish (NB: this carton specification is not intended to be a requirement for other manufacturers).

The target heights of the six conditions were: 0.09mm, 0.12mm, 0.15mm, 0.18mm, 0.21 and 0.24mm. These target heights were agreed because:

- they reflected the widest range of materials currently produced;
- the lowest height was below the estimated minimum acceptable height established in a pilot study by the BSI;
- the highest condition is at a height which is towards the upper limit of what current technologies can emboss;
- the middle of these conditions is around the ‘cracking point’ for many producers;
- the estimated minimum achievable range of embossed heights (or ‘height tolerance’) with current industry tooling methods was 0.03mm.

Of course, a necessary objective of the research was to establish whether these target materials could be produced and to establish a method of measuring the braille height (Aim 4).

To this end, the embossed materials were produced by Field Boxmore to Marburg Medium specification. While the materials produced proved adequate to answer the research aims of the study, the heights of the materials were not as precisely uniform as specified in the research design. Details of the heights and ranges of the braille produced are described below. A cross-section of the dot shape of the embossed braille was provided by Field Boxmore and presented in Appendix 3.

Screen-printed labels

Two different types of label were agreed for testing by the task force: high-gloss synthetic (gloss, both visually and tactually), and LW60 coated paper (matt, both

visually and tactually). The study planned to use the lowest samples produced from a set available – estimated to be around 0.19mm.

As with the embossed braille, a necessary objective of the research was to establish whether these target materials could be produced at this target height and to establish a method of measuring the braille height (Aim 4). To this end, the materials were produced by Kenilworth Products to Marburg Medium specification. Details of the heights and ranges of the braille produced are described below. A cross-section of the dot shape of the screen printed braille was provided by Kenilworth Products and presented in Appendix 3.

Method

Measurement of dot height

In order to find an example simple measuring tool for real-life use, measurement of braille dot height was established in two ways, and results compared with each other:

- 1) Spring loaded dial micrometer (model Mitutoyo 547-320 dial micrometer anvil pressure of 0.55N; Model numbers: Dial and anvil – Mitutoyo No 2046F; Handle – Mitutoyo No. 7321). With anvil measuring height of whole cell (i.e. not measuring individual dots within a cell), taking a cell at beginning, end, and middle of each line of braille text (to assess consistency across rows and columns).
- 2) Optical Comparator (e.g. Eye C Benelux). Measures every individual dot in the sample cells with a scanner, compares braille output against artwork, and provides a full dot height report (as max / min / average) for every dot from the surface of the substrate to the peak of the dot.

Sampling rate for measurement of embossed materials

The embossed materials were developed by Field Boxmore. A total of 45 participants each had exposure to 24 different embossed materials, one fresh set for each participant, giving a total of 1080 embossed samples. A further 288 embossed samples were selected for height measurement (randomly selected ensuring a representative sample of different types of material and different heights). This gave a sample rate of 27% (based upon proportion of 1080).

All the 288 samples were measured with:

- micrometer – measuring the first, middle and last cell of every line of braille text in each row; measured by Field Boxmore and RNIB.
- Optical Comparator – measuring all dots across each braille line and providing an average dot height for the sample. This measuring was carried out by MY Healthcare, in association with Field Boxmore

Sampling rate for measurement of screen printed materials

The screen-printed labels were developed by Kenilworth products. A total of 64 screen printed labels were used in the study with the 45 participants (the same materials were used with more than one participant as the dots do not degrade after

reading). A further 64 screen-printed labels were selected for height measurement (randomly selected ensuring a representative sample of different types of material and different heights).

Of the 64 samples, 32 were measured with each of the following:

- Micrometer - measuring the first, middle and last cell of every line of braille text in each row; measured by RNIB and Field Boxmore.
- Optical Comparator - measuring individual dots in 5 random sample cells on each braille line. Kenilworth Products commissioned the Centre for Research in Engineering Surface Technology to do this, using separate labels.

Results

A Glossary of statistical terms is given in Appendix 2.

Embossed materials

A series of analyses were carried out on the measurement data. The aim of the analysis was to provide empirical evidence to:

- establish the mean and range of heights of embossed braille dots in each of the height conditions;
- confirm whether different conditions had truly different heights;
- establish if there are differences in the heights measured by a micrometer versus an optical comparator.

Table 1a presents summary data for the braille dot heights for each of the height conditions (as measured by the micrometer and the optical comparator), as well as the heights the study aimed to achieve. This is the data which was presented in the Phase 1 report.

Table 1a. Summary of the mean and range of height of embossed braille dots in each of the six height conditions measured by 0.55N micrometer (average) and optical comparator (as presented in Phase 1 report), N=288 embossed cartons.

	1	2	3	4	5	6
Target height (mm) as outlined in protocol						
Minimum	0.09	0.12	0.15	0.18	0.21	0.24
Maximum	0.11	0.14	0.17	0.20	0.23	0.26
Micrometer (average) (mm)						
Mean	0.06	0.14	0.15	0.18	0.19	0.23
Minimum	0.04	0.11	0.13	0.14	0.16	0.19
Maximum	0.09	0.17	0.18	0.20	0.23	0.25
Standard Deviation	0.012	0.015	0.014	0.016	0.017	0.015
Optical comparator (mm)						
Mean	0.07	0.13	0.14	0.17	0.19	0.21
Minimum	0.05	0.11	0.13	0.14	0.17	0.19
Maximum	0.08	0.15	0.16	0.19	0.21	0.23
Standard Deviation	0.008	0.008	0.008	0.011	0.010	0.009

In terms of the calculation of values for the micrometer, three measurements were made for each line of braille sampled (as described above – the beginning cell, the middle cell, and the end cell). The values presented in Table 1a are based upon an analysis which first calculated the average height of a given line of braille and then basing the mean, range and standard deviations on these averages. Following feedback of Phase 1 of the work, the authors carried out further analysis.

Table 1b re-presents summary data for the braille dot heights for each of the height conditions (as measured by the micrometer). Here the values presented are based upon analysis which treats all the values separately – ie. mean, range and standard deviations are based upon all actual measurements made.

The mean and minimum values in Table 1b provide the figures for the height conditions in the user trials and executive summary.

Table 1b. Summary of the mean and range of height of embossed braille dots in each of the six height conditions measured by 0.55N micrometer (all actual values), N=288 embossed cartons.

	1	2	3	4	5	6
Target height (mm) as outlined in protocol						
Minimum	0.09	0.12	0.15	0.18	0.21	0.24
Maximum	0.11	0.14	0.17	0.20	0.23	0.26
Micrometer (mm)						
Mean	0.06	0.14	0.15	0.18	0.19	0.23
Minimum	0.02	0.09	0.09	0.12	0.13	0.15
Maximum	0.11	0.20	0.20	0.24	0.24	0.29
Standard Deviation	0.016	0.023	0.023	0.025	0.026	0.025

Key issues to note:

1. The first clear point is that the 'height tolerance' (the range of heights in a given condition) is greater than the estimated achievable height tolerance of 0.03mm. This is a useful finding because it demonstrates that the amount of control over dot height during production for these custom made samples was not as great as anticipated and this should be considered when applying these findings to the creation of a standard.
2. The height conditions are truly and significantly different from each other, i.e. different height conditions all have significantly different braille dot heights. This is confirmed when different heights are compared with t-tests (ie. mean condition 1 compared to mean condition 2, condition 2 to condition 3, etc.). Each difference was very highly significant ($p < 0.0005$). This is true whether height is measured using the micrometer or the optical comparator.
3. The heights measured by the optical comparator are consistently **lower** than those measured by the micrometer. This is confirmed when the measurements for each condition are compared with t-tests. Each difference was very highly significant ($p < 0.001$) with the exception of condition 1 where no significant difference was found. This is an unexpected finding, as one might expect optical measurements to be higher than micrometer readings as they tend to measure fibres above the dot.
4. The reason for the optical comparator consistently measuring lower than the micrometer is unclear but may include one or more of the following explanations. Firstly, the optical comparator needs careful calibration, and this may have been set too low (because of these complications it was agreed to use a microscope in Phase 2 measurement instead of the optical comparator). Secondly, it was observed that the braille 'settled' after first production (ie. the braille height dropped slightly over a 24 hour period after production). The slightly lower optical comparator scores may be evidence of further 'settling'. Evidence gathered in Phase 2 (see section 'Settling of braille over time') suggests further settling did take place. A third potential explanation was that the micrometer may have flattened the braille before optical comparator measurement. Evidence gathered in Phase 2 (see section 'Micrometers of different pressures') suggests that braille dots appear to recover to their original size following measurements with a micrometer, therefore this explanation is unlikely.
5. Another factor worth discussing is that the beginning, middle and end measurements taken with the micrometer demonstrated a difference in height across a line of braille. The beginning (in particular) and end braille cells were consistently and significantly lower than the middle braille cells. The lower optical comparator measurements may be a product of the different way in which the average dot height was calculated (an average of all *dots* across a sample of braille cells rather than just the height of three whole cells).
6. Finally, some additional measuring was carried out comparing performance of the Spring loaded dial micrometer (model Mitutoyo 547-320, 0.55N) to a second

digital micrometer with a higher pressure (1.47N). A series of tests demonstrated that the 1.47N pressure micrometer measured significantly lower than 0.55N micrometer because of additional compression on the braille cells caused by the additional pressure. This was carried out in Phase 2 and is reported in detail elsewhere (see section 'Micrometers of different pressures').

Screen printed materials

A series of analyses were carried out on the measurement data. The aim of the analysis was to provide empirical evidence to:

- establish the mean and range of heights of screen print dots on the two media – high-gloss synthetic (glossy texture) and LW60 coated paper (matt texture);
- establish if there are differences in the heights measured by a micrometer versus an optical comparator.

The table below presents summary data for the braille dot heights for the two label types (as measured by the micrometer and the optical comparator). Note that the values for the micrometer were calculated as per Table 1b described above.

Table 2. Summary of the mean and range of height of screen printed braille dots produced on high-gloss synthetic (glossy) and LW60 coated paper (matt) measured by 0.55N micrometer (N=32, all actual values) and optical comparator (N=32)

	High-gloss synthetic (glossy)	LW60 coated paper (matt)
Micrometer (all values) (mm)		
Mean	0.21	0.19
Minimum	0.19	0.16
Maximum	0.22	0.20
Standard Deviation	0.008	0.008
Optical comparator (mm)		
Mean	0.24	0.22
Minimum	0.18	* 0.11
Maximum	0.29	0.27
Standard Deviation	0.027	0.024

* Damaged dot.

Key issues to note:

1. The heights of the braille on the labels as measured by the micrometer appear to be close to the 0.19mm target height specified in the research protocol (0.21mm for high-gloss synthetic and 0.19mm for LW60 coated paper using the micrometer).
2. Also the 'height tolerance' (the range of heights in a given condition) is relatively small: 0.03mm and 0.04mm for the high-gloss synthetic and LW60 coated paper respectively, when measured with the micrometer. This suggests a greater consistency of braille dot height for the screen printed braille dots compared with

the embossed braille dots, and this is reflected in the lower standard deviations for the screen printed samples compared with embossed samples. It is also reflected in there being no obvious difference in braille dot height at the beginning, middle or end of a braille line for the screen printed material (again in contrast to the embossed braille tested).

3. One consistent observation for the sample tested was that the braille dots produced on the high-gloss synthetic substrate were **higher** than those produced on the LW60 coated paper. This was a highly significant difference ($p < 0.0005$). This is true whether height is measured using the micrometer or the optical comparator.

A separate set of measuring with an Optical Comparator was carried by the Centre for Research and Engineering Surface Technology (CREST), Dublin Institute of Technology (commissioned by Kenilworth Products). This was carried out on a further set of screen printed labels (from the same set, but different samples to those measured in the micrometer testing above). This analysis used a microscopic scanner attached to an FTA 200. Summary data for this is also presented in the table above.

Key conclusions of the analysis were:

1. The average braille dot heights for all the samples were greater than 0.2mm. The minimum height for the 160 dots measured was 0.17mm and maximum 0.29mm.
2. The analysis also identified some 'damaged dots' (the height of which was around 0.1mm) – and it is this that gives the lowest minimum value of 0.11mm in the table above. There were very few damaged dots on the samples tested, and these were largely restricted to a single label.
3. When comparing the heights measured by the micrometer and optical comparator techniques, the optical comparator gave consistently higher braille heights. This difference was highly significant for both high-gloss synthetic substrate and LW60 coated paper ($p < 0.005$). The producer (Kenilworth Products) suggests this is because the high-gloss substrate is not as absorbent as the LW60 substrate.

PHASE 2: FURTHER INVESTIGATION OF THE MEASUREMENT OF BRAILLE HEIGHT

Introduction

The following sections describe additional investigation of the measuring of embossed braille height carried out in Phase 2. The following sections are taken in turn:

- Micrometers of different pressure;
- 'Settling' of braille over time;
- Commercially produced braille.

Micrometers of different pressure

Introduction and rationale

In Phase 1 the most practical method of measuring braille height was found to be the micrometer. However, micrometers exert downward pressure on the braille during measuring which may distort the braille and affect the measured height. The size of this downward pressure also varies from one micrometer model to another. The extent of this 'measurement problem' is unknown and an analysis was undertaken to try to understand it further. The analysis had four aims, to investigate for two height conditions 3 and 4 (selected because they are around the boundary of where user performance changed from being significantly poorer than baseline to being no different to baseline):

- 1) to compare the impact of two different micrometer anvil pressures ('micrometer pressure') on embossed braille measurement;
- 2) to examine if braille dots 'recover' after being 'squashed' by the micrometer;
- 3) to examine the impact of micrometer pressure upon different heights of braille;
- 4) to examine the impact of micrometer pressure upon different braille dot configurations, ie. 1 dot cell (e.g. letter A), compared to 2 dot cell (e.g. letters B, C), compared to 3 dot cell (e.g. letters D, F), compared with 4 dot cell (e.g. letters G, T), compared with 5 dot cell (e.g. letters Y, Q).

Method

Material

Four different samples of embossed braille were used in the study. Two of the samples were taken from condition 3 of the user trials, and two from condition 4. From each of the samples five braille cells were identified:

- 1 dot cell (letter A);
- 2 dot cell (letters I or E);
- 3 dot cell (letter O)
- 4 dot cell (letter G)
- 5 dot cell (letters Y or Q).

Therefore the analysis focussed upon a total of 20 braille cells, which included 60 individual braille dots.

Instruments

Three instruments were used in the study:

- Micrometer 1: Mitutoyo 547-320 dial micrometer anvil pressure of 0.55N (Model numbers: Dial and anvil – Mitutoyo No 2046F; Handle – Mitutoyo No. 7321)
- Micrometer 2: Mitutoyo 547-320 digital micrometer anvil pressure of 1.47N (Model numbers: Dial and anvil – Number ID-C1012EBS, Code number 543-272BS; Handle – Mitutoyo No: 547-320);
- Microscope: Mitutoyo TM 500 microscope and DP-1VR processor (instead of the optical comparator used in Phase 1).

Procedure

Two researchers first measured the height of the dot / dots of a given braille cell using the microscope. Then they measured the same braille using one of the two micrometers. Finally, they re-measured the height of the dot / dots of the cell using the microscope. This procedure was followed four times, once with each of the four samples of embossed braille (two different height conditions) and using each of the two micrometers (0.55N and 1.47N).

Results

The results relating to each of the research aims are taken in turn.

Aim 1: to compare the impact of two different micrometer anvil pressures ('micrometer pressure') on embossed braille measurement. Braille cell height measured using a micrometer was highly significantly lower than when measured using the microscope (based upon averaging the individually measured braille dots) ($p < 0.0005$). This demonstrates that the micrometer pressure distorts the braille and reduces its height (in the trials this was an average reduction of 0.01mm for the 0.55N micrometer and 0.03mm for the 1.47N micrometer). The mean height difference between microscope and 0.55N micrometer was less than between microscope and 1.47N micrometer. While this trend was not shown to be a statistically significant difference, it was close to significance and more measured braille samples would probably bring the finding to significance.

Aim 2: to examine if braille dots recover after being 'squashed' by the micrometer. Braille dot height measurements made with the microscope before and after micrometer measurement (and related micrometer pressure) were not found to differ significantly (and means were almost exactly the same). This demonstrates that for this sample and both micrometers, the braille dots fully recover to original height following squashing.

Aim 3: to examine the impact of micrometer pressure upon different heights of braille. No evidence was found that suggested that the impact of micrometer pressure was different between height conditions 3 and 4. This demonstrates that conditions 3 and 4 do not squash any differently (although in both conditions, the braille is squashed more with the 1.47N micrometer compared to the 0.55N micrometer).

Aim 4: to examine the impact of micrometer pressure upon different braille dot configurations. There was evidence that braille cells made up of fewer dots are

more greatly effected by the micrometer pressure. This was found to be statistically significant ($p < 0.05$), and the effect was due to the single dot cell (the letter A) being particularly prone to being squashed by the micrometer. Nevertheless, braille cells with more than one dot were still squashed.

Discussion

The analysis provides clear evidence of the impact of different measuring devices upon the measured heights of embossed braille. Measurements using a 0.55N micrometer have been largely used in this research and therefore recommendations must be made based upon that data. However, it is likely that manufacturers will use other measuring devices that may have a greater impact upon measurement (e.g. a 1.47N micrometer) or a lesser impact upon measurement (e.g. a microscope, or other automated techniques involving laser or ultrasound technology). Whatever device is used, manufacturers should ensure that the required braille height is achieved as described in the standard accounting for any 'squash' factor when using the measuring device.

Two other more practical implications are also worth highlighting. Firstly, the impact of the micrometer on measurements is greater on braille cells with fewer dots. Therefore, it is important to be particularly cautious when measuring braille cells with a single dot (letter A) or with just two dots (e.g. letter E).

Secondly, the research team carried out some pilot work investigating the downward pressure on braille when being read by a braille user. In the single case study carried out so far the figure appears to vary between 0.02N and 0.05N. While this figure is only indicative it suggests that braille reading pressure is relatively light (very much lighter than the micrometers used in the study).

'Settling' of braille over time

Introduction and rationale

Producers of braille have thought for some time that the height of embossed braille may drop over a period of time after initial production. It is important to understand this 'settling' phenomenon in order to make recommendations to braille producers who are trying to achieve satisfactory embossed braille height. Therefore, the aim of this analysis was to re-measure some of the embossed braille similar to that used in the user trials to establish whether, and by how much, the braille height had changed.

Method

The previous section ('Phase 1: Braille production and measurement') describes the selection and measurement of 288 embossed braille samples. This measurement took place on 23 May 2007, within 10 days of the embossed samples being produced. These materials were then subject to measurement using an optical comparator and then stored in normal office conditions until 6 December 2007. Given the resources available to the project only one condition was re-measured. The 48 embossed cartons from height condition 4 were then selected for re-

measurement because this was lowest height condition were performance was not significantly different to baseline in the user trials.

The height of the braille on each of the packages was measured in exactly the same way as previously using the same spring loaded dial micrometer as used in Phase 1 (model Mitutoyo 547-320, 0.55N) and following the same procedure, ie. with anvil measuring height of whole cell, taking a cell at beginning, end, and middle of each line of braille text. Therefore, the analysis described below reports a comparison of the measurement (May 2007) and re-measurement (December 2007) of the same 144 embossed braille cells (three cells measured on each of the 48 embossed packages).

Results

The table demonstrates that the braille height for these materials consistently and significantly dropped in the six and half months between measurements. The average drop in height was 0.02mm (from 0.18mm to 0.16mm) and this difference was very highly statistically significant ($p < 0.0005$). The drop in height was found in braille cells at the beginning, middle and end of the braille lines.

Table 3. Summary of the mean, range and standard deviations (SD) of height of embossed braille dots in height condition 4. Measured by micrometer (0.55N) in May 2007 and December 2007. N=48 embossed cartons.

Braille Cell	May mean height (SD), mm	Dec mean height (SD), mm	Statistical significance
Beginning cell			
Mean	0.17	0.15	p<0.0005 (sig)
SD	0.021	0.024	
Middle cell			
Mean	0.19	0.17	p<0.0005 (sig)
SD	0.021	0.015	
End cell			
Mean	0.18	0.16	p<0.0005 (sig)
SD	0.025	0.020	
All cell			
Mean	0.18	0.16	p<0.0005 (sig)
SD	0.016	0.015	
Overall min	0.12	0.11	
Overall max	0.24	0.20	

Discussion

This general findings support previous observations made by manufacturers about 'settling' of embossed braille over time. The amount of settling may also vary according to the original height of the embossed braille, as well the substrate (in this case medium weight calliper coated 400 micron board GC2 with standard water-based varnish). This was not explored in this analysis.

The implications of these findings are potentially far reaching. Firstly, it highlights that when implementing any braille height standard, producers of embossed braille must account for when they measure the braille height and the likely drop in the braille height in the time period between manufacture and eventual use. Perhaps the most important finding is that the study gives evidence of settling taking place. The extent of the settling observed (a mean of 0.02mm in this case) should be treated cautiously because this is likely to vary depending upon the nature of the substrate and the original height of the embossed braille. Indeed, there may be other factors along the supply chain (such as storage, transport and handling) which might also lead to degradation of braille height.

Secondly, it brings into question the exact height of the braille read by participants in the user trials. The user trials took place in June 2007 (between the two measuring periods) and we are unclear of the exact height of the braille at that time. Previous internal research carried out by Field-Boxmore suggests that settling takes place in the four weeks after production, and the majority of the user trials took place after this time. Additionally, other informal user trials using the same embossed braille which took place in Germany and Spain in November 2007 (see User Trials sections) generated results which confirmed those of the main user trials reported in this study. Given these points, this suggests that the braille experienced by participants in the user trials was very slightly lower than previously thought. Nevertheless, we also would highlight again that the phenomenon of 'settling' of embossed braille is not explored fully in this analysis.

Commercially produced braille

Introduction and rationale

A set of commercially-produced pharmaceutical packages with embossed braille were examined. This analysis was carried out for two related purposes.

Firstly, it gave an opportunity to examine how typical are the purpose-made sample of embossed braille produced for the user trials compared to production samples - in terms of means, standard deviations, minimum, maximum heights.

Secondly, it gave an opportunity to consider criteria for categorising the height of embossed braille (which in practice would be similar to the application of a standard).

Method

A selection of 54 pharmaceutical packages with embossed braille was examined. They represented a range of 29 different brand names and were produced by a range of packaging manufacturers (collected from a variety of packaging companies from across Europe including: Belgium, France, Germany, Ireland, Italy, Spain and the UK). The 54 different packages included 25 pairs of packages which were produced from the same production batch. An additional four packages came from four separate production batches.

The height of the braille on each of the packages was measured using the same spring loaded dial micrometer (model Mitutoyo 547-320, 0.55N) used in Phase 1,

with measuring method as described earlier in the report, ie. with anvil measuring height of whole cell, taking a cell at beginning, end, and middle of each line of braille text.

Analysis

Earlier in the report the six different height conditions of the material produced for the user trials were described. This is reproduced in the Table below, with additional information in relation to one and two standard deviations below the mean. Standard deviation is a statistical terms which describes the spread of data around the mean (a definition is given in Appendix 2).

Table 4. Summary of the mean, mean minus one standard deviation, mean minus two standard deviations (SD), and actual minimum height of embossed braille dots in each of the six height conditions (measured by micrometer 0.55N, all measurements in mm). N=54 embossed production braille samples.

	1	2	3	4	5	6
Mean (mm)	0.06	0.14	0.15	0.18	0.19	0.23
Mean minus 1 SD (mm)	0.04	0.12	0.13	0.16	0.16	0.21
Mean minus 2 SD (mm)	0.03	0.09	0.10	0.13	0.14	0.18
Minimum Value (mm)	0.02	0.09	0.09	0.12	0.13	0.15

These values were used to create four criteria which could be used to categorise each of the 54 packages. The four alternative criteria vary in terms of stringency and are listed below:

- **Mean criteria** – The mean braille cell height for a given package was calculated. This mean value was compared to the mean value of the height conditions.
- **Mean minus 1 SD criteria** – The minimum braille cell height for a given package was calculated. This minimum value was compared to the mean value of the height condition minus 1 standard deviation.
- **Mean minus 2 SD criteria** – The minimum braille cell height for a given package was calculated. This minimum value was compared to the mean value of the height condition minus 2 standard deviations.
- **Minimum value criteria** – The minimum braille cell height for a given package was calculated. This minimum value was compared to the minimum braille cell height of the height condition.

These four criteria offer four alternative ways of determining whether braille reaches the threshold of falling within a given height condition. Each of the 54 packages was analysed in this way.

Results and summary

The Table 5 below summarises how the commercial packages were categorised into one of the six height conditions using the criteria described above. Results demonstrate that embossed braille on commercially-produced pharmaceutical packages comes in a variety of heights (the materials are approximately evenly distributed across the six height conditions). Also, whichever criteria was applied, all of the commercially-produced braille examined in this study could be categorised into one of the six height conditions.

The Table 6 below re-presents these results as a percentage achieving criteria threshold or higher, and this is discussed below.

Table 5. Percentage of commercial samples categorised into the six height conditions. Four different methods of applying the criteria are presented. N=54 embossed production braille samples.

Criteria	1	2	3	4	5	6	Total
Mean	22%	7%	20%	7%	22%	20%	100%
Mean minus 1 SD	15%	2%	30%	30%	0%	24%	100%
Mean minus 2 SD	2%	6%	17%	9%	30%	37%	100%
Minimum Value	2%	13%	0%	9%	15%	61%	100%

Note: Some aggregate scores on tables do not add to 100%. This is caused by 'Rounding error' – See Appendix 2, Glossary of some statistical terms.

Table 6. Percentage of commercial samples which would reach 'threshold' based upon criteria derived from the six user trial height conditions. Four different methods of applying the criteria are presented. N=54 embossed production braille samples.

Criteria	1	2	3	4	5	6
Mean	100%	78%	70%	50%	43%	20%
Mean minus 1 SD	100%	85%	83%	54%	24%	24%
Mean minus 2 SD	100%	98%	92%	75%	67%	37%
Minimum Value	100%	98%	98%	85%	76%	61%

Discussion

Even using the most stringent criteria for categorising the braille into height conditions (comparison of means), 50% of the commercially-produced braille analysed fell within the height condition 4 or above (height condition 4 is used here as a point of interest because it was the lowest height condition in which braille users did not perform worse than baseline). Indeed, 20% of the commercially-produced braille analysed fell within height condition 6 or above (the highest braille condition

studied in the user trials). None of the commercially-produced braille samples was lower than the height condition 1 irrespective of the criteria applied.

Results also demonstrate that there is relative consistency in braille height for a given production batch. Correlation between mean braille heights for the 25 pairs of packages from the same production batch was very highly significant (correlation of 0.813, $p < 0.0005$), i.e. consistency of mean braille heights within a production batch was very good.

In summary, we can conclude that the height conditions used in the user trials are typical of the height of commercially-produced embossed braille on the pharmaceutical packages investigated. There is also evidence that there is some consistency of the height of commercially-produced embossed braille within a given batch.

PHASE 1: USER TRIALS – METHOD

Participants

Forty-five participants took part in the user trials, representative of the blind, braille-using, medicine-taking population. The participant characteristics were as follows:

- All were braille users.
- Age range from 15 to 77 years. Participants fell into three age groups:
 - <21 years (N=11);
 - 21 – 59 years (N=16);
 - 60+ years (N=18).
- The majority of participants (N=38, 84%) first learnt braille when at school (under the age of 17 years). 11% (N=5) learnt between ages 17 and 59 years, and the remaining 2 participants (4%) learnt when over the age of 59 years. The majority of participants in the 60+ age group (14 of 18, 78%) learnt braille while at school.
- The majority of participants (N=41, 91%) read Grade 2 (contracted) and Grade 1 braille. Four participants read Grade 1 braille only.
- Participants were asked to rate their braille competency – 21 (47%) described reading braille 'fluently on a daily basis', while 7 (16%) described only reading braille 'only to get by'. The remaining 17 (38%) described themselves as 'somewhere in between' these statements. Of those who described only occasionally using braille to get by typically said that they used braille for labelling. A range of other applications of braille were described by other participants including reading novels, work, correspondence (e.g. gas bills), magazines, and shopping lists.
- Participants were from a broad geographical area in central and southern England. Some testing was carried out in one school, and one college where some of the participants were studying / working. However, much of the testing took place in participants' homes or place of work as this was most convenient.
- 58% (N=26) told us they were currently on medication. It should also be noted that older people were more likely to take medication (78% of 60+ age group were on medication compared with 44% of the <60 age group). Four participants (9%) had diabetes. A 46th participant has been excluded from the analysis because their braille reading skills had recently deteriorated due to diabetes and they were unable to complete the baseline reading task.

All participants were told about the purpose of the research and gave written consent of their willingness to take part.

Tasks / Procedures

The research procedure was piloted with two participants, and following this there were no changes made. Their results have not been included in this data.

The testing of the braille materials took between 30 minutes and one hour with each of the participants. The testing was carried out by one of four researchers each with specialist knowledge of teaching and assessing braille. Each researcher had a training session in which they learned the testing procedure and materials. The testing was split between four tasks which will be described in turn:

1. Introductions, consent and background information.
2. Baseline testing.
3. Embossed braille testing.
4. Screen-printed braille testing.

[Details of the production and height of the braille under investigation is described in the previous section – ‘Braille production and measurement’.]

1. Introductions, consent and background information

Before carrying out the tests, the researcher explained to the participant the purpose of the research, and the value and importance of their responses in meeting our objectives. They were then all asked to read and sign a consent form.

In order to find out more about each participant and to put them at ease, a short questionnaire established relevant information about the participants (e.g. age group, age when braille was first learnt, etc). The summary of this data is presented under ‘Participants’ section above.

2. Baseline testing

Following introductions, consent and background:

- Participants then read some simple braille passages in standard braille to establish reading ability. Passages were presented in grade 1 braille. This was followed by reading two common medicine names (penicillin and paracetamol). This gave a practice task to aid grade 2 braille readers to get used to reading grade 1, as well as giving a chance to assess the participants' braille reading ability, and familiarise them with the type of activities they were to undertake.
- Participants were then presented with two target words in turn. The target words were fictitious medicine names (and matched in length and complexity to medicine names used in the testing phase – see Appendix 1). Errors made during this reading were recorded, and this reading performance gave the ‘baseline performance’ which was used in the analysis described below.
- Braille was produced on an Index Braille Embosser, on standard braille paper, which is very commonly used in the UK.
- One participant was unable to complete the baseline task and consequently their data was not included in the analysis (this is the 46th participant mentioned earlier).

3. Embossed Braille testing

- Participants then were presented with two target words at each height condition on embossed braille on made up medicine boxes (see Appendix 1).
- Participants started at the lowest height condition and worked up the six different heights in turn.
- Reading errors were noted for each activity, and after each activity participants were asked whether they thought they would be able to identify the medicine from the labels they had just read. They were given a choice of answers: 'Yes, definitely', 'Yes, probably', 'Probably not', and 'Definitely not'. General participant comments were also noted.
- When all data was collected for the six different braille height conditions presented on boxes, a similar procedure was followed for 'flat' medicine boxes (ie. card carton shapes which were not yet made up into boxes). In this case, the experimenter worked from highest braille height condition to lowest.
- In addition, if the researcher judged the participant was able to read the braille in the three highest conditions with ease in the boxed presentation then these were not repeated for the flat conditions (this was to save unnecessary participant time and prevent fatigue).
- Each participant was presented with fresh samples of embossed braille for testing. Materials were balanced to control for the target word medicine name.

4. Screen-printed braille testing

A similar procedure was followed when testing the screen-printed braille. In this case the conditions were two different types of label – high gloss synthetic (gloss) and LW60 coated paper (matt) – and two different kinds of packaging (bottle and box). This gave a total of four conditions (gloss-bottle, matt-bottle, gloss-box, matt-box), each of which was tested with two target words (see Appendix 1).

As with the embossed braille testing, reading errors were recorded by the researcher as well as participant's opinions. The testing was balanced to control for medicine names and order.

Analysis

All data was recorded by researchers onto printed forms at the time of testing. This data was entered into an SPSS database. For the purpose of this report, the key data analysed is that related to reading performance (product identification) and participant's confidence of product identification in the various presentation conditions.

The key approach to the analysis of reading performance was to establish whether performance in a given presentation condition matched performance when reading in baseline condition. This control is important to ensure that poor identification is not invalidly attributed to low braille dot height instead of to the reading skills of the braille user.

The key results presented in relation to performance are based upon percentage of participants who match (or better) their baseline performance. In such an analysis, the criteria for when baseline performance is matched are crucial and the following method was used:

1. If the participant cannot read the braille label at all, baseline performance is *not* matched.
2. If the participant attempts to read the braille, but makes three or more errors greater than made in baseline, baseline performance is *not* matched.
3. If the participant attempts to read the braille, and makes two or less errors more than made in baseline, baseline performance *is* matched.

Therefore, the threshold chosen slightly 'favours' the braille reading from the labels under investigation – that is, the criteria are such that participants can make two *more* errors when reading from the braille labels before they are judged to have not achieved baseline performance. The reason for this was that we felt that it was reasonable that participants might make the occasional reading error over a number of repeated trials and this should not to be falsely attributed to the presentation of braille. We think the strategy is justified empirically because, as can be seen from the results, performance tends to 'plateau' at the higher braille conditions and the analysis strategy made this plateau clearer.

PHASE 1: USER TRIALS – EMBOSSED BRAILLE OF DIFFERENT HEIGHTS

Based upon the analysis presented in the “Braille production and measurement” section above, it is useful to remind the reader of the key figures for the estimated braille dot heights for the six different height conditions in the study - presented in Table 7 below.

Table 7. Summary of the mean and range of height of embossed braille dots in each of the six height conditions measured by 0.55N micrometer (all actual values)

	1	2	3	4	5	6
Micrometer (mm)						
Mean	0.06	0.14	0.15	0.18	0.19	0.23
Minimum	0.02	0.09	0.09	0.12	0.13	0.15
Maximum	0.11	0.20	0.20	0.24	0.24	0.29
Standard Deviation	0.016	0.023	0.023	0.025	0.026	0.025

Data in the following sections is presented both in graphical and tabular format, or as a table only, for ease of reference. Key findings are also presented in narrative form.

Reading Performance

The following figure and table give alternative presentations of reading performance (compared with baseline) against each of the six embossed braille height conditions (on BOX).

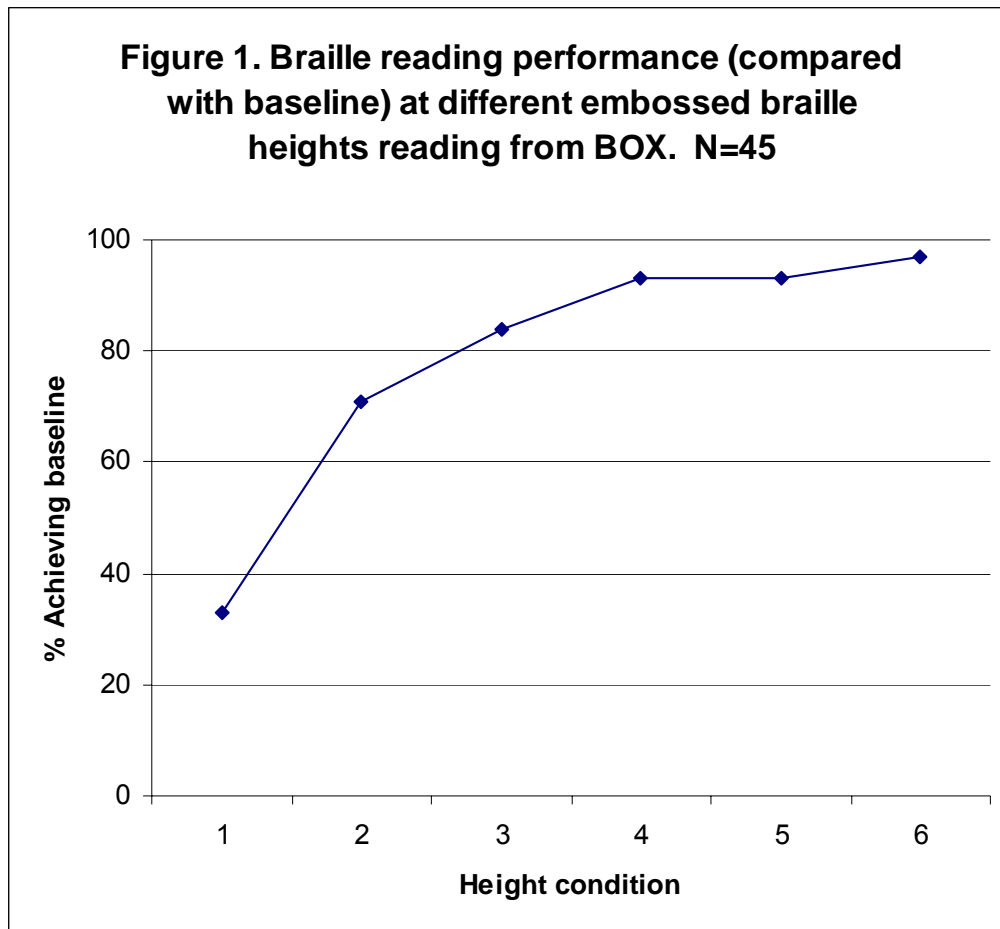


Table 8. Braille reading performance (compared with baseline) at different embossed braille heights reading from BOX. Statistical difference (p) of reading performance in condition compared to baseline presented. N=45.

Height Condition	% Achieving Baseline	Statistical significance (sig = significant, ns = not significant)
1	33%	p<0.05 (sig)
2	71%	p<0.05 (sig)
3	84%	p<0.05 (sig)
4	93%	p>0.05 (ns)
5	93%	p>0.05 (ns)
6	97%	p>0.05 (ns)

Results show that only a third of participants achieved baseline performance in height condition 1 (the lowest height). While this rose to 71% and 84% in conditions 2 and 3 respectively, it is not until height condition 4 and above that more than 90% of participants achieved baseline performance. It was found that reading performance was significantly lower than baseline reading performance for height conditions 1, 2 and 3. There were no significant differences for height conditions 4, 5 and 6.

A summary of the figures of Table 8 is as follows:

Height condition 1:

- 33% of participants matched their baseline performance.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height condition 2:

- 71% of participants matched their baseline performance.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height condition 3:

- 84% of participants matched their baseline performance.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height Condition 4:

- 93% of participants matched their baseline performance.
- No significant difference between performance and baseline ($p > 0.05$).

Height Condition 5:

- 93% of participants matched their baseline performance.
- No significant difference between performance and baseline ($p > 0.05$).

Height Condition 6:

- 97% of participants matched their baseline performance.
- No significant difference between performance and baseline ($p > 0.05$).

Phase 2 – Validation study

In November 2007, two visual impairment organisations (ONCE, Spain, and Deutsche Blindenstudienanstalt e.V., (blista) Germany) expressed an interest in trialling some of the embossed braille materials with braille users in their countries. While these trials were less formal than the user trials described in this report, the research team felt this was an opportunity to carry out some rapid validation.

The studies involved 29 braille readers (25 in Spain, 4 in Germany). Each participant was shown an example of braille from each height condition and asked for their opinion (on a scale). The findings broadly followed the findings reported in this study:

- Nearly all participants thought height condition 1 unacceptable.
- Most participants found height conditions 2 and 3 difficult (some finding them unacceptable).

- Some participants found height condition 4 difficult, but most found it acceptable.
- Nearly all participants thought height conditions 5 and 6 were legible and the best.

While these are only indicative results that braille users in different countries have similar responses to the materials, they are encouraging in that they provide some validation of results presented in this report.

Participant Confidence

It is important to contrast reading performance with participant's perceived confidence that they could identify the medicine name from the embossed braille labels of different heights. Participants were asked whether they thought they would be able to identify the medicine from the labels they had just read. They were given a choice of answers: 'Yes, definitely', 'Yes, probably', 'Probably not', and 'Definitely not'. The following figure and table give alternative presentations of participant perceptions of the braille when presented on box. The findings tend to mirror those of the reading performance in the previous section – the key trend was that the percentage of people who felt that they could 'definitely' or 'probably' identify the medicine increased with the height of the braille. Perhaps some key summary figures here are that it was only in the two lowest conditions (1 and 2) where more than 10% of participants answered 'definitely not' to being able to identify the medicine. Also, it was only in the three highest conditions (4, 5 and 6) where 90% or more of participants answered 'Yes, definitely' or 'Yes, probably' to being able to identify the medicine.

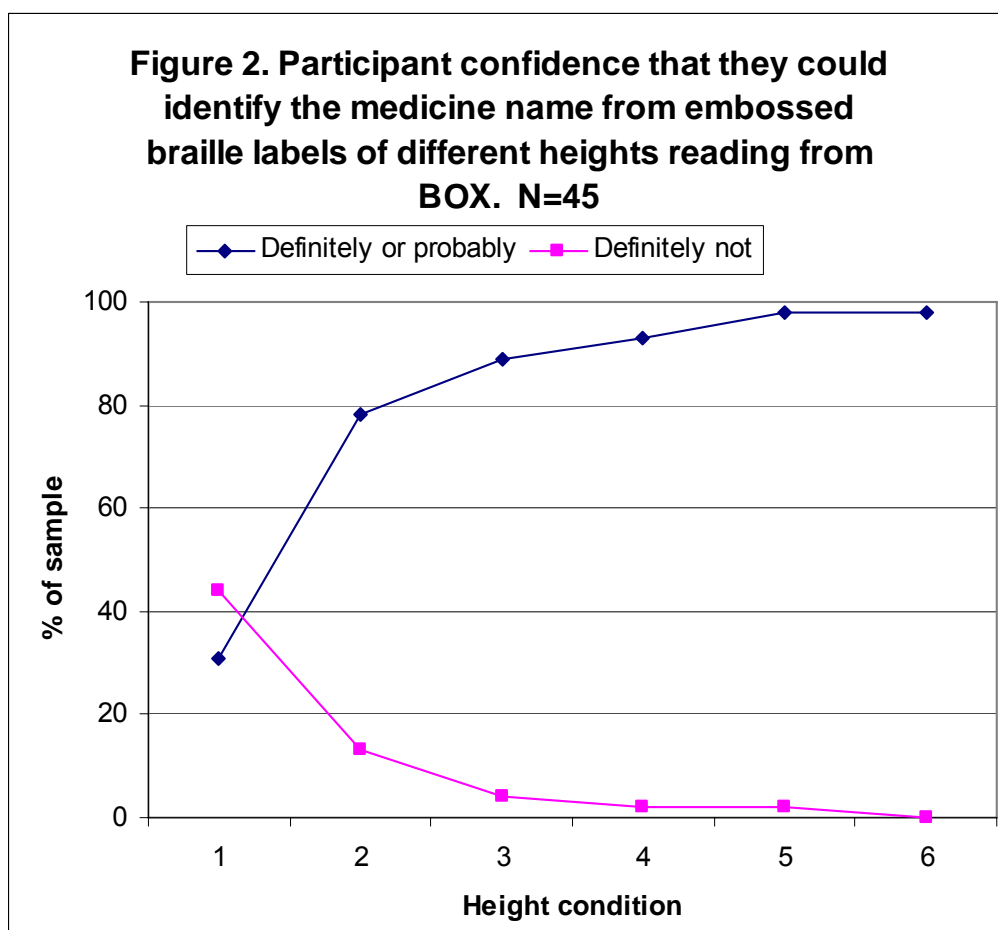


Table 9. Participant confidence that they could identify the medicine name from embossed braille labels of different heights reading from BOX (cumulative % in brackets). N=45.

Height Condition	Yes, Definitely	Yes, Probably	Probably not	Definitely not
1	9% (9%)	22% (31%)	24% (56%)	44% (100%)
2	27% (27%)	51% (78%)	9% (87%)	13% (100%)
3	58% (58%)	31% (89%)	7% (96%)	4% (100%)
4	67% (67%)	27% (93%)	4% (98%)	2% (100%)
5	73% (73%)	24% (98%)	0% (98%)	2% (100%)
6	93% (93%)	5% (98%)	2% (100%)	0% (100%)

This was also reflected in comments made by participants about some of the lower height conditions.

Condition 1:

- "Poor braille, needs to be more pronounced"
- "Oh dear, this seems as though it has been rubbed"
- "Cannot read, not raised enough"

Condition 2:

- "Still not raised enough"
- "Just about got away with it"

Condition 3:

- "Would struggle and would need practice"

Condition 4:

- "Lot better, braille felt sharper"

Other Factors

Another key quality of the study design was that we purposefully recruited a sample which included a broad range of braille users, including people of different ages. As presented in the following table and graph, when we compare the reading performance for those <60 years of age to those who are 60+ years old there is clearly a link with age: older people find the lower braille heights more difficult than younger people. Perhaps this difference is most relevant in height condition 3 – here 96% of participants <60 years matched baseline performance while this is only 67% of participants 60+ years old. This is consistent with other research which indicates that touch sensitivity drops with age. It should also be noted that older people are more likely to live alone and more likely to take medication (this was true for this sample: 78% of 60+ age group were on medication compared with 44% of the <60 age group).

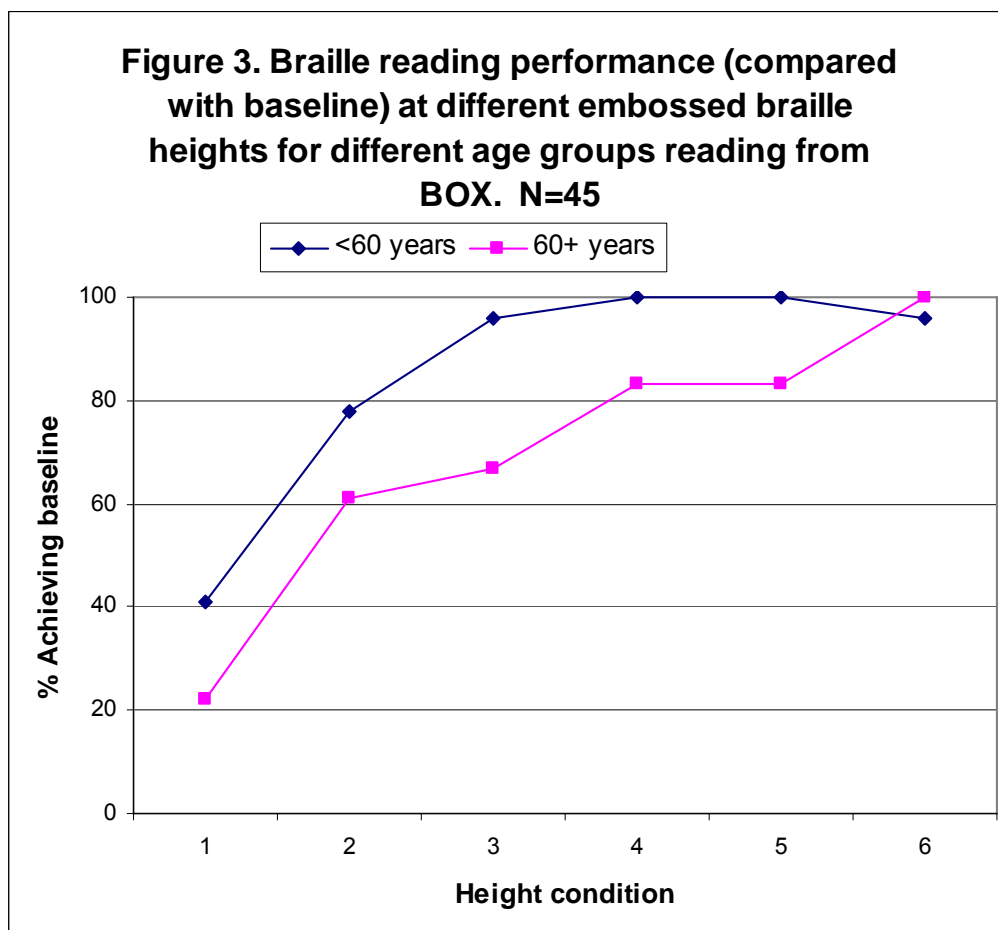


Table 10. Braille reading performance (% achieving baseline) at different embossed braille heights for different age groups reading from BOX (<60 years and 60+ years). N=45.

Height Condition	<60 years (n=27)	60+ years (n=18)
1	41%	22%
2	78%	61%
3	96%	67%
4	100%	83%
5	100%	83%
6	96%	100%

Again participant comments reflected these findings:

- “Can only read it, I have sensitive fingers, older people may not be able to” (Condition 2)
- “Far too faint. Newly blinded person would not cope at all” (Condition 1)

The study also included a ‘flat’ set of conditions as well as boxed conditions. The reason for this was that we thought that it might be harder to read braille from a box than from the flat irrespective of the height or quality of the braille.

The graph and table below offer alternative presentations of results for flat and box conditions of the same height. The results suggest there is indeed a negative impact of the box, suggesting people find reading lower braille easier when it is on a flat piece of card. A number of participants also commented that they thought it was easier, e.g.

- “Don't think I would recognise this if it had been on box” (flat, condition 3)
- “Easier than boxed condition as it is flat” (flat, condition 1)

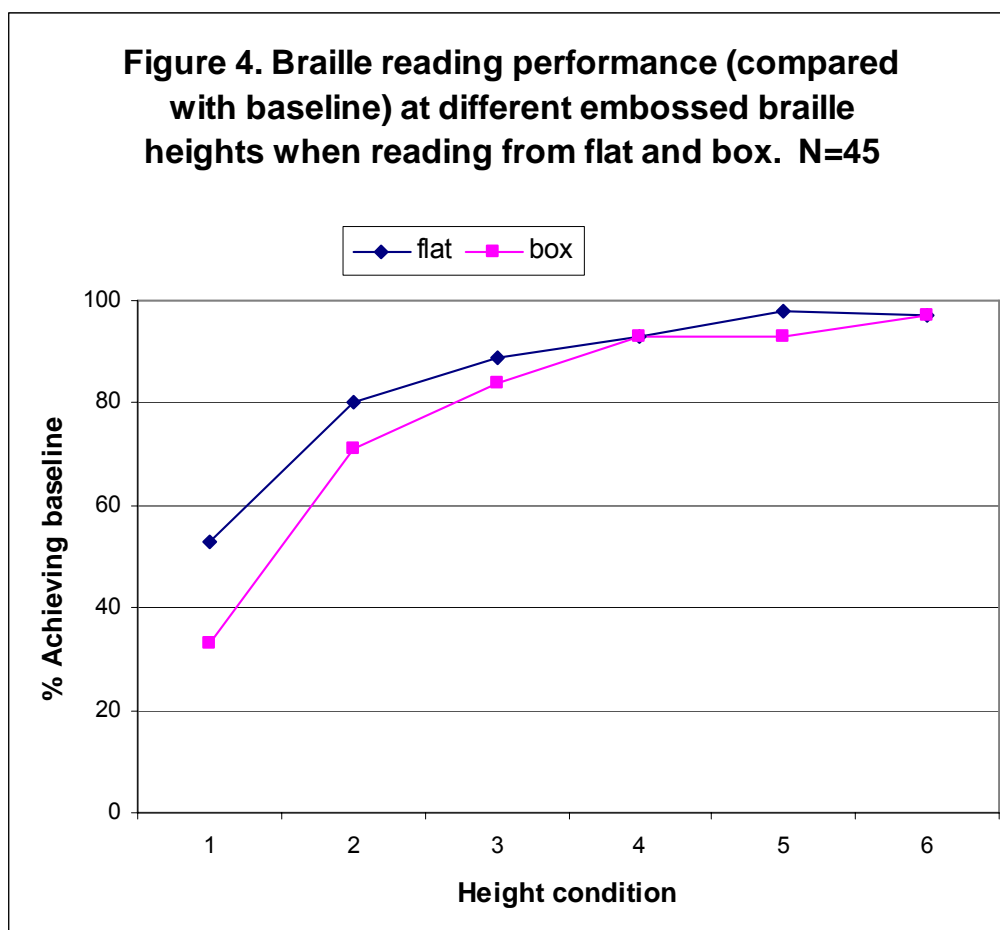


Table 11. Braille reading performance (% achieving baseline) at different embossed braille heights reading from FLAT and BOX. N=45.

Height Condition	Flat	Box
1	53%	33%
2	80%	71%
3	89%	84%
4	93%	93%
5	98%	93%
6	97%	97%

Finally, the proportion of errors made when reading medicine doses (which included a number) and medicine (fictitious) names appeared broadly similar, ie. reading doses and medicine names seemed equally difficult.

Summary and conclusions - embossed braille

Performance in the identification of the products across the six height conditions and levels of subjective confidence was as follows (where 'baseline performance' is performance when reading from standard Braille).

Height condition 1:

- 33% of participants matched their baseline performance, with 31% feeling confident that they could definitely or probably identify the product.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height condition 2:

- 71% of participants matched their baseline performance, with 78% feeling confident that they could definitely or probably identify the product.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height condition 3:

- 84% of participants matched their baseline performance, with 89% feeling confident that they could definitely or probably identify the product.
- Performance was significantly poorer than baseline ($p < 0.05$).

Height Condition 4:

- 93% of participants matched their baseline performance, with 93% feeling confident that they could definitely or probably identify the product.
- No significant difference between performance and baseline ($p > 0.05$).

Height Condition 5:

- 93% of participants matched their baseline performance, with 98% feeling confident that they could definitely or probably identify the product.
- No significant difference between performance and baseline ($p > 0.05$).

Height Condition 6:

- 97% of participants matched their baseline performance, with 98% feeling confident that they could definitely or probably identify the product.
- No significant difference between performance and baseline ($p > 0.05$).

The research suggests that braille users 60+ years old find reading braille at low heights harder than people who are under 60 years of age. It should also be noted that older braille users (>60 years) are more likely to be medicine takers, and also more likely to live alone.

PHASE 1: USER TRIALS – SCREEN PRINTED BRAILLE

Reading Performance

The following table presents reading performance (compared with baseline) against each of the four screen printed braille label conditions (glossy label on a bottle; glossy label on a box; matt label on a bottle, and matt label on a box). It also presents a breakdown by age groups.

Table 12. Braille reading performance (% achieving baseline) for different screen printed label types (Gloss and Matt) on different packages (Bottle and Box) for different age groups (<60 years and 60+ years). N=45.

Condition Label-Packaging	<60 years (n=27)	60+ years (n=18)	Total (all sample)	Statistical significance of Total (sig = significant, ns = not significant)
Glossy-Bottle	93%	56%	78%	p<0.05 (sig)
Glossy-Box	100%	83%	93%	p>0.05 (ns)
Matt-Bottle	96%	72%	87%	p<0.05 (sig)
Matt-Box	100%	89%	96%	p>0.05 (ns)

The following summarises some of the key figures from Table 8 (as well as statistical significance of the difference between reading from labels and baseline):

Glossy label on bottle:

- 78% of participants matched their baseline performance.
- Performance was significantly poorer than baseline (p<0.05).

Glossy label on box:

- 93% of participants matched their baseline performance.
- Performance not significantly different from baseline (p>0.05).

Matt label on bottle:

- 87% of participants matched their baseline performance.
- Performance was significantly poorer than baseline (p<0.05).

Matt label on box:

- 96% of participants matched their baseline performance.
- Performance not significantly different from baseline (p>0.05).

The results show that there is no demonstrated difference in performance when reading from labels and reading from baseline. However, the results suggest that reading labels from a (curved) bottle appears to be harder than reading from (flat) baseline. Some participant comments reinforce this observation:

- “More difficult because it was curvy but braille height is not bad” (Bottle, glossy)

- “Better than gloss bottle, round is difficult for me personally” (Bottle, matt)

There were some suggestions that reading from the glossy labels (high-gloss synthetic) may be harder, but this was *not* statistically significant. If there is an effect here, then this is likely to be due to the finger more easily sticking to the glossy finish of the high-gloss synthetic label if the fingers are slightly moist, or a lack of friction across the surface when the fingers are dry; and a number of participants mentioned this in their comments, e.g.

- “Sticks to my fingers” (Bottle, glossy)
- “Stickier than matt label but would be alright” (Bottle, glossy)
- “Slippery” (Box, glossy)

As with the embossed braille of different heights, the age of the participants was a significant factor. Participants who were 60+ years old found glossy labels on bottles particularly difficult (only 56% achieving baseline performance).

Participant Confidence

Around 90% of participants were relatively confident that they could identify the medicine from any of the labels (full presentation in the table below). Nevertheless, the general pattern of ‘gloss label on bottle’ being hardest and ‘matt label on box’ being easiest which was observed in the reading performance was also observed in terms of participant confidence, where 87% of participants felt they could probably or definitely identify the product on glossy-bottle, 91% both on glossy-box and matt-bottle, and 98% on matt-box.

Table 13. Participant confidence that they could identify the medicine name from different screen printed label types (Gloss and Matt) on different packages (Bottle and Box). Cumulative % in brackets. N=45.

Condition Label-Packaging	Yes, Definitely	Yes, Probably	Probably not	Definitely not
Glossy-Bottle	51% (51%)	36% (87%)	9% (96%)	4% (100%)
Glossy-Box	56% (56%)	36% (91%)	7% (98%)	2% (100%)
Matt-Bottle	58% (58%)	33% (91%)	4% (96%)	4% (100%)
Matt-Box	62% (62%)	36% (98%)	2% (100%)	0% (100%)

Summary and conclusions – screen-printed braille

The following presents reading performance (compared with baseline) against each of the four screen printed braille label conditions (glossy label on a bottle; glossy label on a box; matt label on a bottle, and matt label on a box):

Glossy label on bottle:

- 78% of participants matched their baseline performance, with 87% feeling confident that they could definitely or probably identify the product.
- Performance was significantly poorer than baseline ($p < 0.05$).

Glossy label on box:

- 93% of participants matched their baseline performance, with 91% feeling confident that they could definitely or probably identify the product.
- Performance not significantly different from baseline ($p>0.05$).

Matt label on bottle:

- 87% of participants matched their baseline performance, with 91% feeling confident that they could definitely or probably identify the product.
- Performance was significantly poorer than baseline ($p<0.05$).

Matt label on box:

- 96% of participants matched their baseline performance, with 98% feeling confident that they could definitely or probably identify the product.
- Performance not significantly different from baseline ($p>0.05$).

The braille heights of the two types of screen printed labels relate to (as measured by a micrometer of 0.55N pressure):

- Glossy label: high-gloss synthetic labels, mean dot height of 0.21mm and minimum dot height of 0.19mm.
- Matt label: LW60 coated paper labels, mean dot height of 0.19mm and minimum dot height of 0.16mm.

PHASE 2: USER TRIALS – FOLLOW-UP MISCUE ANALYSIS

Introduction and rationale

The research protocol described a 'braille height tolerance study' which would seek to investigate the acceptable variance of the dot heights within a given braille cell. However, one of the findings of Phase 1 of this study was that the limitations of the production process of embossed braille are such that the materials for the height tolerance study could not be produced. Nevertheless, the funders of the research still required as much information about the variance of braille dot heights as possible. The solution agreed was two-fold. Firstly, additional data collection and analysis was carried out in relation to the measurement of the braille material used in the study (reported above). Secondly, a further analysis of the reading errors made by participants in the user trials of the embossed braille was carried out. It was hoped that these reading errors (or 'miscues') might reveal the reasons why the errors took place, and this might include errors being caused by variation in dot height (e.g. individual dots in a braille cell being particularly low or high). This section presents the findings from this analysis.

Method

Data – the miscue analysis focussed upon the reading errors made by participants when reading embossed braille in height conditions 3 and 4 (in both flat and boxed conditions) in the user trials. These height conditions were chosen because they were at the boundary where there was a significant difference in performance from baseline, ie. participants were found to perform significantly worse than baseline in height condition 3, and show no difference in height condition 4 (see User Trials above). During the user trials, the researcher noted when participants made a reading error, as well as the nature of that error (the so-called 'miscue') – for example, the letter 'C' (the error) read for the letter 'M' (the target). A total of 91 errors were recorded across conditions 3 and 4. These errors were made by 21 of the 45 participants.

Procedure – Three researchers (the first three authors) worked through the 91 errors. A description of each error was made in terms of missing/added dots and misalignments. In addition, a visual inspection of the relevant braille cell was made in which the researchers looked for evidence of physical qualities of the braille which would explain the error. To aid this process, digital photographs of the relevant braille cells were taken. This enabled enlarged pictures of the braille cells to be inspected by the researchers working together.

Results and conclusions

The following table presents a categorisation of the 91 miscues made by the participants when reading embossed braille in height conditions 3 and 4 in the user trials. The miscues were categorised as follows:

- **Missed dot(s)** – when the miscue appeared to involve the participant missing one or more braille dot, e.g. braille letter A read for C (dot 4 missed);

- **Missed bottom dot(s) in the cell** – when the miscue appeared to involve the participant missing one or both of the dots at the bottom of the cell (dots 3 or 6, or both), but also not missing any other dots, e.g. braille letter C read for M (dot 3 missing);
- **Added dot** – when a miscue appeared to involve a participant adding one or more dot, e.g. braille letter C read for A (dot 4 added);
- **Alignment error** – when a miscue appeared to involve a participant misaligning dots to construct a similar character;
- **Other** – when a miscue could not be explained.

The most obvious difference is that more errors were made in height condition 3 than 4 (which obviously reflects the conclusions of the user trials). Beyond this, little further conclusion can be drawn. Most importantly, the careful visual inspection of the relevant braille cells revealed very little, if any, evidence of specific features of the braille which might be the source of the reading errors. The only obvious case was when a missed dot was next to a dot which was unusually high (due to extreme cracking), and this may have effectively obscured the missed dot.

Table 14. Categorisation of the 91 errors made by participants when reading embossed braille in height conditions 3 and 4.

Error	Height 3	Height 4	Total
Missed dot(s)	20	11	31 (34%)
Missed bottom dot(s) in cell	11	8	19 (21%)
Added dot	9	4	13 (14%)
Alignment error	1	4	5 (5%)
Other	17	6	23 (25%)
Total	58 (64%)	33 (36%)	91 (100%)

In conclusion, this analysis did not reveal any explanation for differences in performance in height conditions 3 and 4 *other than those discussed elsewhere*, ie. height condition 4 had braille dots which were higher and more cracked than height condition 3. There was little evidence to support the hypothesis that inconsistent dot heights within a given cell may lead to reading errors within the ranges found in these embossed carton samples. Therefore, no conclusions can be drawn regarding braille height tolerance from this analysis. One additional observation was that eleven errors were made on the first or last braille letters. This may be related to an earlier conclusion (see section ‘Phase 1: braille production and measurement’) that the first (in particular) and last braille cells in the line tended to be lower than the middle braille cells.

PHASE 2: VISUAL INSPECTION OF EMBOSSED BRAILLE

Introduction and rationale

As well as investigating the quality of the braille on pharmaceutical packaging, the project was also concerned with the impact of the braille on the legibility of any underlying print. The reason for this was that there is a responsibility for the pharmaceutical industry to also ensure that the print on their packaging to be legible, and there was some concern that braille might interfere with this legibility.

For this reason two studies were designed and carried out. The first study involved gaining the subjective views of a number of people as to relative impact of the braille of different heights upon the 'readability and aesthetics' of the underlying print. The second study involved systematically analysing the impact of embossed braille of different heights upon the cracking of the packaging surface.

Both studies were carried out using samples of the embossed braille materials described in earlier sections of this report. The text beneath embossed braille was 7 point (which is minimum allowed in EU), and different background and text colour combinations were used.

Visual inspection and impact upon readability

Method

Participants – 55 sighted industry experts: 8 from CEN Task Force meeting in Peterborough (18 September 2007); 17 through the Patient Information Quality department, Medicines and Healthcare products Regulatory Agency (MHRA), UK (October 2007); 9 through the Quality Review of Product Information Department, National Institute of Pharmacy, Hungary (November 2007); 21 from the CEN Working Group meeting in Berlin (21-22 November 2007).

Materials – Four examples of embossed braille on flat cartons of a given height condition were attached to a piece of card. This was done for each of the six height conditions. The height conditions were not known by the participants.

Task – Participants were asked to look at each set of materials in turn. Participants were given the following instructions:

“You will have six different versions of braille produced on flat card pharmaceutical packages (fictional). These are labelled ‘A’ to ‘F’, and for each there are four example packages. For each set of labels we would like you to rate how you think the braille has affected the underlying print. We are interested in whether you think the braille has a detrimental effect upon the “readability or aesthetics” of the print.”

The response sheet required participants to rate each from 0 (no effect) to 4 (large negative effect). Participants were also asked to make comments if they chose.

Results

The following figure and table show expert ratings of the impact of braille on the readability and aesthetics of the underlying print at each height condition.

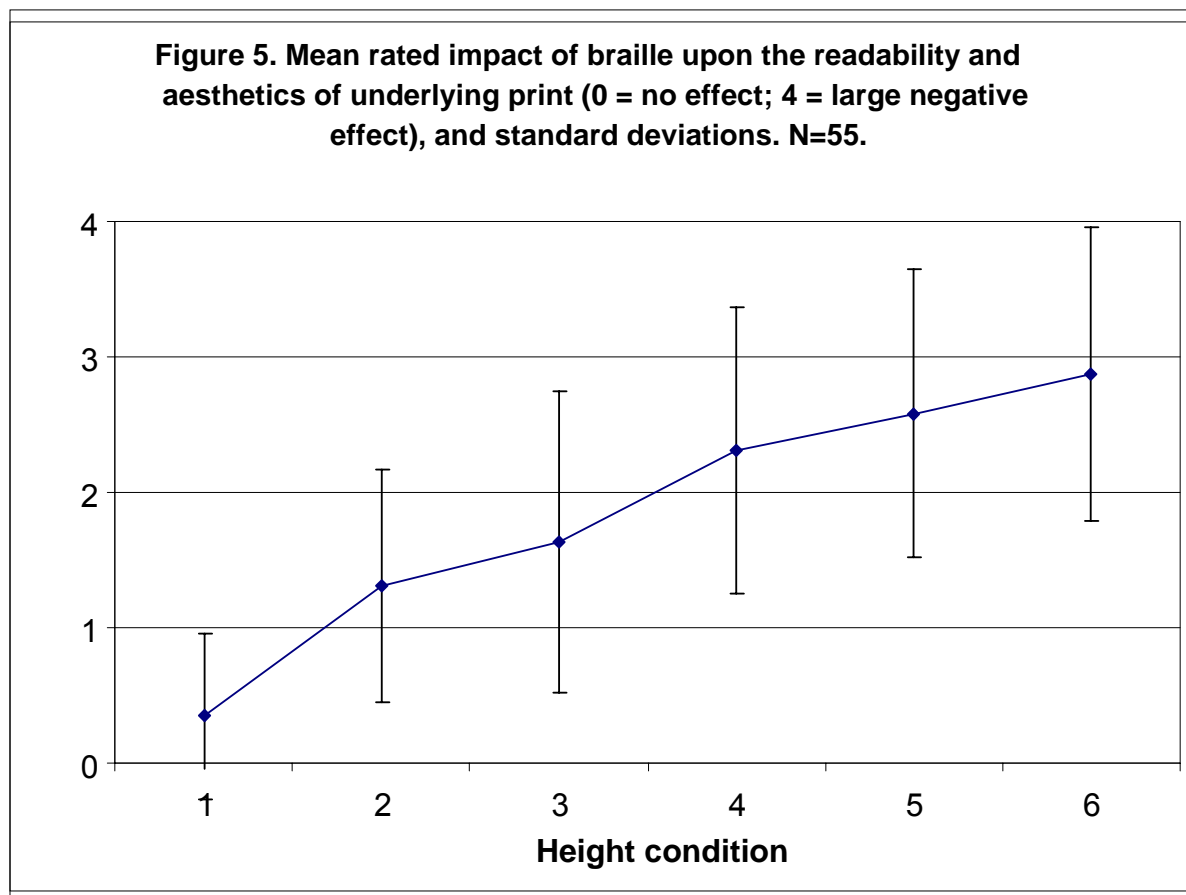


Table 15. Mean rated impact of braille upon the readability and aesthetics of underlying print (and % responses under each rating – 0 = no effect; 4 = large negative effect). N=55.

Height Condition	Rating 0	Rating 1	Rating 2	Rating 3	Rating 4	Mean rating	SD
1	71%	26%	2%	2%	0%	0.35	0.62
2	20%	35%	40%	6%	0%	1.31	0.86
3	18%	24%	42%	9%	7%	1.64	1.11
4	4%	22%	26%	38%	11%	2.31	1.05
5	6%	9%	26%	42%	18%	2.58	1.07
6	4%	9%	16%	38%	33%	2.87	1.09

The mean rating for each of the height conditions was found to be significantly different to the mean rating of the adjacent height condition ($p < 0.05$), ie. the braille in height condition 6 had a higher impact rating than in height condition 5; the braille in height condition 5 had a higher impact rating than in height condition 4. etc.

In terms of the comments provided, none of the comments suggested that any of the cartons were *unacceptable* (although no direct question was asked). Also, it was interesting to note that the majority of comments appeared to focus upon the colour contrast of print against background rather than the actual impact of the Braille upon the print. Nevertheless there were a number of comments which were more specifically related to the braille. Two key themes were raised in this regard. The first theme related to cracking and its impact upon readability and aesthetics, and how this appeared to interact with colour. This is summed up in the following quotes:

“The combination of dot height and background colour of the package seems to have an impact on the overall aesthetics and readability of the text. For example, where the Braille dot height is increased on a dark background, the negative impact of the aesthetics and readability of the underlying print is magnified, especially compared to when the same dot height is added onto a white or light coloured background”.

“Where the Braille height is such that it has breached the top smooth surface of the carton, and especially where the carton is coloured, and the white of the carton layer beneath is exposed, readability of written text is poorest”.

It should be noted that this is *not* more cracking on embossed braille upon darker coloured inks, but rather it is just more noticeable because of the contrast between the crack the darker colour (ie. the second quote above is a good summary).

The second theme related to the effect of lighting and glare:

“Reflection of light plays a large part on how one reads the print under the Braille”.

“The readability is worse when viewed at an angle for all samples due to reflection”

Systematic analysis of cracking of embossed braille

As well as asking people to subjectively rate different braille packages for the readability of underlying print, we also carried out a more objective systematic analysis of the surface cracking around the embossed braille.

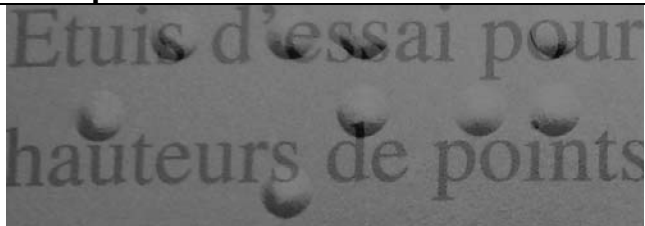
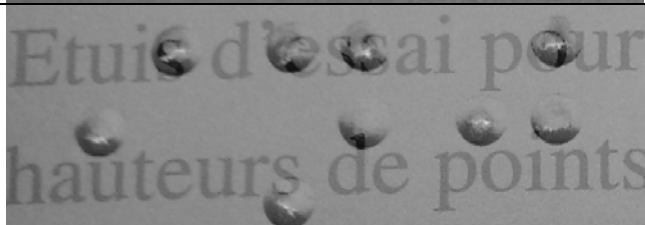
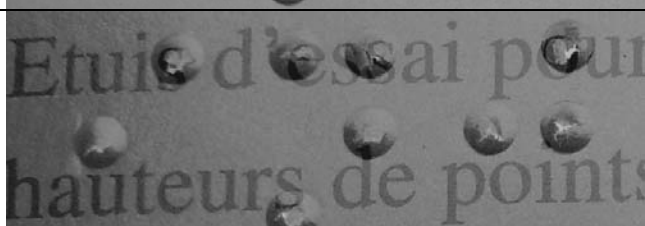

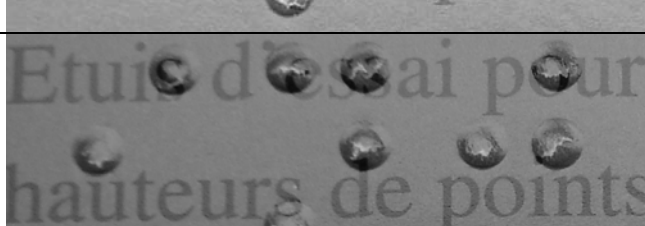
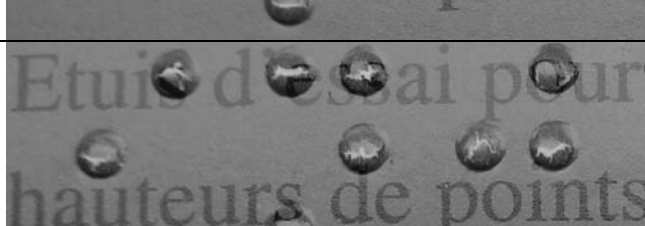
Method

The analysis involved visual inspection of six different embossed braille cartons (flat box), one for each of the height conditions. Sections of the braille were inspected, and each dot was categorised according to the following criteria:

- no crack;
- crack <50% of braille dot width;
- crack 50% or greater than braille dot width.

To aid scoring, each of the six cartons was digitally photographed which allowed the photograph to be enlarged on screen. The braille was matched in each condition (a total of 41 braille dots in each). The card colour and background print was also matched. Examples sections of four of the six conditions are presented as illustration in the figure below.

Figure 6. Examples of cracking on braille dots in six different height conditions

Condition	Example
1	
2	
3	
4	
5	
6	

Three researchers (the first three authors) initially independently scored the braille against the criteria, and following discussion, agreed the scores presented in the results table below.

Results

Table 16. Cracking of card surface on braille dots in six different height conditions (% and number of braille dots cracked). N = 41 braille dots per height condition.

Condition	No crack	Crack <50% dot width	Crack 50%+ dot width
1	100% (41)	0	0
2	22% (9)	61% (25)	17% (7)
3	12% (5)	68% (28)	20% (8)
4	0	29% (12)	71% (29)
5	0	37% (15)	63% (26)
6	0	7% (3)	93% (38)

The results indicate that the extent of surface cracking increases with height condition (and therefore with the height of the braille dots as produced here). Closer inspection of the results suggests that the six conditions might be categorised into four groups:

- no cracking (condition 1);
- little cracking (conditions 2 and 3);
- medium cracking (conditions 4 and 5);
- high cracking (condition 6).

Discussion and conclusions – Visual Inspection

The analysis highlights a number of issues. Clearly there is a link between embossed braille height and subjectively judged impact upon the readability and aesthetics of the underlying print – the higher the braille the greater the impact. This is due the greater amount (and greater extent) of the cracking of the card surface at greater braille heights. It is important to highlight that these results should only be limited to the method of braille production and substrate used in this study (medium weight calliper coated 400 micron board GC2 with standard water-based varnish) – for example, other substrates may crack to a greater or lesser extent at these braille heights. It should also be noted that damage to card surface is also more visible on darker card.

Appendix 1 – Braille test materials

Creating standardised target words for the study allowed braille height to be isolated from other variables affecting identification accuracy (not possible using 'real' cartons/labels) - for example, it prevents people from guessing what the next letters are if they might be familiar with a particular product name, or if the word is very short.

Fictitious but realistic target words have been made up, and checked against the Trade Mark index, and are controlled in the following ways:

- Same length and complexity (12 characters, 4-6 syllables)
- Use all letters of alphabet (A-Z), all numbers (0-9), and all braille dots (1-6)
- Include a product name and unit, and half also have a medium/product presentation.

The materials thereby created ensured that a full range of letters and letter combinations will be experienced at different dot heights by the sample and true letter identification can be easily measured. To allow the research to explore the impact of embossed braille on underlying print, the embossed materials were designed using a range of colour combinations, text characters, font size and colour. The words are presented below.

Two practice words and two target words used in Baseline activity:

Word used	Familiar medium	Amount/unit
Practice Words:		
- Paracetamol	Tablet	1 g
- Penicillin		1 l
Target Words:		
- Netanowebite	Injection	1.4 ml
- Whitonizotin	Cream	0.5 mg

12 target words for embossed cartons, to be produced at every height in both flat and box conditions, so samples can be randomised across trials (partially balanced):

Nonsense 'drug' (fictitious name)	Familiar medium	Amount/unit
Zybrewstanol		20 g
Duncrofixate	Solution	1 l
Montersoform		0.4 mg
Gosaraquikon	Injection	1.6 ml
Mikytrexemol		75 mg
Jonhe vitalip	Tablet	30 g
Larsidexocot		75 mg
Tyleroxynate	Capsule	0.85 µg
Tridougonite		3 l
Svenisotrope	Caplet	200 ml
Lionisinepic		2 g
Isodietermos	Cream	0.2 mg

Eight target words for screen-printed labels in each substrate, on both carton and bottle, so samples can be randomised across trials (fully balanced):

Nonsense 'drug' (fictitious name)	Familiar medium	Amount/unit
Olibaxmalimp		3.8 µg
Arperonetol	drops	40 ml
Elkingvicise		2.7 mg
Dyjatzbatexon	caplet	6 g
Quicohenides		0.4 µg
Briantismolt	injection	9 mg
Welcomeadols		1.4 g
Intesillinol	Solution	500 ml

Appendix 2 – Glossary of some statistical terms

This report contains some reference to statistical notation. Some additional detail and definitions are presented here:

Balanced and controlled research design

When designing experiments, researchers seek to carefully control variables so that they can understand the impact of the variable of interest to them. The research protocol for this research outlines in detail how this was done for this study. In short, the research was interested in the impact of different types of braille on people's ability to identify medicine. When participants carry out the reading tasks we must ask them to carry out the tasks in different orders and with different words so that we do not draw the wrong conclusions. This is called 'balancing' the research.

Standard deviation

Standard deviation is a measure of data dispersion, or 'spread'. In this report standard deviations are reported for the measured heights of the braille cells (Tables 1 and 2). The mean cell height gives an average for the height of all the braille cells measured. The standard deviation gives us an idea of the spread of all the measurements made. One useful way of thinking about standard deviation is that 68% of all data measured will be within one standard deviation greater than or less than the mean.

Statistical probability (e.g. $p < 0.05$)

If two averages are different it is often difficult to know whether this difference 'means something' or whether it has just happened by chance. For example, is the performance when reading from low embossed braille different than when reading from standard braille produced on a braille embosser? Statistical probability (or 'p') gives an indication of the likelihood that an observed difference has happened by chance. For example:

- $p < 0.05$ indicates that there is *less* than a 5% probability that the difference is caused by chance;
- $p < 0.001$ indicates that there is *less* than a 1% probability that the difference is caused by chance;
- $p > 0.05$ indicates that there is *greater* than a 5% probability that the difference is caused by chance.

A $p < 0.05$ (5%) is the internationally agreed standard of when a difference can be reported as a 'real difference'.

Statistical tests

Different statistical tests have been developed to enable researchers to test for the probability of observed differences being caused by chance – ie. these tests give a value for statistical probability ('p'). In this study three statistical tests have been used – a 't-test' and 'ANOVA' have been used when comparing the height measurements of the different braille conditions (see section 'Phase 1: Braille production and measurement' and 'Phase 2: Further investigation of the measurement of braille height'); a 'Wilcoxon match-pairs signed-ranks test' has been used to compare participant's performance when reading from the various conditions (e.g. embossed braille boxes) and the baseline condition (see 'User Trials' sections).

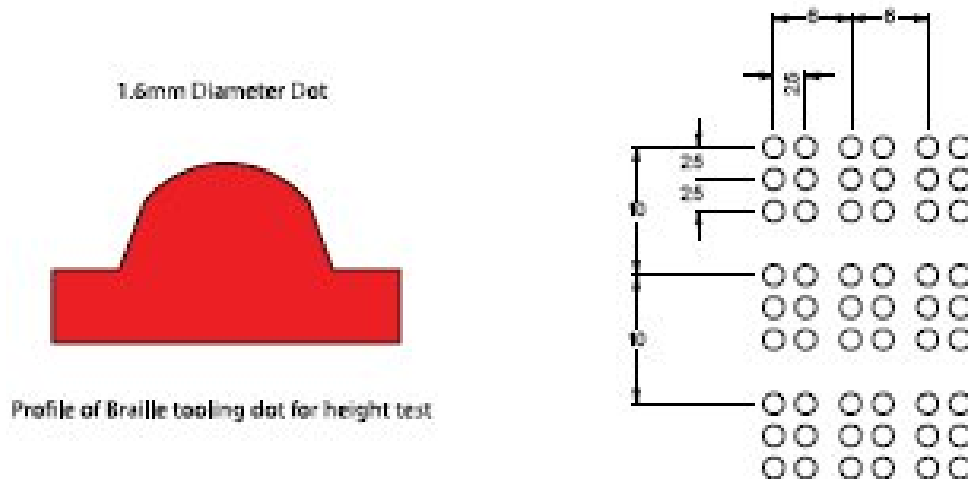
Rounding error

Throughout the document percent values are rounded to the nearest 1%. This is because it makes the document easier to read, and also does not imply inappropriate precision. A consequence of this is that sometimes aggregated scores do not add to 100%.

Appendix 3 – Cross-sections of embossed and screen printed braille

Cross-section of embossed braille provide by Field Boxmore

Braille Specification For Fields Boxmore Trials
Braille specification to Marburg Medium



Dedicated forces & universal blocks are CNC machined

Cross-section of screen printed braille provide by Kenilworth Products

