

An investigation of laboratory test methods for predicting the in-use leakage performance of urine absorbing aids in nursing homes.

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Abstract

The Absorption before leakage (ABL) method for measuring the absorption capacity of urine absorbing aids was investigated. Along with the existing international standard (ISO 11948-1, the Rothwell method [1]), it was run on 12 experimental products whose in-use leakage performance was established by 55 incontinent nursing home residents. Methods were evaluated by considering their simplicity, their repeatability within - and their reproducibility between - six laboratories, and their correlation with in-use product performance. ISO 11948-1 – which measures the absorption capacity of products under simple conditions - showed good repeatability and reproducibility, and reasonable correlation with in-use data. However, it proved blind to the effects of leg cuffs that conferred measurable benefits in real use. It should, therefore, be used with caution. The ABL method – which measures how much a product will hold before leakage when it is mounted on a manikin and standard aliquots of liquid are applied - is more complex and had poorer repeatability and reproducibility. However, it had stronger correlations with in-use data and successfully detected the benefits of leg cuffs on insert products. It is concluded that it holds potential as a new international standard to replace or complement ISO 11948-1, and the necessary refinement work has been ongoing since the 2007 project described here.

Two other laboratory methods were run opportunistically. A rewet method (Spanish national standard UNE 153601-2:2008 [2]) - for measuring the escape of fluid from a product under pressure – showed poor repeatability and reproducibility. Finally, an acquisition method was used to measure how quickly products absorbed two successive standard aliquots of liquid. It proved robust, showing good repeatability and reproducibility. Although measurements generally correlated well with in-use leakage performance, a direct causal link is unlikely. Products with high absorption capacity tend also to absorb quickly.

Keywords: Incontinence, Urine absorbing products, Fluid absorption, International standards, Laboratory-clinical correlations.

1 Introduction

Single-use, urine absorbing aids - the mainstay products for managing intractable moderate / heavy urinary incontinence - come in only a limited number of different generic designs but each is available in many variants from different companies. As a result, buyers face the challenge of choosing from a bewildering array of products which, though having similar appearance, may vary considerably in both price and performance. Traditionally, purchasing bodies have run user evaluations to compare

products before making bulk-buying decisions but this has become increasingly impractical; unless they are pointlessly small, user evaluations are prohibitively time-consuming and expensive and they yield data of only limited shelf-life as companies typically change their products over time in their quest for improvement. For this reason, an international laboratory standard to measure the leakage performance of products - the key functional requirement - was developed during the 1990s (ISO 11948-1 [1]) and was subsequently used by purchasing agencies to help with product selection. It involves measuring the absorption capacity of a product under simple laboratory conditions and published studies show that this capacity correlated quite well with the leakage performance of products in real use up to about the year 2000 [3, 4]. However, the method has well-documented shortcomings [4, 5], the most fundamental of which is that it merely measures the absorption capacity of the materials in a product, ignoring any benefits to leakage performance that might be conferred by such features as elasticated cuffs to impede lateral leakage, or carefully engineered composite core structures. In response, a group of companies belonging to EDANA - the International Association serving the Nonwovens and related Industries (referred to as the *EDANA group* in this paper) - initiated a project to develop a new method (the Absorption before leakage (ABL) method) which aimed to address the limitations of ISO 11948-1. The aim of the work described here was to investigate the potential for developing the ABL method as an international standard test method, and the strategy was to evaluate it alongside ISO 11948-1 by gathering and comparing data from laboratory and in-use measurements on a set of 12 different products. In addition, the opportunity was taken to run too other laboratory methods (measuring rewet performance and acquisition time) which – though not seen as rival contenders to ABL for a new standard – might yet deliver useful insights on product performance.

2 Materials: the experimental products

The 12 product variants used for the work were specified by the EDANA group and manufactured in 2007¹ by the six participating companies (Arboria & Ausonia S.L.Unipersonal, Spain; Laboratorios Indas S.A., Spain; Ontex N.V., Belgium; Paperpak Sweden AB, Sweden; Paul Hartmann AG, Germany; and SCA Personal Health Care, Sweden). They comprised six variants of a *brief* design (two intended for day use and four for night use) and six variants of an *insert* design (four intended for day use and two for night use). Single use (as opposed to washable) briefs and inserts (Fig 1) are the two primary absorbent product designs currently used by men and women with moderate to heavy urinary incontinence. The inserts were used as part of a two-piece system in which the product was secured in position with close fitting stretch pants (net or mesh), each manufacturer supplying their own pants for use solely with their inserts. The brief is an all-in-one design with built in resealable adhesive tabs to facilitate optimum positioning. The briefs and stretch pants were supplied to fit a 'medium' body size; the inserts were each supplied in one size / absorbency level only.

[insert Figure 1.]

¹ Although products have evolved since 2007, the generic designs of the products described here have not changed dramatically; products continue to incorporate variations on - and developments of - the design elements of the 2007 products.

The key features of the 12 product variants are summarised in Table 1. Many of the variants were designed to be considered in pairs; for example, variants 1 and 2 were identical apart from (not) having cuffs. The coefficient of variation of the dry weights for products coming off a regular production line is typically around 10% but, in order to reduce noise in the data for the current project, only those products with weights close to a target value for a given variant were retained. As a result, no coefficient of variation exceeded 1.5% (Table 1). The dry weight of the labeled bags in which used products were saved for weighing (see below) was 4.4g.

[insert Table 1.]

Although the product variants were manufactured specifically for this study, only materials and methods already in use with products commercially available in the UK were used in their construction, an important requirement for securing ethics committee approval. Individual products and packaging were supplied 'unbranded'; that is, they did not display any print that could link them to their manufacturer.

3 Methods: laboratory studies

Each of the six companies in the EDANA Group ran the same four laboratory test methods on all 12 product variants and pooled their data for analysis. The first method (Fig 2) was ISO 11948-1 (often known as the Rothwell method, after the pharmacist who devised it), the existing international standard method for measuring the absorption capacity of products [1]. A product is laid flat on a horizontal, coarse wire grid with its water-permeable surface facing downwards and lowered into a reservoir of normal saline. After 30 min of soaking, the grid is raised and the product is allowed to drain under gravity for 5 min. The wet product is weighed and its dry mass subtracted to determine the mass of liquid absorbed.

[insert Figure 2.]

Second, was the ABL method (Fig 3) developed by the EDANA group as a potential international standard method to replace or complement ISO 11948-1. It involves delivering aliquots of 162 ml of normal saline into a product secured on an anatomically accurate manikin held in the posture shown in Fig 3. The flow-rate-time profile with which the aliquots are delivered – by a computer-controlled pump, and via a “urethra” – was chosen to mimic one of a set of flow-rate time profiles from patients in a urodynamics clinic (Fig 4). Aliquots of liquid are delivered repeatedly until leakage is observed from the product, with five minute intervals between the end of one delivery and the beginning of the next. If leakage begins during the delivery of an aliquot, the full aliquot is still delivered. The wet product is then weighed and its dry mass subtracted to determine the absorption before leakage (ABL) of the product.

[insert Figure 3 and Figure 4.]

The remaining two methods were included opportunistically to provide complementary data and insights, rather than being considered as rivals to the ABL method as candidates for a new international standard relating to product leakage performance. One method (Fig 5) was a rewet test chosen to represent a number of somewhat similar procedures that are used for measuring how readily liquid that is

already in a product escapes under pressure. It is published as Spanish national standard UNE 153601-2:2008 [2]. A weighted circular plate (diameter, 107 mm) is applied to the crotch region of a product laid flat and horizontal with its water-permeable surface facing upwards and two aliquots of 150 ml of normal saline are delivered under gravity from a dropping funnel into a cylinder from which liquid enters the product through a central hole (diameter 21 mm) in the plate. The weight of the delivery apparatus (excluding the liquid) is 3.7 kg. The dropping funnel tap is opened to start the delivery of the second aliquot 15 min after the funnel has finished delivering the first into the chamber. A further 15 min after the dropping funnel tap has been opened for the second time, the fluid delivery apparatus is removed from the product and replaced by a stack of 30 filter papers (90 mm diameter, and known dry weight), and loaded with a 90 mm diameter Perspex plate carrying a 10 kg weight which, together, apply a pressure of 15.2 kPa to the filter paper. After 30 s the plate and weight are removed, the filter papers are weighed, and their dry weight is subtracted to determine the rewet weight for the product.

[insert Figure 5.]

The final method (Fig 6) was an acquisition test formulated to represent a number of somewhat similar procedures that are used to measure how quickly a product absorbs liquid. A weighted, inverted, cylindrical cup (external and internal diameters, 80 mm and 70 mm, respectively) is placed on the crotch region of a product laid flat and horizontal with its water-permeable surface facing upwards. A pump is then used to deliver 150 ml of normal saline into the cup at $15 \text{ ml}\cdot\text{s}^{-1}$, and the time taken for the liquid to be absorbed into the product is measured using a stopwatch. This time is designated *Acquisition 1*. After a delay of ten minutes, the procedure is repeated and the time for a second aliquot of liquid to be absorbed is measured, and designated *Acquisition 2*. The combined mass of the weight and cup is 610 g and the upper surface of the cup is vented with two holes to allow air to escape when liquid is delivered into it. The saline is stained red with fuchsin to facilitate visual inspection of the process through the transparent walls of the cup.

[insert Figure 6.]

Each laboratory ran six replicates on each of the test methods except ABL, on each of the product variants. Some laboratories ran more replicates with the ABL method (up to nine for each product variant) in order to build experience with it. Means and standard deviations were calculated for the results for each test method and each product variant for each laboratory. Finally, the Hampel estimator was used – as described in a German national standard [6] - to identify and remove any outliers in the data before calculating means and standard deviations on pooled data across all six laboratories for each test method, for each product variant.

4 Results: laboratory studies

Table 2 provides means and coefficients of variation for data for each of the five outcome variables (two for the acquisition method, one for each of the other three methods), for each of the 12 product variants, for each of the six laboratories, as well as coefficients of variation across means from all laboratories, for each product variant. It also provides means and coefficients of variation for pooled data across all

six laboratories for each outcome variable and each product variant, before and after use of the Hampel estimator (6). Data for ISO 11948-1 (Rothwell) measurements showed the best repeatability within laboratories (CV never exceeded 3.9% for any product variant in any laboratory) and between laboratories (CV for pooled data across all laboratories never exceeded 6.5% for any product variant, after use of the Hampel estimator). At the other end of the spectrum, Rewet measurements showed the least agreement: CV exceeded 10% for 33 of the 72 product variant / laboratory combinations, of which 16 were $\geq 20\%$. CV for pooled data across all laboratories was also high: 11.2-58.7% (after use of the Hampel estimator), depending on the product variant. There was also evidence of systematic variation between laboratories: in particular, Laboratory 5 returned the lowest rewet value for each of the 12 product variants. The repeatability of the other three outcome variables (Acquisition 1, Acquisition 2 and ABL) generally fell between those for Rothwell and Rewet.

[insert Table 2.]

5 Methods: *in use* testing

5.1 Study design

The purpose of in-use testing was to establish the leakage performance of the experimental product variants as a function of urine mass for comparison with laboratory measurements. With Local Research Ethics Committee approval, residents currently using absorbent products designed to contain moderate to heavy urinary incontinence were recruited from five nursing homes in the London area of the UK. Recruits had to be at least 18 and of medium body size (defined as having a waist measurement of 70-110 cm) since – at the time – the ABL mannequin was only available in the medium size. Subjects were excluded if they were acutely ill, in the terminal stage of an illness, or regularly incontinent of faeces.

Over 60 residents were recruited to the study, but some never started and the data from some others was discarded because their contribution was minimal. Testing was conducted during 2007 and, of the 55 participants who contributed data to the final analysis, there were 44 women and 11 men. Based on previous studies [7, 8] this was estimated to be sufficient to provide data on the 300-500 product changes per product variant needed to produce adequately robust estimates of leakage performance. The median age of subjects was 86 (range 54-101). Nine participants (16%) were able to consent for themselves and assent was obtained for the remaining 46 (84%) from their relatives or nursing home manager.

During the day, 48 (87%) of the participants spent most of the time sitting (upright or semi-recumbent) and seven (13%) lying down. All participants spent most of the night lying flat or semi-recumbent in bed. Forty (73%) of the participants were unable to walk at all while a further 12 (22%) were able to walk with a walking aid or personal help. Only three (5%) were able to walk unaided. In addition, 30 (55%) of the participants were unable to bear weight. In summary, the test population was elderly and frail.

Each participant used each of the 12 product variants (six for day use; six for night use) for two weeks, giving an overall testing period of 12 weeks. The order of testing

product variants was the same within each nursing home but randomised between nursing homes, in orders determined using Latin Squares [9]. The experimental products were used by the participants as a direct replacement for their usual products; that is, product changes were carried out in the same way as if they had been using their usual products. At each product change, care staff placed the used product in an individual labeled bag and wrote on the label the date and time of the product removal, the identity of the wearer, where (in bed or out of bed) and when (day or night) the product had mostly been worn and the extent of leakage from the product. As in several previous studies [3, 7, 8, 10] the extent to which the product (not the product wearer, note) had leaked was scored on a simple three-point scale: *a lot of leakage* (leakage beyond undergarments eg onto bedding or outer clothing); *a little leakage* (undergarments wet); or *no leakage*. Once every 24 hours, all the used products were weighed in their labeled bags and the labels completed, giving details of the participant and product variant code and the combined weight of bag and wet product. The labels were then removed from the bag and stuck into a data record book, and the data subsequently entered into *Excel* for analysis. Prior to analysis, a colleague who had not been involved in the data transfer checked a randomly selected 10% of the data, and found too few errors to justify checking the remaining 90%.

5.2 Statistical modelling of in-use product leakage and laboratory test data

The objective of the statistical modelling was to provide curves that estimated how the probability of *no leakage* and the probability of (*no leakage* or *a little leakage*) depended on the mass of the urine in a product. For convenience, rather than subtracting the dry mass of each individual product from its wet mass to provide urine mass, the mean values shown in Table 1 were used. A standard procedure for analysing ordinal scores with levels *no leakage*, *a little leakage* or *a lot of leakage* is to model the dependence on the factors under consideration of the odds on *no leakage* versus (*a little leakage* or *a lot of leakage*), and the odds on (*no leakage* or *a little leakage*) versus *a lot*. In each of these two cases, a commonly used model is the logistic regression model; for the former case, this model is

$$\ln\left(\frac{p}{1-p}\right) = f(m) \quad (\text{Equation 1})$$

where p is the probability of *no leakage* and $f(m)$ is a function of the urine mass m . On the left hand side of the equation, the quantity $p/(1-p)$ is the odds on *no leakage*, and the left hand side is then the (natural) logarithm of this odds, the *logit* of p . Under this model, the leakage performance curve for the probability of *no leakage* is

$$p = \frac{1}{1 + e^{-f(m)}} \quad (\text{Equation 2})$$

For the function $f(m)$, the data were examined to see if the simple linear function

$$f(m) = \alpha + \beta m \quad (\text{Equation 3})$$

was appropriate or, if it was not, whether on the right hand side m could be replaced by another simple function of m . Assuming that was possible, a leakage performance curve was then estimated by obtaining estimates of the unknown parameters α and β

from the in-use data collected for the study. A leakage performance curve for the probability of *no leakage* or a *little leakage* was similarly estimated where p is now this probability. The above describes a model for a single product variant only but by introducing notation to make α and β depend on product variant number, a single model may be formed that includes all 12 product variants.

To obtain a model for leakage performance from a particular laboratory test method, the product variant terms in this single model were replaced by their corresponding laboratory means, and the unknown parameters in this model then estimated from the data.

After replacing the unknown parameters in the in-use model by their estimates and entering a urine mass of interest for m , predictions of leakage performance (eg estimate of probability of *no leakage*) for each product variant were obtained at this urine mass. These predictions are referred to as *in-use predictions* below. Similarly, corresponding predictions were obtained from the technical model and correlations between *in use prediction* and *technical predictions* calculated.

6 Results: *in use* studies

6.1 Data from weighed products

A total of 9633 products were saved and weighed but after cleaning - and removing data for any subject who tested fewer than 40 individual products - this reduced to 8877 products, relating to 55 participants. The urine mass distribution for these 8877 saved products is shown in Fig 7 while the cumulative mass distribution for the same data is given in Fig 8 and various percentile urine masses used in subsequent data analysis, indicated.

[insert Figure 7 and Figure 8.]

6.2 Product leakage performance curves

Fig 9 shows the leakage performance curves for all 12 product variants as a function of urine mass for the probability of *no leakage* and of (*little or no leakage*). It is apparent that nine of the 12 product variants had somewhat similar leakage performances while the other three (Coded 1, 2 and 3) had poorer performances.

[insert Figure 9.]

Ten of the 12 product variants had been manufactured as five pairs, the two variants in each pair differing from one another in well-defined ways (eg variants with and without elasticated cuffs, Table 1) and the leakage performance curves for such pairs are given in Figs 10 to 14. Confidence intervals (95%) have been added to the curves for the five urine masses highlighted in Fig 8.

Products 1 and 2 were inserts (Fig 1) constructed in the same way apart from having cuffs (Product 1) or not (Product 2). Given their common cores, their Rothwell absorption capacities were unsurprisingly similar (differing by ~4%), but the ABL value for the cuffed variant exceeded that of the uncuffed by 25%. The leakage

performance of the cuffed variant (Product 1) in in-use testing was also significantly better ($p < 0.05$) than that of uncuffed Product 2 at all five urine masses and for both *no leakage* and (*little or no leakage*) (Fig 10).

[insert Figure 10.]

The impact of cuffs was less clear in the three pair-wise comparisons involving briefs (Fig 1). Product 6 (with cuffs) and Product 7 (without cuffs) had similar Rothwell absorption capacities (differing by ~3%) while the ABL value for the cuffed Product 6 exceeded that of the uncuffed Product 7 by 13%. Differences in in-use leakage performance between the two variants were not significant ($p > 0.05$) at any of the five urine masses for (*little or no leakage*), but there were some significant differences for *no leakage*: the probability of Product 7 (without cuffs) not leaking was higher than that for Product 6 (with cuffs) at 100 g of urine, while the reverse was true at 600 g (Fig 11). Products 8 (without cuffs) and 11 (with cuffs) had similar Rothwell absorption capacities (differing by ~1%) and the ABL value of the cuffed Product 11 exceeded that of the uncuffed Product 8 by 6%. However, the in-use leakage performance of the two variants did not differ significantly ($p > 0.05$) at any of the five urine masses for either *no leakage* or for (*little or no leakage*) (Fig 12).

[insert Figure 11 and Figure 12.]

In the third comparison of briefs with and without cuffs, Product 9 (with cuffs) and Products 10 (without cuffs) had similar Rothwell absorption capacities (differing by ~1%) while the ABL value for the cuffed Product 9 exceeded that of the uncuffed Product 10 by 12%. Differences in in-use leakage performance between the two variants were not significant ($p > 0.05$) at any of the five urine masses for *no leakage*, but there were some significant differences for (*little or no leakage*): the probability of *no leakage* for Product 9 (cuffed) was higher than that for Product 10 (uncuffed) at 100g and at 200g of urine ($p < 0.05$) (Fig 13). However, subsequent investigation revealed that, due to a production defect with the adhesive, the cuff system for Product 9 was attached in such a way that it did not lift into position readily as intended when put on users. This may have reduced its in-use leakage performance. By contrast, the technicians conducting laboratory tests would have made sure that the cuffs did lift into the correct position by running their fingers beneath their edge before testing, so separating them from the main body of the product.

Finally, a useful comparison may be made between Products 4 and 5 which had similar insert constructions – both with cuffs – but Product 4 had a more absorbent core than Product 5 (Table 1). The Rothwell absorption capacity and ABL values for Product 4 exceeded those for Product 5 by 8% and 3%, respectively, but the modest improvement in in-use leakage performance in Product 4 over Product 5 did not reach statistical significance ($p > 0.05$) at any of the five urine masses for either *no leakage* or for (*little or no leakage*) (Fig 14).

[insert Figure 13 and Figure 14.]

6.3 Impact on product leakage performance of participant gender, day / night use and use in / out of bed

The in-use data were also examined to see if the leakage performance curves depended on the gender of the wearer, when the product was worn (day or night)

and where it was worn (in bed or out of bed). Some evidence for such a dependence was found in a small number of cases. For example, the results for Products 8 and 11 for *no leakage* and Products 4 and 9 for (*little or no leakage*) suggest different leakage performance curves for males and females; however, these conclusions should be viewed with caution as there was much less data for males than females. A similar imbalance of data also applied for the factor *when worn* where the results for Products 0, 2, 5, 8 and 10 for *no leakage* and Products 5 and 8 for (*little or no leakage*) suggest different leakage performance curves for day and for night use. For the factor *where worn* the only strong evidence of a difference was for Products 2 and 7 for (*little or no leakage*) where for these two variants the amount of data was more in balance between the two levels of the factor.

However, it was finally decided not to include these three factors in constructing product leakage performance curves: including them would have made a significant difference in only a minority of cases and, also, dividing the data into an increased number of subcategories would have reduced the power of any analysis.

7 Results: correlation studies

The strength of correlations between in-use predictions and technical predictions (based on pooled data from all six laboratories) is summarised in Table 3 which lists correlation coefficients for each of the laboratory measurements. Correlations were generally strong, apart from those involving the probability of (*little or no leakage*) for a product containing 100 g of urine in in-use testing. This was presumably because a *lot of leakage* was a rare occurrence for such a low urine mass (Fig 9). Otherwise, correlation coefficients always exceeded 0.8.

Correlations were quite strong for ISO 11948-1 but they were generally stronger for ABL, an important result given that the primary aim of the project was to compare the two methods. The other methods also yielded some high correlation coefficients – especially Acquisition 2 – but strong correlation alone is not enough to justify elevation to international standard status, as discussed below.

[insert Table 3.]

8 Discussion and conclusions

The primary aim of the project was to investigate the possible adoption of the ABL method as a new international standard to replace or complement ISO 11948-1 and, in weighing the evidence, it is useful first to consider the two methods against the requirements for a good standard test method. Ideally, such a method would be simple, quick and easy to perform; involve simple and inexpensive equipment; produce data with good repeatability (within laboratories) and reproducibility (between laboratories), and show strong correlation with in-use data. Table 4 summarises how well the ISO 11948-1 and ABL methods met these criteria.

[insert Table 4.]

The ISO 11948-1 method demonstrated good repeatability within - and reproducibility between - laboratories (Table 2) and yielded data showing reasonable correlations

with in-use data (Table 3). However, the results presented here support the concern that it may be blind to the benefits of some features of products; in particular, it did not detect the significant impact of leg cuffs that in-use testing revealed in comparing insert Products 1 and 2 (Fig 10). In view of this limitation, the method – which is the current international standards for estimating the leakage performance of urine absorbing products – should be used with caution.

By comparison, the ABL method generally produced stronger correlations with in-use data than ISO 11948-1 (Table 3) and – unlike ISO 11948-1 – was able to detect the benefits of the cuffs in insert Product 2 compared with the cuff-less equivalent, Product 1 (Tables 1 and 2, and Fig 10). However, its repeatability and reproducibility were poorer (Table 2) and the equipment and procedure more complex. Indeed, the greater complexity probably contributed to the poorer repeatability and reproducibility. There is considerable potential for replicates of the equipment to differ from one another in unintended ways, and for different technicians to interpret differently the instructions for using it. For these reasons, since the completion of the 2007 study reported here, the International Standards Organisation working group responsible for developing standards in this area (ISO TC173 SC3 WG2) has conducted several Round Robin exercises aimed at (i) identifying and describing precisely the critical aspects of the equipment, (ii) closely defining the test methodology, and (iii) capturing it in clear, unambiguous instructions. In each round, technicians in 6-10 laboratories in several countries have made measurements and pooled their data to address specific issues. The intention is that this will lead to a new standard which delivers the benefits described here while reducing the identified limitations to an acceptable level.

The results for the Rewet and Acquisition methods are also interesting. Although some of the correlations with in-use data were impressively high (especially for Acquisition 2, Table 3), this is not enough to identify a test as a strong candidate as an international standard for measuring a particular function: correlation does not prove causation. The task at hand is to develop a standard that can be used to predict the absorption capacity of products and it is not hard to imagine a design which, though having low rewet and short acquisition times, also had poor absorption capacity. Nevertheless, it is interesting to note that – for the experimental products used here - this was not the case; for these products, which contained broadly similar materials and structures, high absorption capacity generally went hand in hand with low rewet and short acquisition times.

Whatever it is used for, the Rewet method had poor repeatability and reproducibility, also showing evidence of systematic variation between laboratories (Table 3). It should therefore be used with caution. Acquisition 1 measurements were more robust: coefficients of variation for measurements within laboratories and across laboratory means were usually less than 5% (Table 3). Figures were a little poorer for Acquisition 2: coefficients of variation for measurements within laboratories were generally 5-10% and across laboratory means were usually 10-15% (Table 3).

In conclusion this study suggests that:

1. ISO 11948-1 [1] – the existing international standard for measuring the absorption capacity of products - should be used with caution. Although it is relatively simple, with good repeatability (within laboratories) and

reproducibility (between laboratories) and reasonable correlation with in-use product performance, in this study it proved blind to the benefits – apparent in real use - of elasticated cuffs on inserts. It is likely also to be blind to the impact of other features, such as the use of core structures in which the mix of constituent materials varies with location.

2. The ABL method shows potential as a new international standard to replace or complement ISO 11948-1. In particular, in this study – and unlike ISO 11948-1 - it was able to detect the in-use benefits of insert cuffs. It showed good correlation with in-use product performance, but it is quite complex and its relatively poor repeatability and reproducibility indicate that further development is needed to make it suitable for an international standard. This work has been underway since the 2007 project described here.
3. The Rewet method (Spanish national standard UNE 153601-2:2008 [2]) showed poor repeatability and reproducibility, and it should be used with caution.
4. The Acquisition method is supported as a robust way of measuring the speed with which products absorb fluid. The repeatability and reproducibility of measurements were good for Acquisition 1, and reasonable for Acquisition 2. However, although measurements generally correlated well with in-use leakage performance, a direct causal link is unlikely. Products with high absorption capacity tend also to absorb quickly.

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Declaration of conflicting interests

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Tables

Product variant code	Manufacturer	Design category	Cuff system present?	Intended for use during:	Target ISO 11948-1 (Rothwell) absorption capacity (g)	Product mass		
						Mean (g)	SD (g)	Coefficient variation (%)
0	A	Insert	Yes	Day	2000	85.5	1.23	1.43
1	B	Insert	Yes	Day	1250	61.4	0.47	0.77
2	B	Insert	No	Day	1250	60.5	0.45	0.75
3	C	Insert	Yes	Day	1870	71.2	0.43	0.61
4	D	Insert	Yes	Night	2708	135.1	0.85	0.63
5	D	Insert	Yes	Night	2487	125.7	0.78	0.62
6	E	Brief	Yes	Day	2160	95.6	1.23	1.28
7	E	Brief	No	Day	2160	94.2	0.85	0.90
8	F	Brief	No	Night	2880	124.6	1.42	1.14
9	E	Brief	Yes	Night	3270	150.4	1.33	0.88
10	E	Brief	No	Night	3270	149.0	1.94	1.30
11	F	Brief	Yes	Night	2880	127.4	1.03	0.80

Table 1: Principal features of the experimental product variants. Mean masses were for 12 pieces of each product variant. NB The design of the cuff system was not the same in all the “with cuffs” products.

		Product variant	0	1	2	3	4	5	6	7	8	9	10	11
ISO 11948-1 (Rothwell)	Lab 1	1886 (1.5)	1269 (2.0)	1325 (0.9)	1810 (2.0)	2863 (1.4)	2595 (0.7)	2052 (0.5)	2143 (0.6)	2761 (1.0)	3188 (1.5)	3178 (1.8)	2683 (1.6)	
	Lab 2	1905 (1.0)	1276 (2.1)	1320 (1.5)	1793 (2.0)	2703(2.4)	2480 (1.3)	1921 (1.8)	2117 (2.4)	2821 (2.4)	3135 (1.0)	3123 (1.6)	2728 (2.1)	
	Lab 3	1930 (1.3)	1383 (2.5)	1431 (0.8)	1794 (1.1)	2648 (0.8)	2619 (1.1)	2066 (1.4)	2097 (1.9)	2869 (1.8)	3324 (2.0)	3245 (2.0)	2832 (0.7)	
	Lab 4	1956 (1.4)	1373 (2.2)	1434 (2.1)	1899 (2.6)	2992 (0.8)	2730 (1.4)	2131 (1.4)	2192 (1.8)	2988 (1.5)	3265 (2.4)	3359 (2.7)	2892 (1.3)	
	Lab 5	1915 (2.8)	1315 (1.9)	1357 (1.1)	1802 (2.5)	2827 (1.3)	2548 (2.8)	2058 (1.8)	2096 (2.4)	2808 (1.1)	3256 (3.0)	3282 (2.2)	2841 (0.9)	
	Lab 6	1914 (1.8)	1378 (3.9)	1446 (1.9)	1935 (1.0)	2909 (1.3)	2646 (2.7)	2178 (1.4)	2161 (2.0)	2890 (0.3)	3330 (1.3)	3431 (1.0)	2951 (0.9)	
	CV of lab. Means (%)	1.2	3.9	4.2	3.4	4.5	3.3	4.2	1.8	2.8	2.3	3.5	3.5	
	All labs	1917 (2.0)	1332 (4.3)	1385 (4.1)	1839 (3.6)	2824 (4.4)	2603 (3.5)	2068 (4.1)	2134 (2.5)	2856 (2.9)	3250 (2.8)	3270 (3.7)	2821 (3.5)	
	All labs: after Hampel	1918 (2.2)	1332 (5.6)	1385 (4.8)	1839 (4.1)	2824 (6.5)	2603 (4.6)	2068 (5.0)	2134 (2.9)	2856 (3.5)	3250 (3.5)	3270 (4.8)	2821 (4.6)	
ABL (g)	Lab 1	503 (18.5)	413 (0.8)	309 (2.7)	419 (18.1)	759 (12.3)	760 (8.4)	564 (15.1)	515 (10.9)	792 (12.3)	802 (10.1)	712 (13.4)	849 (9.5)	
	Lab 2	426 (25.2)	394 (8.4)	315 (1.7)	464 (3.3)	745 (9.8)	724 (16.0)	537 (15.0)	521 (13.1)	777 (9.2)	812 (0.3)	750 (11.5)	753 (10.4)	
	Lab 3	517 (25.1)	434 (7.8)	413 (6.2)	534 (20.1)	769 (11.1)	716 (8.9)	775 (13.2)	579 (11.5)	832 (7.0)	793 (7.3)	771 (7.0)	891 (18.3)	
	Lab 4	530 (12.8)	431 (9.5)	297 (4.4)	528 (0.6)	766 (6.4)	659 (6.1)	621 (3.4)	560 (13.7)	749 (18.4)	727 (11.5)	664 (18.7)	876 (10.3)	
	Lab 5	664 (15.1)	465 (7.4)	403 (3.4)	526 (3.4)	721 (14.4)	737 (11.2)	647 (0.8)	613 (8.7)	776 (9.5)	859 (12.4)	649 (8.4)	817 (2.2)	
	Lab 6	537 (13.4)	425 (6.7)	312 (3.4)	503 (7.8)	748 (9.7)	770 (5.8)	637 (5.7)	552 (2.1)	835 (7.4)	840 (5.3)	773 (12.2)	851 (1.5)	
	CV of lab. Means (%)	14.6	5.5	15.2	9.2	2.3	5.4	13.2	6.6	4.3	5.6	7.5	5.9	
	All labs	529 (22.1)	427 (8.6)	341 (14.6)	496 (13.9)	751 (10.5)	728 (10.8)	630 (15.5)	557 (11.8)	793 (11.2)	806 (9.9)	720 (13.6)	840 (11.3)	
	All labs: after Hampel	526 (9.0)	427 (6.7)	328 (8.3)	496 (14.6)	739 (4.5)	737 (4.8)	614 (8.0)	557 (6.7)	800 (5.1)	814 (5.5)	720 (6.4)	840 (7.8)	
Rewet (g)	Lab 1	8.8 (7.6)	17.9 (5.6)	17.2 (5.4)	16.4 (6.7)	11.8 (17.2)	15.2 (1.5)	17.2 (2.2)	16.5 (2.4)	15.1 (5.5)	10.3 (9.4)	10.2 (10.4)	15.0 (5.1)	
	Lab 2	6.8 (22.2)	18.1 (2.3)	17.8 (6.4)	14.7 (7.4)	9.2 (19.7)	14.1 (10.4)	18.1 (3.2)	17.3 (7.6)	14.0 (13.2)	10.6 (14.2)	9.8 (14.2)	13.5 (8.4)	
	Lab 3	9.5 (19.6)	20.6 (4.2)	21.3 (3.9)	16.3 (9.8)	11.2 (10.8)	14.3 (9.5)	20.0 (7.2)	19.4 (5.2)	17.4 (8.0)	8.7 (20.0)	9.5 (14.0)	17.3 (5.7)	
	Lab 4	5.7 (11.6)	16.8 (7.0)	16.8 (5.0)	14.4 (13.6)	7.4 (20.2)	11.9 (8.8)	16.6 (5.8)	15.4 (11.2)	11.4 (24.4)	8.3 (16.5)	8.2 (12.4)	10.9 (14.1)	
	Lab 5	1.3 (37.8)	11.3 (27.8)	12.7 (19.0)	11.2 (35.4)	2.2 (40.1)	3.1 (30.5)	5.2 (44.8)	12.8 (25.5)	2.6 (31.8)	1.9 (23.8)	2.5 (45.7)	3.2 (63.3)	
	Lab 6	10.4 (1.9)	21.0 (2.6)	18.7 (2.0)	16.1 (2.5)	11.2 (2.2)	14.0 (3.6)	18.1 (4.4)	19.2 (3.5)	18.1 (2.2)	11.0 (14.2)	10.5 (5.0)	14.7 (2.8)	
	CV of lab. Means (%)	46.7	19.8	16.3	13.4	41.0	37.7	33.7	14.7	43.4	40.0	35.6	40.2	
	All labs	7.1 (45.4)	17.6 (20.0)	17.4 (16.5)	14.8 (17.7)	8.8 (40.7)	12.1 (35.7)	15.8 (32.0)	16.8 (16.5)	13.1 (41.7)	8.5 (39.9)	8.5 (35.1)	12.4 (38.4)	
	All labs: after Hampel	7.1 (58.7)	17.8 (19.2)	17.4 (17.8)	15.1 (11.2)	9.2 (35.3)	13.9 (17.6)	18.0 (11.9)	16.8 (17.3)	13.7 (37.8)	8.9 (32.1)	8.95 (25.6)	12.9(34.5)	
Acquisition 1 (s)	Lab 1	21.9 (2.4)	33.6 (8.5)	33.7 (4.5)	23.1 (3.9)	18.7 (6.6)	16.3 (6.9)	26.1 (4.0)	27.7 (4.1)	18.5 (2.3)	20.2 (3.7)	20.9 (3.3)	20.0 (3.0)	
	Lab 2	20.7 (3.4)	31.6 (5.5)	30.7 (4.5)	21.8 (4.1)	18.3 (4.8)	14.7 (4.5)	26.5 (4.2)	28.0 (6.0)	16.5 (3.2)	20.0 (2.2)	20.1 (3.8)	18.3 (4.2)	
	Lab 3	22.6 (4.4)	33.0 (2.1)	31.6 (6.4)	27.1 (7.9)	17.8 (13.3)	16.3 (7.9)	30.7 (7.9)	28.9 (7.2)	18.0 (5.8)	21.2 (7.0)	22.4 (2.3)	18.7 (6.6)	
	Lab 4	20.6 (3.1)	35.5 (5.8)	30.1 (10.0)	23.7 (8.2)	17.7 (5.8)	15.4 (5.2)	28.3 (3.3)	29.5 (1.8)	17.9 (2.1)	20.4 (3.7)	22.1 (2.4)	18.2 (3.7)	
	Lab 5	21.2 (4.9)	31.6 (10.5)	29.6 (6.5)	23.1 (4.0)	17.8 (6.6)	16.3 (7.0)	26.2 (4.2)	27.2 (5.0)	17.7 (4.0)	19.2 (3.7)	20.8 (1.7)	17.7 (6.0)	
	Lab 6	20.7 (5.0)	34.0 (4.2)	34.2 (2.2)	23.5 (7.0)	17.8 (6.6)	15.7 (3.3)	25.2 (3.9)	26.3 (5.7)	17.5 (3.1)	20.7 (5.0)	21.7 (3.8)	18.3 (5.6)	
	CV of lab. Means (%)	3.8	4.4	6.1	7.5	2.1	4.1	7.4	4.1	3.8	3.3	4.1	4.3	
	All labs	21.3 (5.1)	33.2 (7.4)	31.6 (7.9)	23.7 (9.1)	18.0 (7.2)	15.8 (6.8)	27.1 (8.3)	27.9 (6.1)	17.6 (4.9)	20.3 (5.2)	21.3 (4.7)	18.5 (6.1)	
	All labs: after Hampel	21.3 (5.2)	33.2 (8.4)	31.6 (9.5)	23.6 (8.3)	18.0 (5.9)	15.8 (7.4)	27.1 (7.6)	27.9 (6.7)	17.7 (5.1)	20.3 (5.8)	21.3 (5.8)	18.5 (6.9)	
Acquisition 2 (s)	Lab 1	24.7 (6.0)	59.1 (8.8)	63.1 (5.2)	39.7 (7.9)	23.3 (6.8)	23.1 (7.8)	43.7 (7.4)	45.3 (6.4)	27.4 (5.7)	25.9 (7.5)	28.1 (6.8)	28.3 (6.7)	
	Lab 2	23.5 (6.2)	63.6 (5.7)	62.7 (2.4)	46.0 (14.9)	23.3 (13.6)	21.2 (7.0)	42.5 (7.8)	46.3 (9.7)	27.5 (3.6)	22.7 (4.8)	25.2 (5.9)	28.5 (8.8)	
	Lab 3	32.4 (3.7)	70.0 (3.0)	66.2 (3.7)	50.0 (6.0)	29.3 (14.3)	28.9 (9.1)	56.6 (5.3)	53.8 (3.5)	33.5 (7.2)	31.1 (6.8)	34.6 (7.9)	35.5 (5.0)	
	Lab 4	24.9 (5.4)	66.4 (7.2)	58.4 (4.4)	51.7 (12.8)	23.0 (7.1)	22.4 (7.4)	50.6 (8.8)	50.1 (7.4)	25.6 (3.8)	27.1 (7.3)	27.7 (7.0)	27.0 (6.1)	
	Lab 5	23.7 (7.4)	54.5 (9.4)	62.2 (5.1)	40.0 (10.3)	24.2 (8.2)	23.6 (8.7)	37.6 (14.2)	45.2 (8.7)	26.1 (5.5)	20.7 (5.2)	24.1 (2.8)	29.6 (6.1)	
	Lab 6	23.3 (3.5)	67.0 (1.3)	61.0 (2.3)	37.8 (3.9)	20.8 (3.6)	22.2 (11.9)	40.2 (2.9)	39.7 (3.4)	23.8 (3.2)	25.2 (6.8)	23.8 (6.7)	25.8 (10.2)	
	CV of lab. Means (%)	13.6	9.0	4.1	13.2	11.9	11.7	15.7	10.3	12.1	14.2	14.8	11.7	
	All labs	25.4 (13.6)	63.4 (10.2)	62.3 (5.3)	44.2 (15.6)	24.0 (14.6)	23.6 (13.6)	45.2 (16.4)	46.7 (11.5)	27.3 (12.3)	25.5 (14.5)	27.3 (15.0)	29.1 (12.7)	
	All labs: after Hampel	24.0 (7.5)	63.4 (10.6)	62.3 (5.5)	44.2 (17.1)	23.9 (12.9)	23.4 (12.6)	45.2 (18.9)	46.7 (14.9)	27.1 (12.3)	25.5 (19.7)	26.8 (13.0)	28.9 (12.9)	

Table 2: Mean (coefficient of variation) for data for each of the five outcome variables (ISO 11948-1 (Rothwell), ABL, Rewet, Acquisition 1, and Acquisition 2), for each of the six laboratories, for each of the 12 product variants; coefficients of variation across means for all laboratories; and mean (coefficient of variation) for pooled data across all six laboratories for each outcome variable and each product variant, before and after use of the Hampel estimator (6).

Urine mass (g)		ISO 11948-1 (Rothwell)	ABL	Rewet	Acquisition 1	Acquisition 2
No leakage	100	0.82	0.88	0.70	0.78	0.78
	200	0.91	0.96	0.83	0.90	0.92
	300	0.92	0.96	0.86	0.92	0.95
	450	0.93	0.95	0.87	0.94	0.96
	600	0.92	0.93	0.87	0.94	0.97
Little or no leakage	100	0.39	0.37	0.44	0.27	0.35
	200	0.82	0.89	0.83	0.81	0.86
	300	0.90	0.95	0.89	0.90	0.94
	450	0.93	0.95	0.90	0.94	0.97
	600	0.94	0.94	0.90	0.94	0.98

Table 3: Correlation coefficients for in-use and technical predictions of the leakage performance of the product variants for each of the five test methods, having applied the Hampel estimator to technical data.

Test	Method simple?	Range of CVs within labs (%)	Range of CVs across lab means (%)	Correlations with user data*	Detected user benefit of cuffs in insert product variant 1 (cf variant 2)?
ISO 11948-1 (Rothwell)	Yes	0.3-3.9	2.2-6.5	0.82-0.94	No
ABL	No	0.3-25.1	8.6-22.1	0.89-0.96	Yes

Table 4: Summary of the key characteristics of the ISO 11948-1 (Rothwell) and ABL test methods. Range of CVs within labs = the range of the 72 coefficients of variation within labs (12 products x 6 labs, Table 2). Range of CVs across lab means = the range of the 12 coefficients of variation (1 for each product variant) across the labs (Table 2). * The values for correlations with user data (Table 3) exclude the result for (little or no leakage) at 100 g, for which neither method yielded strong correlations – presumably because a lot of leakage was rare at such low urine masses.

Figures

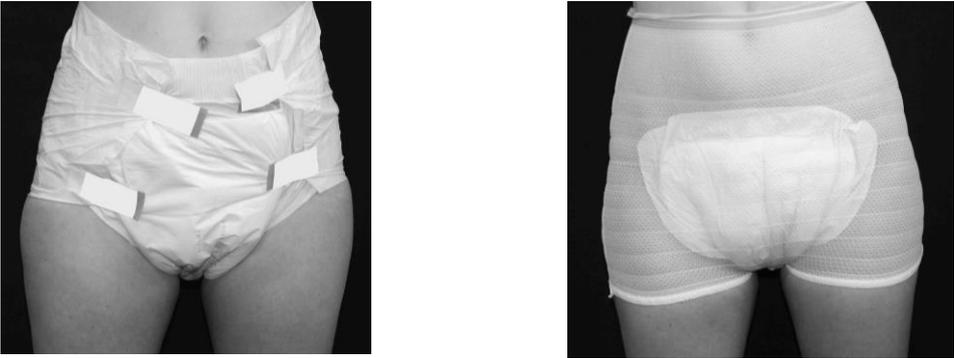


Fig 1: Example brief (left) and insert (right)

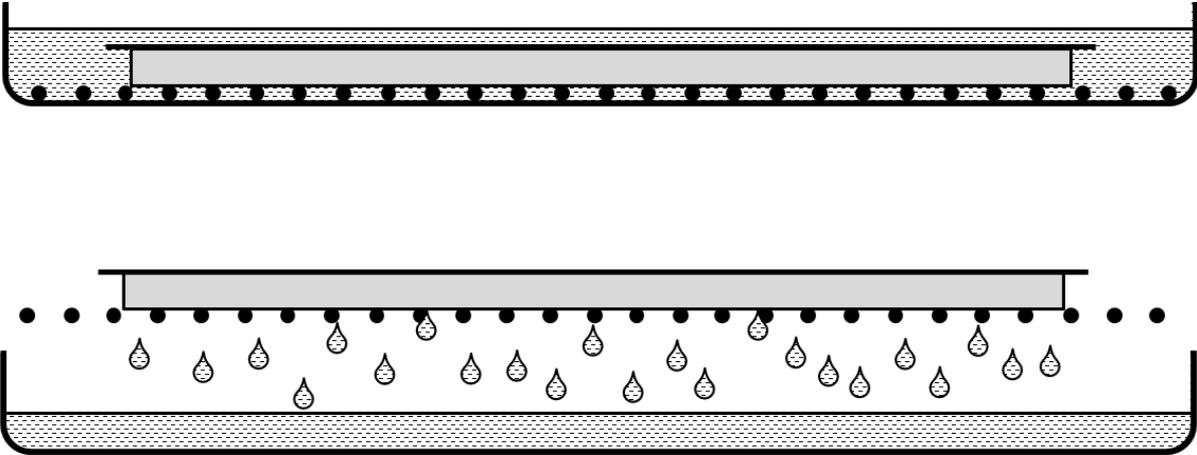


Fig 2: Equipment for performing ISO 11948-1: Urine absorbing aids. Part 1: Whole-product testing (the Rothwell method) [1]: soaking phase (above) and draining phase (below).



Fig 3: Equipment for measuring the absorption before leakage (ABL) of products.

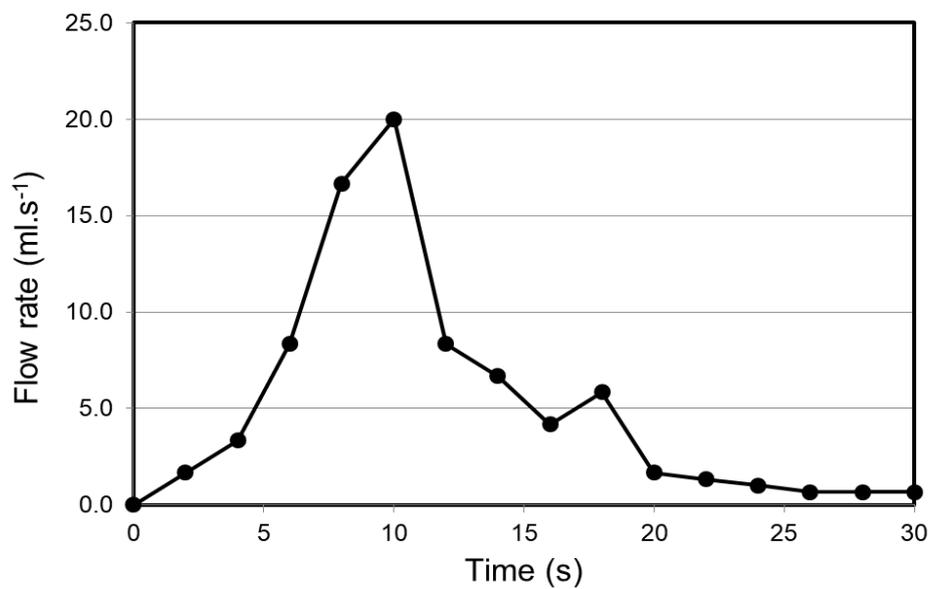


Fig 4: The flow-rate-time profile for the 162 ml aliquots of normal saline delivered to a product using the ABL method.

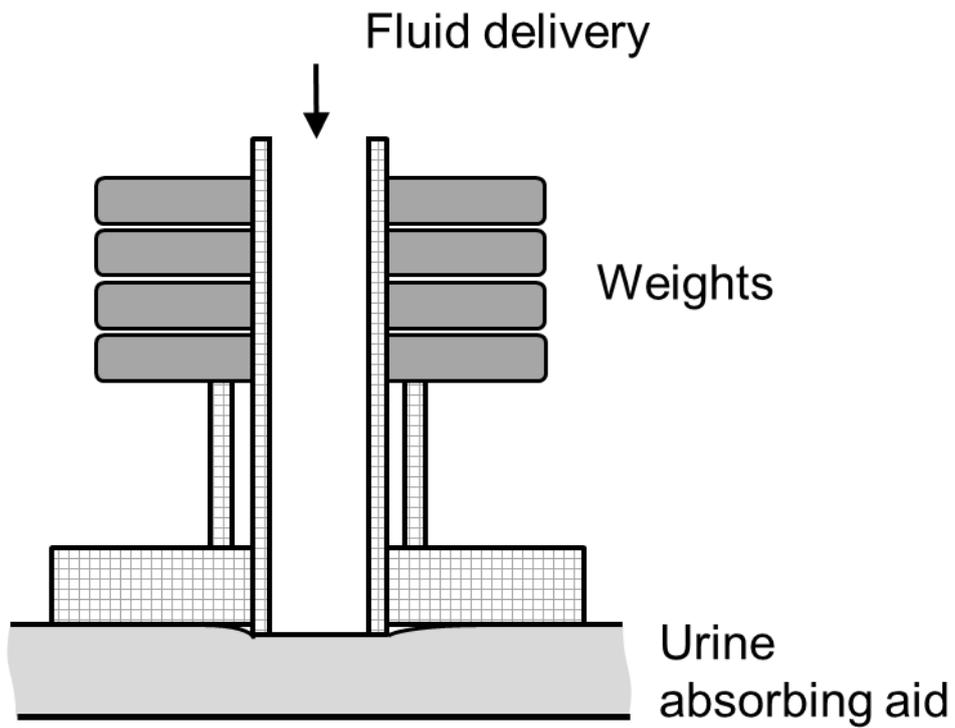


Fig 5: Equipment for performing the rewet test method, Spanish national standard UNE 153601-2:2008 [2].

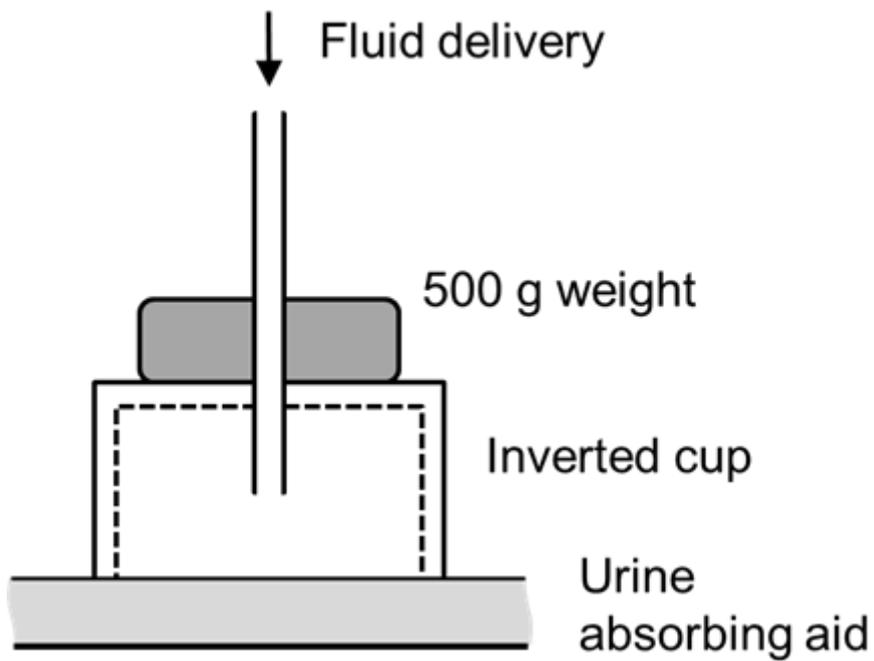


Fig 6: Equipment for performing the acquisition test method.

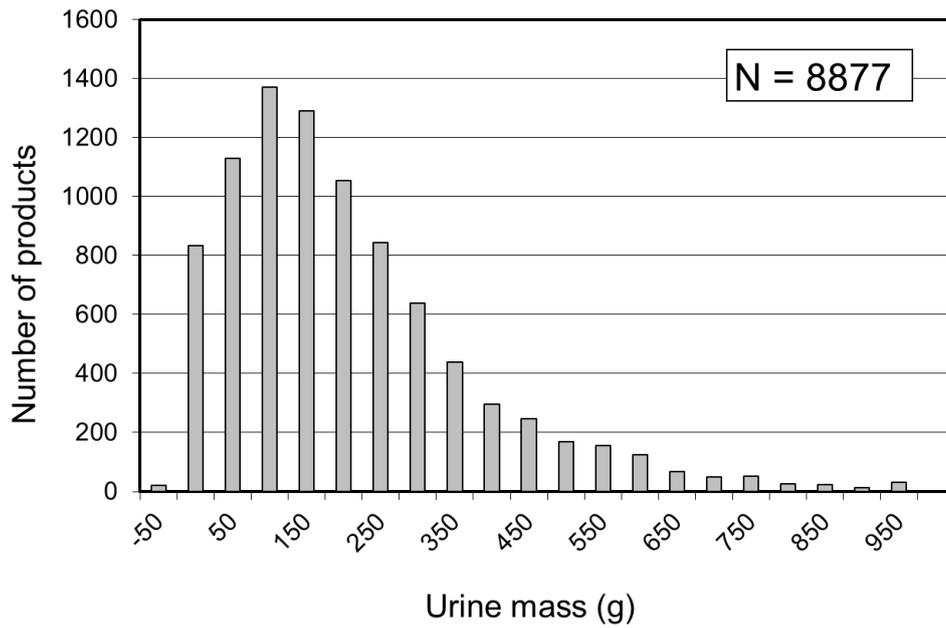


Fig 7: Urine mass distribution in all weighed products.

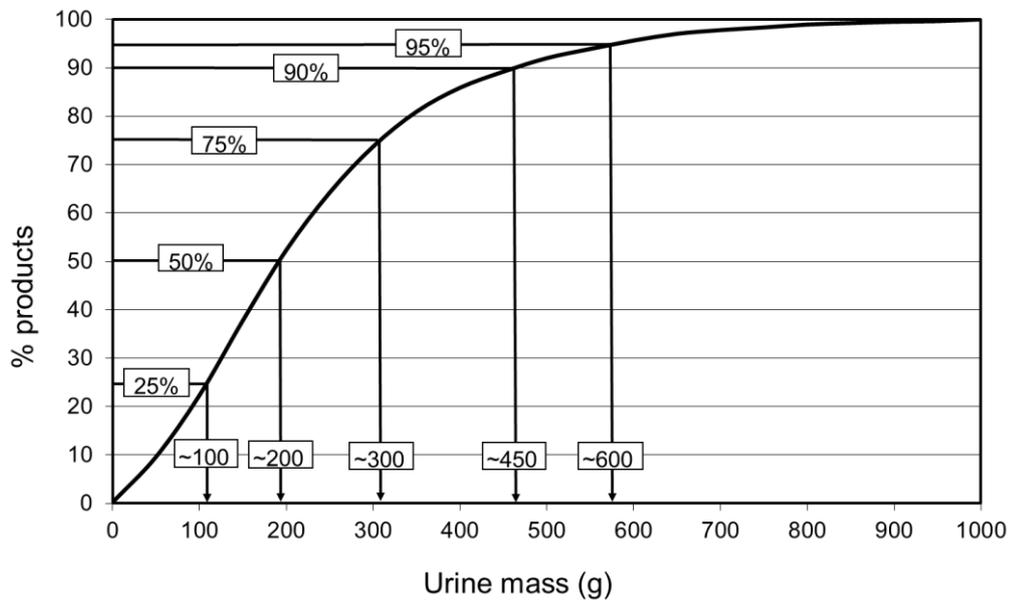


Fig 8: Cumulative urine mass distribution in all weighed products with 25, 50, 75, 90 and 95%ile urine masses indicated.

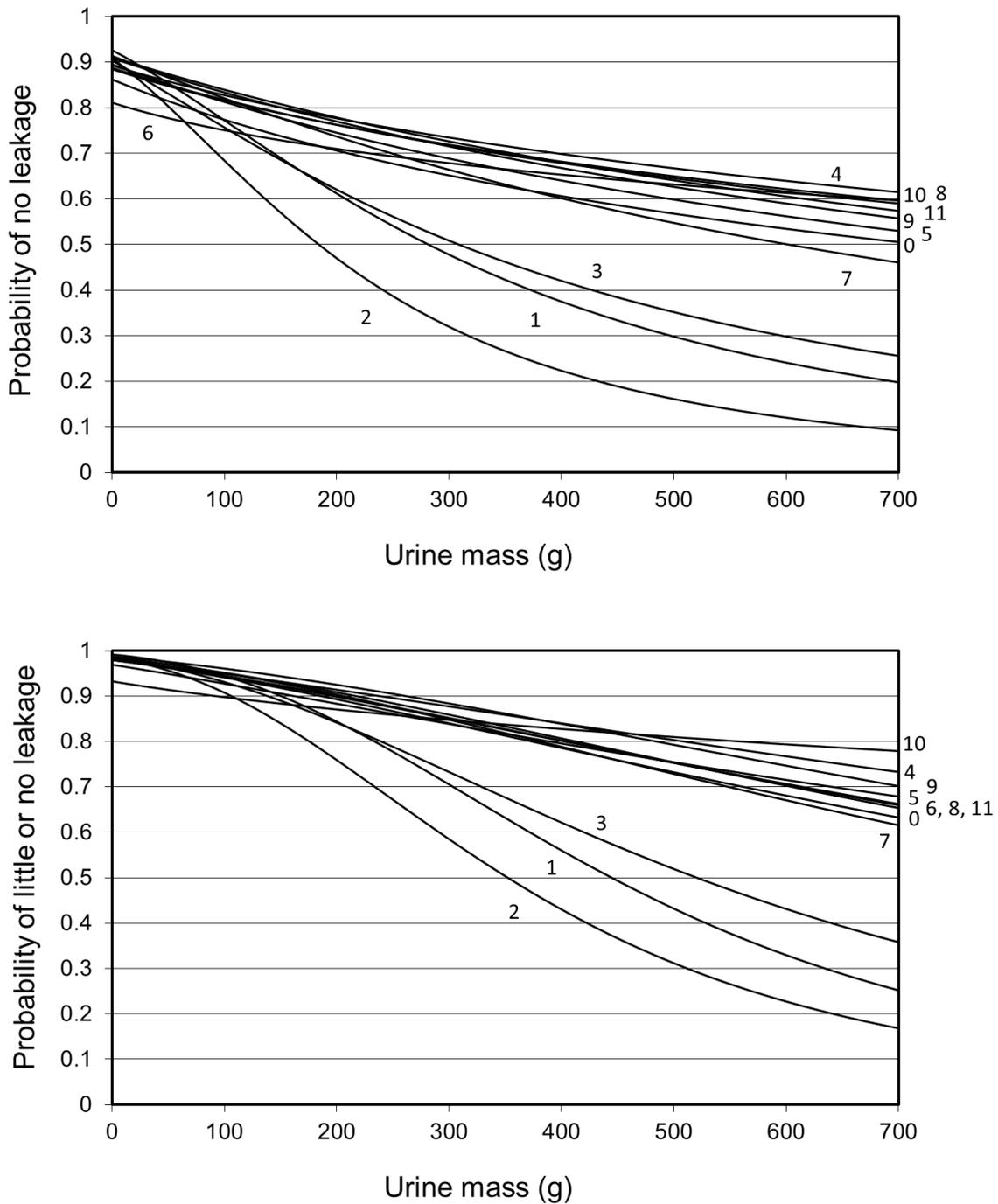


Fig 9: Probability of no leakage (top) and little or no leakage (bottom) as a function of urine mass for the product variants 0-11, labeled.

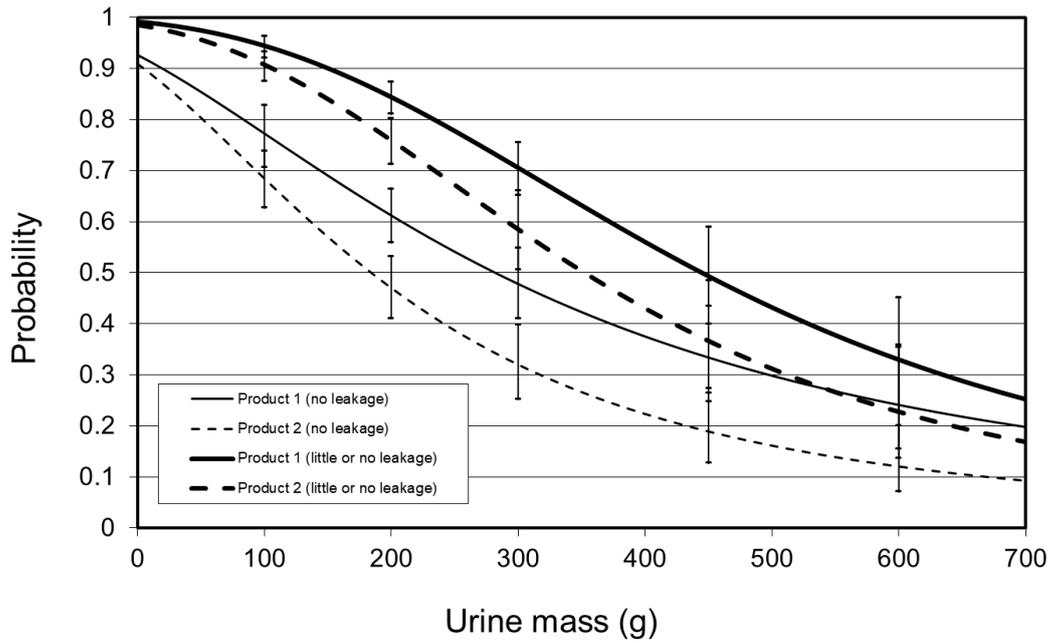


Fig 10: Comparison of in-use leakage performance curves for Product 1 (Insert with cuff; Rothwell, 1333g; ABL, 427g) and Product 2 (Insert without cuff; Rothwell, 1385g; ABL, 341g).

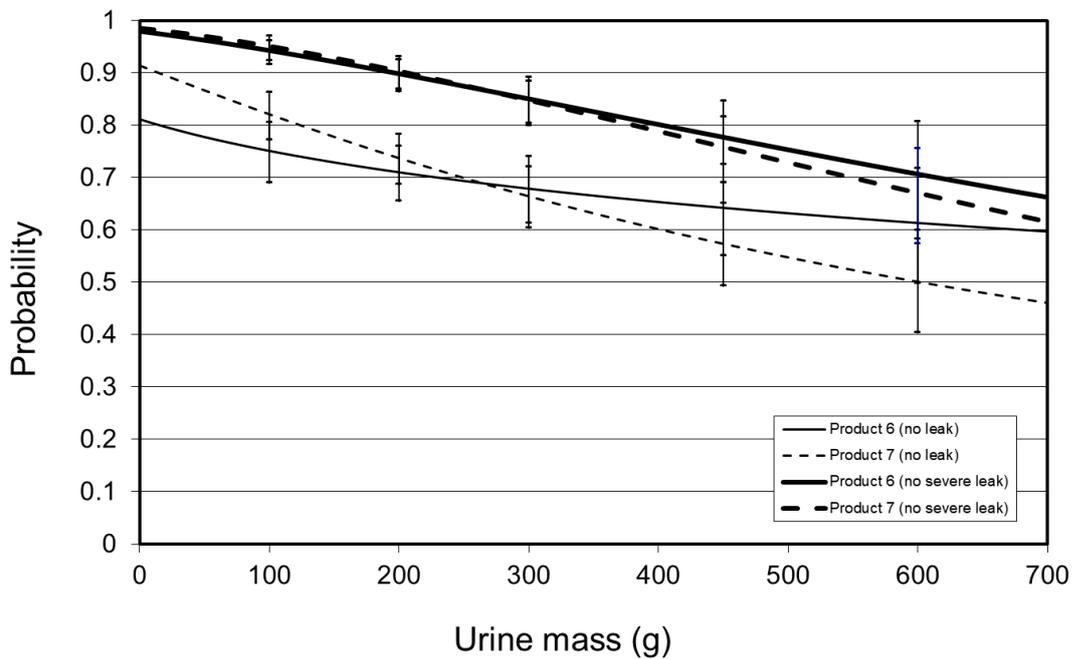


Fig 11: Comparison of in-use leakage performance curves for Product 6 (Brief with cuff; Rothwell, 2068g; ABL, 630g) and Product 7 (Brief without cuff; Rothwell, 2134g; ABL, 557g).

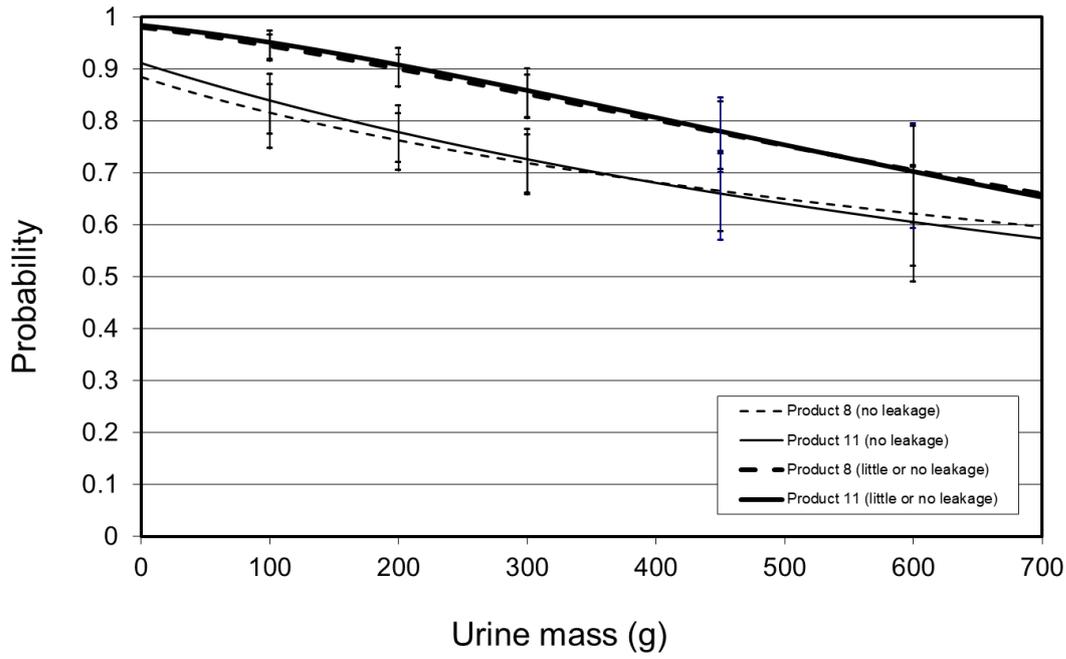


Fig 12: Comparison of in-use leakage performance curves for Product 11 (Brief with cuff; Rothwell, 2821g; ABL, 840g) and Product 8 (Brief without cuff; Rothwell, 2856g; ABL, 794g).

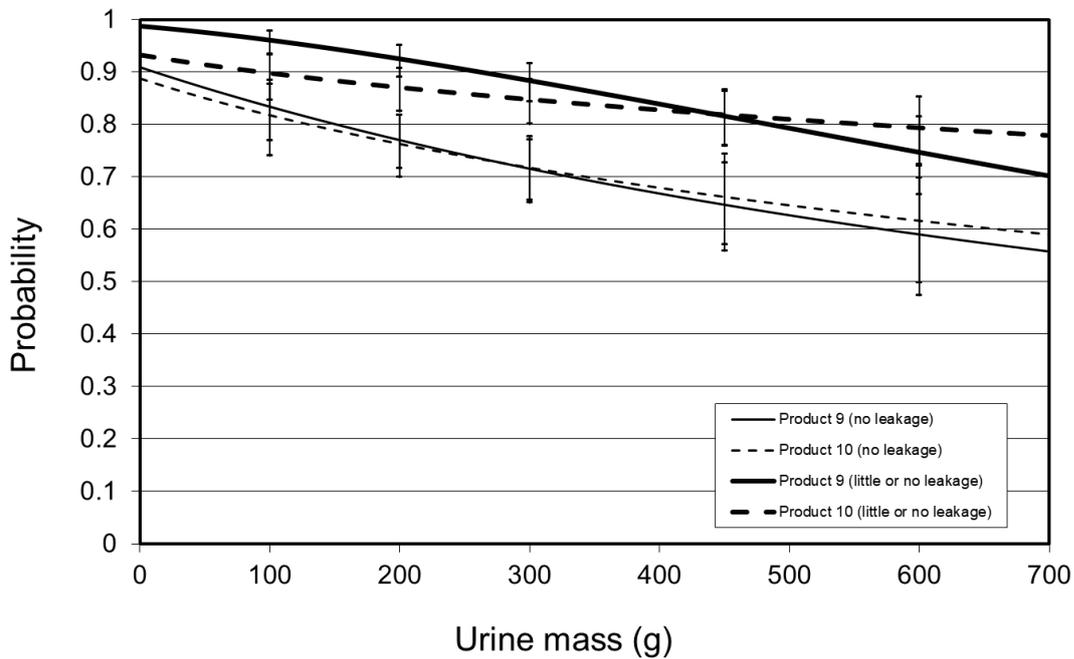


Fig 13: Comparison of in-use leakage performance curves for Product 9 (Brief with cuff; Rothwell, 3250g; ABL, 806g) and Product 10 (Brief without cuff; Rothwell, 3270g; ABL, 720g).

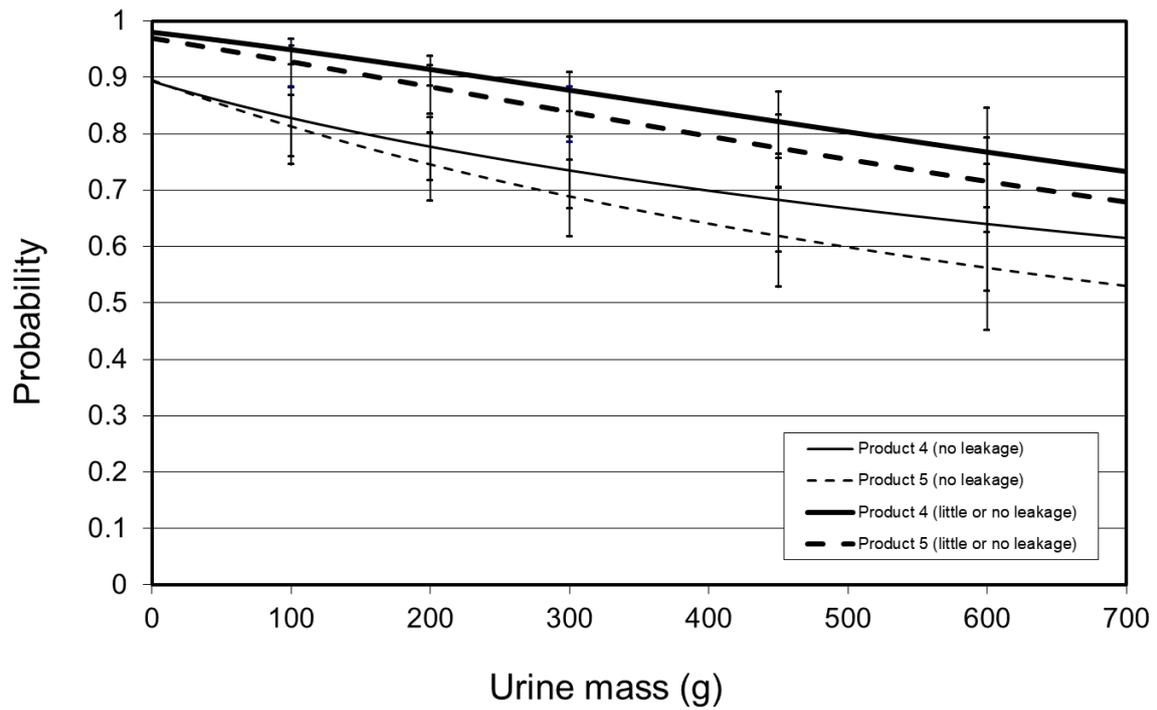


Fig 14 Comparison of in-use leakage performance curves for Product 4 (Insert with cuff; Rothwell, 2824g; ABL, 751g) and Product 5 (Insert with cuff; Rothwell, 2603g; ABL, 728g).