Reading the small print – labelling recommendations for orthopaedic implants

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ABSTRACT

INTRODUCTION There exist, currently, no clear guidelines regarding standards for surgical implant labelling. Dimensions of the laminar flow canopies in orthopaedic use fixes the distance at which implant labels can be read. Mistakes when reading the label on an implant box can pose health risks for patients, and financial consequences for medical institutions.

SUBJECTS AND METHODS Using scientifically validated tools such as the Snellen Chart Formula, a theoretical minimum standard for text on implant labels was reached. This theoretical standard was then tested under real operating conditions. After discovering a minimum practical standard for implant labels, the authors then audited current labels in use on a wide range of orthopaedic implant packages. Furthermore, other non-text-related labelling problems were also noted.

RESULTS There is a definite minimum standard which should be observed when implant labels are manufactured. Implants in current use bear labels on the packaging that are of an insufficient standard to ensure patient safety in theatre.

CONCLUSIONS The authors have established text parameters that will increase the legibility of implant labels. In the interests of improving risk management in theatre, therefore, the authors propose a standard for orthopaedic implant labelling, and believe this will provide a useful foundation for further discussion between the orthopaedic community and implant manufacturers.

KEYWORDS

Implant labels – Text – Risk management – Orthopaedics

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Laminar flow ventilation reduces airborne bacterial load and lowers postoperative deep wound infection rates in arthroplasty surgery^{1–4} with appropriate clothing further reducing infection rates.^{5,6} The movement of unscrubbed theatre members into an area of laminar flow results in turbulence, and significant alterations in the microbiological environment surrounding the surgical field.⁶ During daily surgical activities, the authors have observed frequent ingress of orthopaedic packaging into the laminar flow tent at the time that the surgeon needs to confirm the details on the label visually. The packaging is usually held by an unscrubbed bare arm, sometimes actually over open trays of sterile surgical instruments. This is because details on the label are often perceived to be unclear or too small to be read comfortably from a distance. The alternatives to holding the implant closer to the surgeon's eyes are equally unsatisfactory: either requiring the surgeon to leave the operating table and move to the edge of the tent for a closer look, or otherwise to risk misidentifying the prosthesis in the box. The latter event would result in either the wrong implant being inserted into a patient, or incurring the

expense of discarding an erroneously opened implant. A literature search by the authors has revealed no clear guidelines regarding the labelling of surgical implants in general and orthopaedic implants in particular. This paper, therefore, attempts to produce a sensible set of guidelines for simplifying the identification of implants and increasing the legibility of the packaging labels. The ultimate aim is to improve risk management in theatres further.

Subjects and Methods

The authors started by calculating the theoretical letter height required to allow comfortable reading when held outside the canopy. This is based on the formula for Snellen chart construction.⁷ This formula states that the required letter size is proportional to distance of the eye from the letter (Fig. 1). The theoretical figure from this calculation was then subject to practical testing under real-life conditions in order to refine further the recommendation. After a firm conclusion regarding letter height was reached, implant packaging in our orthopaedic theatres was audited against

this value, while also looking for further factors which might be complicit in reducing label clarity.

The first consideration in reaching a theoretical letter height was to identify the distance over which surgeons working inside a laminar flow tent need to be able to read the labels on implant packaging. Standard laminar flow canopy sizes used in orthopaedic surgery are 2.8 m × 2.8 m, 3.2 m × 3.2 m and 3.5 m × 3.5 m (source: Medical Air Technology, UK). Any calculations we performed clearly had to cater for the largest canopy size. The standard arrangement with respect to lower limb arthroplasty has the surgeon standing close to the middle of the laminar flow tent (Fig. 2). Furthermore, implant packaging should be presented in such a way as to avoid the surgeon having to turn their unsterile back towards the operative field. As shown in Figure 2, the distance from surgeon to implant label is, therefore, just greater than half the length of one side of the canopy. In other words, the surgeon needs to be able to read the label at a distance slightly greater than 1.75 m for a 3.5 m × 3.5 m canopy. At the near-vision end of a standard Snellen chart, the distances for the smallest lines of letters are designed to be read at 4 feet, 7 feet, 10 feet and 15 feet. The next closest distance on a Snellen chart is, therefore, 7 feet (2.13 m). This also allows for a small safety buffer zone beyond the edge of the canopy.

The human eye can only distinguish two points as being separate if they are 1 minute of an arc apart, or greater.⁸ This is 1/60th of a degree. In order to discriminate similar-appearing letters (*e.g.* B, F and E, or O and C), the internal elements of a letter must be spaced 1 minute apart. Therefore, the minimum height of a letter to be legible is 5 minutes of an arc (Fig. 1).

According to the Snellen chart formula, therefore, the minimum text size legible at 7 feet should be 3 mm high. However, this value is what an eye of 20/20 visual acuity

should only just be able to make out under single-eye testing conditions.

In the real world, surgeons will use both eyes to read a label. Binocular vision improves visual acuity by 10–15%.⁹ However, there are several other factors that will collectively serve to degrade visual acuity in the setting of the operating theatre. The effect of these cannot be individually quantified, and may also have varying effect between individual persons.¹⁰ These factors include:

1. The effect of looking from a pool of bright light under the operating lamps into an area of lower light intensity.¹⁰
2. Operating light glare reflected off the back of a plastic visor into the surgeon's eyes.¹⁰
3. The distortion of visual information passing through curved plastic visors, especially when there is a fold line down the middle.

LPCTZDBFEO
ZCOEFLDPBT
ETOLEBZEFDC
BOFCPTBLEBZCPEO

Figure 3 Crowded visual acuity chart.

4. Spatter of visors by opaque fluid droplets during surgery.
5. Horizontal crowding of letters on a line of text.¹⁰⁻¹²
6. The effect of optical convergence and pupillary accommodation in order to read lettering at 7 feet, which is well below optical infinity (20 feet).¹⁰
7. The effect of corrective eyewear on visual acuity at 7 feet, particularly in cases where such eyewear is calibrated to optimise the eye-to-hand working distance.
8. Furthermore, it should be noted that there exists a difference between threshold of visual acuity, and being able to comfortably read a letter at 7 feet. The latter consideration will require a letter size larger than the calculated size.

In order to fine-tune the theoretically-calculated text height of 3 mm, real-life testing was performed on 22 different persons taking the role of lead surgeon during live operations. This occurred in the setting of a medium-to-large sized orthopaedic department in a district general hospital, with four operating theatres.

A crowded visual acuity chart mimicking normal text crowding on implant labels was held at 7 feet from the surgeon at the same time as the implant presentation (Fig. 3). Any normally-worn corrective visual aids were permitted, and testing involved binocular vision. After the first set of readings, a second, modified, visual acuity chart was immediately presented for testing. The letters and the text size thereof remained identical, but the letters were spaced further apart from each other by including an extra horizontal space between each letter in

L P C T Z D B F E O
Z C O E F L D P B T
E T O L E B Z E F D C
B O F C P T B L E B Z C P E O

Figure 4 Widely spaced visual acuity chart.

a row, and by including an extra line of clear space between each row of letters (Fig. 4).

After the results of visual testing were assessed, the orthopaedic implants in our theatre complex were audited. A total of 57 different implants from five main distributors were measured. The parameters assessed were:

1. Text height, including: (i) text providing implant description (*e.g.* intramedullary plug); (ii) text providing implant dimensions; (iii) text detailing the implant side (*i.e.* left or right); and (iv) text providing supplementary information (*e.g.* implant material properties, method of implant fixation, other matching implants in modular systems, *etc.*).
2. Text colour and background colour.
3. Other information found on the label deemed unnecessary for surgeons.
4. Any other packaging problems influencing legibility of the text.

Measurements were made using a flat paper ruler in current surgical use (Viomedex surgical skin marker set; Vio Healthcare, UK) in order to eliminate the error of parallax. Text size was rounded up or down to the nearest 0.5 mm. If a word had letters in both uppercase and lowercase, the average height between the two was used. In all cases of repetition on the same label, the largest text size was recorded.

Results

The visual acuity of 22 surgeons under live operating conditions was recorded. The surgeons were made up of 14 consultants, six specialist registrars and two trauma fellows. Mean age was 40 years (range, 26–59 years).

Corrective eyewear (glasses or contact lenses) were worn by 12 of 22 (55%), with 9 of 22 (40%) wearing no corrective eyewear for the label reading. Surgeons looking over the tops of their glasses were classed in the latter group. In one case (5%), reading glasses were worn that were too large to look over, and which significantly degraded the visual acuity at 7 feet. The readings for this surgeon were kept in the dataset as they represent true-life conditions.

Additional protective eyewear was worn by 12 of 22 surgeons, with 7 of 22 (32%) wearing a mask and visor, and 5 of 22 (23%) wearing a sealed helmet as part of an extraction system. Ten of 22 (45%) surgeons wore no protective visor, but these surgeons were already wearing spectacles.

The results of the visual acuity testing using the crowded and more widely-spaced visual acuity charts are presented in Table 1. With the crowded visual acuity charts, 4 of 22 surgeons made errors with text at 4 mm height. Of these

Table 1 Results of visual acuity testing of 22 surgeons, using first the crowded and then the widely spaced visual acuity charts

Text height (mm)		Number of surgeons	
		Crowded chart	Widely spaced chart
7	Entire line correct	22	22
	Errors made	0	0
	Entire line unreadable	0	0
4	Entire line correct	18	20
	Errors made	4	2
	Entire line unreadable	0	0
3	Entire line correct	7	15
	Errors made	10	5
	Entire line unreadable	5	2
2	Entire line correct	0	1
	Errors made	7	13
	Entire line unreadable	15	8

Further details of those lines of text where errors were made will be found in the article text.

four, one had 90% correct score for that line of text, two had 80%, and one had 20% correct score for that line.

With the spaced visual acuity charts, only 2 of 22 surgeons made errors with text 4 mm height. Of these two, both had 80% correct score for that line of text. This measurement includes the surgeon whose reading glasses reduced his 7 foot reading ability.

This confirms that the effect of increasing the area of clear space around letters will lead to an improvement in visual acuity.^{10–12}

Because the surgeons were reading random letters on the visual acuity testing charts and because visual acuity results improve when letters combine to form recognized

words,¹⁵ 4 mm was taken as an acceptable minimum letter height for the purposes of our recommendations.

The results of auditing the labels of 57 orthopaedic implants are revealed in Table 2. Note, not all labels displayed all the subsets of data, so the comparisons were drawn across those implants with the information present. Text size for implant description spanned an enormous range, starting extremely small (1.25 mm). The mean of this data subset was well below the minimum recommendation of 4 mm. Similar findings occurred for text size depicting implant dimensions and text size depicting supplementary information. Note, the mean result of 4.1 mm for implant dimensions – this dataset has a median of 3.5 mm, implying that more than half of the implants have a value less than our recommended minimum of 4 mm. The only reasonable result was with implant siding. However, a side was only printed in 3 of 57 packages, so it renders this outcome largely irrelevant in the overall set of results.

There is research showing that best visual acuity is achieved by a strong visual contrast between text and background.¹⁰ During the audit, the following text/background colour combinations were encountered: (i) black text on a white background; (ii) dark blue text on a white background; (iii) white text on a dark blue background; (iv) white text on a medium green background; (v) black text on a yellow background; and (vi) black text on a red background. While the top three combinations were acceptable, the fourth combination was more difficult to read, and the last two combinations were interpreted as producing eye-strain, owing to the poor contrast between text and background.

Some unnecessary information was encountered on the label facing the surgeon, including: (i) unnecessarily large company logos, although this is a subjective observation; (ii) translations of the implant description into several languages on the same label; (iii) repetition of the implant dimensions on the same label, often with varying text heights; (iv) manufacturing reference numbers, in some cases with text size larger than the text for the implant dimensions; (v) barcodes; and (vi) manufacturers' addresses.

Finally, it was common to find the seam of the cellophane wrapper lying directly over the label's text, thereby further obscuring the information.

Discussion

Risk management is always an important concept in the workplace. To the authors' knowledge, no study has yet looked at recommendations for surgical implant labelling and, in particular, for orthopaedic implants. By matching the visual acuity testing in an operating theatre under live surgical conditions with surgeons wearing corrective eyewear, this study was able to make some interesting observations and can, therefore,

Table 2 Results of auditing text size on the labels of 57 different orthopaedic implant packages

Parameter	<i>n</i>	Range (mm)	Mean (mm)	Median (mm)
Description	57	1.25–7.5	2.9	3
Dimensions	51	1.5–11	4.1	3.5
Side	3	3–7	5.7	7
Supplementary	50	1–9	2.6	2.5

reach more practical recommendations. Our findings uncover a clear lack of uniformity in labelling standards, and highlight potential hazards to patients undergoing orthopaedic surgery.

The arguments presented in this paper hinge on the following main points:

1. Orthopaedic theatres require laminar flow.¹⁻⁴
2. Dimensions of the laminar flow canopy fix the distance at which implant labels can be read.
3. Movement about an area of laminar flow increases turbulence.⁶
4. Turbulence increases the dispersion of bacteria, especially when appropriate dress code in the laminar flow tent is not observed.^{5,6}

Labels that are insufficiently legible introduce practices that put patients at increased risk of infection or risk of implantation of an incorrect prosthetic component. Furthermore, in a climate of budget-consciousness in the healthcare provision sector, opening an implant in error is an expensive mistake.

Looking at the results of our research, the authors recommend the following as a standard for orthopaedic implant labels:

1. A separate label on one side of the pack containing only the following information: (i) implant description; (ii) a graphic (photograph or clear line drawing); (iii) implant side; (iv) implant size; (v) expiry date; and (vi) matching component dimensions.
2. The following standards should be observed: (i) text height should be a minimum of 4 mm; (ii) information should be presented in one language only; (iii) good visual contrast should exist between text colour and background colour (ideally black text on a white background); (iv) information should not be repeated on the same label; and (v) the seams or folds of transparent outer sleeves should not obscure the label.
3. Larger text size need not automatically require larger labels or even larger implant boxes. Labels can be kept at an acceptable size by de-cluttering the information, as de-cluttering will improve visual acuity by increasing the clear space surrounding the letters or digits.^{10,11} This can be achieved by presenting the following information elsewhere on the box: (i) manufacturer's address; (ii) sterilising information; (iii) proprietary and legal notices; (iv) reference numbers; and (v) barcodes.

During the audit process, it was noted that one particular range of implants already match this standard of labelling. Interestingly, however, the distributor of that particular implant range still continues to distribute other implant ranges bearing labels at the very weakest end of the audit results. Apart from

confirming that there is no standard across the different product ranges even from a single distributor, the suggestion is that positive pressure is required from the orthopaedic community in order to bring about a change so that all implant labels are of a high standard.

Although other methods of information transfer to the surgeon are available, such as package inserts¹¹ within the implant packaging bearing details of the implant, introducing an extra process into package manufacture must certainly further increase manufacturing expense and the need for an extra step in quality control. The authors believe the most direct means would be to modify the external label on the package.

The authors recognise that they are neither ophthalmologists nor experts in ergonomics. However, our recommendations are derived through scientific methods using validated tools⁷ and based upon information published in peer-reviewed journals.¹⁻¹⁵ Furthermore, it provides manufacturers with a subset of data to which they would not have previously had access, namely the results of visual acuity testing under live operating conditions. If this paper results in more wide-spread discussion of implant labelling between orthopaedic surgeons and representatives of the various implant manufacturers, then the aims of this study will have been met.

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