Threshold for detection of diabetic peripheral sensory neuropathy using a range of research grade monofilaments in persons with Type 2 diabetes mellitus.

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Abstract

Aims: To identify the threshold of reduced sensory perception in Type 2 diabetes mellitus (Type 2 DM) using a range of research grade monofilaments.

Methods: Three groups of participants were recruited into a between subject, cross-sectional study. Group 1(NEW), persons with Type 2 DM diagnosed for less than 2 years (n = 80); Group 2 (EST) persons with Type 2 DM diagnosed for more than 2 years (n = 91), and Group 3, a Comparison group without Type 2 DM (n = 73), resulting in a total study population, n = 244. Research grade monofilaments (2, 4, 6, 8 and 10-gramme) were employed using standardised protocol, at 6 sites on the plantar aspect of both feet. The demographic and anthropometric measures of the participants of each group were analysed.

Results: Perception of the research grade monofilaments differed significantly between the 3 groups ($p<0.05$). The 6-gramme monofilament was found to be the threshold of normal perception, based on 90% of the Comparison group perceiving the 6-gramme monofilament at all sites in contrast to 64% of NEW and 48% of EST groups.

Conclusions: The 6-gramme monofilament was identified as the threshold of normal sensory perception. Employing a range of monofilaments, 6, 8 and 10-grammes in Type 2 DM foot screening would enable the clinical detection of deteriorating sensory perception and implementation of foot protection strategies at an earlier stage than is currently practised.

Keywords: Research grade monofilaments; diabetic peripheral sensory neuropathy; Type 2 diabetes; diabetic foot.

Background

One of the common long-term complications of diabetes is neuropathy [1] of which there are several types with varying clinical features. A suggested clinical definition of diabetic peripheral sensory neuropathy (DPSN) is:

> '*a condition in which patients with diabetes experience symptoms such as pain, burning, hyperaesthesia, or are found to have signs of nerve damage of which they are unaware, principally the anaesthetic and deformed foot*.' [2]

Prevalence of DPSN varies widely in studies, depending on the criteria for diagnosis and the sensitivity of its detection [3]. A community-based study [4] found a prevalence of 42% in persons diagnosed with Type 2 diabetes for more than 2 years, of whom only 48% reported significant neuropathic symptoms.

It has been recorded that 99% of diabetes care is self-care [5], and it is part of the role of the health care professional to enable people to improve their diabetes-related coping skills, encouraging them to improve self-care behaviour, metabolic outcomes and thereby quality of life. The use of simple clinical tests allows a person with diabetes to understand a developing complication, such as loss of protective sensation in its early stages. This empowers those with early Type 2 diabetes to make the behavioural changes that may be required to prevent foot problems such as ulceration and amputation.

Whilst acknowledging that assessment of both vibration perception threshold and 10-gramme monofilament together provide the most specific and most sensitive method of assessing sensory status in the diabetic foot [6], for the purpose of this paper the authors have concentrated on monofilament assessment alone [7, 8, 9].

The inability to perceive the 10-gramme monofilament at non-callused sites on the plantar aspect of the foot indicates that there is a loss of protective sensation which increases the risk of neuropathic foot ulceration [7, 9, 10]. One study [11] calculated that lack of perception of the 10-gramme monofilament equated to a 10-fold increased risk of ulceration. The employment of a range of monofilaments have been used since the development of the Semmes-Weinstein monofilaments circa 1950 [12] and there has been some disparity amongst researchers as to the minimum weighted monofilament that qualifies as the 'normal' threshold [13, 14, 15]. One study [16] concluded that perception of a monofilament of approximately 2-grammes placed a person within the normal range whereas another [6] used a 5-gramme monofilament as the reference for normal perception in the foot.

Therefore for this study a range of research grade monofilaments (2, 4, 6, 8 and 10-grammes) applied to specific sites, avoiding overlying callus, were employed in order to identify the threshold for normal perception, thus enabling both clinician and person with diabetes to appreciate diminished sensory perception prior to the 10-gramme threshold which indicates loss of sensory perception [7, 9, 10, 11]

The sites tested by monofilament and number of applications at each site, vary widely in studies as may be seen in Table 1 [17].

The six sites selected for testing for this study were the plantar aspect of hallux, first, second, third, fourth and fifth metatarsal heads, avoiding callus [18] with loss of perception to one site indicating loss of perception to that weight of monofilament [7, 9, 19, 20].

Investigating specific sites in the forefoot with a range of monofilaments in order to ascertain when perception deviates from the expected level would allow both preventative therapeutic action and education to be initiated at an earlier stage than is currently the norm. This study was designed to identify the threshold at which it is clinically feasible to detect reduced sensory perception in Type 2 DM. Therefore the experimental hypothesis was: there is a difference between three groups, new and established Type 2 diabetic participants and a Comparison group, and their perception of a range of research grade monofilaments applied to six sites on the plantar aspect of the foot.

Methods

Ethical approval was granted by Torbay Local Research Ethics Committee. Information sheets were provided and written consent obtained from each participant prior to the commencement of the study. Persons with any condition (other than diabetes) associated with peripheral neuropathy or impaired nerve responses, cancer therapy (current or in the past five years), myocardial infarction, angioplasty or bypass graft, rheumatoid arthritis, alcoholism, history of or current ulceration, gross pedal deformity, use of walking aid and pregnancy were excluded from the study.

Three groups of participants were recruited for the study by convenience sampling and all were Caucasian except one South Asian. As indicated in Table 2, there was a group of 80 persons with Type 2 DM diagnosed for less than two years (NEW), and a group of 91 persons with established Type 2 DM of more than 2 years since diagnosis (EST). Both groups with Type 2 DM were recruited from G.P practices in the community and were recruited as they became available providing they fulfilled the inclusion and exclusion criteria. The third group of 73 participants (Comparison) did not have Type 2 diabetes mellitus or any known family history of the disease, with normal glucose tolerance on 75 gramme oral glucose tolerance test, were recruited from friends and hospital staff.

In order to test sensory perception, research grade monofilaments (Bailey Instruments, Manchester) 2, 4, 6, 8, and 10-gramme were employed in accordance with the predetermined protocol. This was informed by a pilot study [20], and incorporated the approach suggested by Booth and Young [21], in which the monofilament was 'bounced' three times prior to the test and not used more than 100 times in a 24 hour period.

In this study, inability to perceive a monofilament at any of the sites on the foot was recorded as loss of perception to that weight of monofilament. The test was clearly explained to the participant, and a monofilament was demonstrated on the inside of the investigator's forearm and then repeated at the same site on the participant. They were asked to say 'yes' every time they perceived the monofilament on their foot. Six sites were marked and tested on each foot; the participant closed their eyes and was therefore unable to see which site was being tested [20]. The testing of each site with a single monofilament took approximately 2 seconds, and the ascending method of

limits was employed, commencing with the 2-gramme monofilament. The six sites; pulp of hallux, 1st, 2nd, 3rd, 4th and 5th MTPJs on each foot were tested, once with each monofilament, but the timing between each test was varied. One investigator conducted all the monofilament testing. Data from both feet of the participants were collected and is available but right foot only data were analysed in detail, as in other studies [22]. Data were analysed using SPSS Release 10 software. Comparison of gender was tested by Chi-square and demographic, anthropometric and biochemical data between the three groups were tested by one way analysis of variance (ANOVA). Monofilament data were deemed to be ordinal and statistical analysis was performed using the Jonckheere-Terpstra (J-T) test, a non-parametric test for several independent samples [23].

At completion of data collection all monofilaments were retested by the manufacturer and they were found to deform to their relevant weight.

The level of significance selected for the results was 0.05 for hypothesis testing.

Results

Data were collected from the 244 participants, see Table 1.

There was a significant difference between the Comparison group and the diabetes groups, for gender when the chi-square test was performed, $p = 0.013$, this was due to the limitation of the recruitment process. As expected the Comparison group show lower blood pressure (systolic and diastolic), lower body weight, BMI and HbA_1c than the groups with diabetes (ANOVA with Bonferroni multiple comparisons $p<0.001$). Interestingly the BMI, and diastolic blood pressures are significantly greater in the NEW group compared with the EST diabetes group ($p = 0.016$ and $p<0.001$ respectively), suggesting that optimum control of Type 2 DM in the NEW group had not yet been achieved. The Comparison group was significantly younger than the two diabetes groups, $p<0.001$ (mean ages: NEW = 59.6; EST = 61.4 and Comparison = 52.6), which was due to the recruitment process.

The results of the monofilament testing for the three groups at the six sites are presented in Figures 1a-1e, which show the percentage of sites perceived in each group with each weight of monofilament on the right foot.

Figure 1a shows that 10% of the NEW, 22% of the EST and 3% of the Comparison group could not perceive the 2-gramme monofilament at any of the sites. Only 19% of the NEW, 9% of the EST and 52% of the Comparison group, could perceive all six sites when the 2-gramme monofilament was applied.

It can be seen in Figure 1b that with the heavier weighted monofilament more participants in all 3 groups perceived the 4-gramme monofilament at all 6 sites; 51% of the NEW, 33% of the EST and 81% of the Comparison participants.
In Figure 1c, the numbers of participants in each group able to perceive the 6-gramme monofilament at all sites has increased again: 64% NEW; 48% EST and 90% Comparison.

In Figure 1d, 75% NEW, 66% EST and 99% of the Comparison group perceived all six sites with the 8-gramme monofilament and in Figure 1e, 84% of NEW, 79% of EST and 100% of the Comparison group perceived the 10-gramme monofilament at all sites.

The summary of monofilament perception at all sites and the Jonckheere-Terpstra test (2 degrees of freedom) results are shown in Table 3 which illustrates the results for the 6-gramme monofilament, that is 64% NEW, 48% EST and 90% of the Comparison group perceived the 6-gramme monofilament at all sites, and puts them into the context of results from other weighted monofilaments. Figure 2 interprets the results in Table 3 graphically and demonstrates that the greatest difference between the 3 groups occurred with the results of the 4 and 6-gramme monofilaments.

In the context of the results presented above, the null hypothesis was rejected as there were significant differences between the groups ($p<0.05$).

Discussion

In this study a series of research grade monofilaments; 2, 4, 6, 8 and 10-gramme, were used at six sites on the plantar aspect of the foot to test sensory perception. The study showed that only 52% of the Comparison group could perceive the 2-gramme monofilament at all sites, which suggests that its routine use for screening for diminished sensation is not appropriate. The results of the 4-gramme monofilament suggest that a clinical sensory threshold was becoming apparent but only 81% of the Comparison group in our study could perceive the 4-gramme at all sites and this percentage was considered too low to warrant recognition as the sensory threshold. However, two other studies, a Japanese study [24] and an American study [25] concluded that using the 4-gramme and the 4.5-gramme monofilament respectively, rather than the traditionally used 10-gramme monofilament would be clinically useful for detecting DPSN at an earlier stage. When the 6-gramme monofilament was employed in our study, the percentage of persons able to perceive it at all sites rose to 90% of the Comparison group, 64% of the NEW and 48% of the EST group. These data indicate that while less than 100% of the Comparison group were able to perceive the 6-gramme monofilament, it never the less showed a greater differential between the sensory capability of non-diabetic and diabetic participants than at 8-grammes or 10-grammes. The Comparison group were younger than the participants in the other two groups and this might have affected the results. In addition, the findings indicate that the group with diabetes of longer duration (EST) was less able to perceive the 6-gramme monofilament than the group of participants with newly-diagnosed diabetes (NEW), reinforcing the notion that sensation diminishes as the duration of diabetes increases.

The results suggest that using a range of monofilaments (6, 8 and 10-gramme) provides the ability to detect diminished sensation at an earlier stage than use of the 10-gramme monofilament alone. Persons with diabetes frequently do not regard DPSN as a problem unless it causes discomfort, and large discrepancies exist between foot care knowledge, perceived vulnerability and behaviour [26]. It might be anticipated that the use of a range of monofilaments could clearly demonstrate the need for increased vigilance with foot care to the person with diabetes. The employment of a range of monofilaments would allow protection and prevention programmes for foot care to be introduced at an earlier stage as required by the National Service Framework for Diabetes [27].

The monofilaments used in this study are estimated, by the manufacturer Bailey Instruments, Manchester, using unpublished archive data on file (1998), to be able to endure approximately 24000 'bounces' before they lose their integrity (that is equivalent to 2000 patients using the testing protocol used in the study). Currently, the cost of an individual monofilament manufactured by Bailey Instruments Manchester is £14 plus VAT, therefore setting the cost of a series of monofilaments (6-gramme, 8-gramme and 10-gramme) of £42 plus VAT against the mean weekly cost of £59 for a non-infected foot ulcer [28, 29] clearly demonstrating the potential cost-effectiveness of a range of monofilaments.

The results of this study are based on the criteria of testing 6 sites and application of each monofilament once at each of those sites. Other workers have used different criteria; such as testing a different number of sites, from 1 site [7], 3 sites [11, 19] to 9 sites [9] and applying the monofilament 3 times at each site and recording the

majority response [11, 30]. Another criterion in this study determined that the selected monofilament had to be perceived at all 6 sites whereas other studies used different criteria such as 3 sites perceived out of 6 [18]. Thus it may be seen that it is difficult to compare studies when different criteria are used. This study reveals that more research is required into the use of monofilaments. Future research should include the development of a standardised protocol incorporating the method of application to include selection and identification of the precise sites to be tested, number of applications at a particular site with each monofilament, the order of the sites tested by the individual monofilaments, and translation of results.

Conclusion

Most (90%) healthy persons without Type 2 DM were able to perceive the 6-gramme monofilament at the selected sites on the plantar aspect of the foot. It is therefore reasonable to use the 6-gramme monofilament as a threshold measure for screening persons with Type 2 DM. This would be followed by the 8-gramme monofilament if perception was not apparent at all sites and finally the 10-gramme monofilament. This method would allow stepwise progression of education for the person with Type 2 DM at annual review.

Acknowledgements

The statistical support for this study was provided by Mrs S High of the Department of Social Statistics, University of Southampton.

Abbreviations

ANOVA: analysis of variance

DM: diabetes mellitus

DPSN: diabetic peripheral sensory neuropathy

EST, participants diagnosed with Type 2 diabetes for more than 2 years

MTPJ, metatarso-phalangeal joint

NEW, participants diagnosed with Type 2 diabetes for less than 2 years

Competing interests

The authors declare that they have no competing interests.

Authors contributions

MT conceived and designed the study, undertook all data collection and analysis and wrote the paper.

JP supervised the study at all levels from the design stages, interpretation of data through to completion of the paper to which she has given permission for publication.

PF has been involved in intellectual discussions with regard to the study throughout, revising the manuscript for important intellectual content and has given approval for the final version to be published.

RP has actively participated and supported the conception and design of the study, supervising all the recruitment of the participants actively discussed the interpretation and implications of results and proof read the final paper and given approval for the final version to be published.

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Table 1. To show the number of sites tested with 10-gramme monofilament in various studies.

Author (s)	**Number of Sites tested/recommended**	**No. of sites insensitive to represent PN**
Holewski, Stess et al (1988)	6	3/6
Kumar, Fernando et al (1991)	1	1
Rith-Najarian, Stolusky et al (1992)	8	1 but retested twice
McNeely, Boyko et al (1995)	9	1/9
Dorgan, Birke et al (1995)	5	Not stated
Litzelman, Marriott et al (1997)	3	1
Frykberg, Lavery et al (1998)	3	2/3
Boyko, Ahroni et al (1999)	9	1/9
International Working Group on the Diabetic Foot (1999)	3	2/3 retested twice
Pham, Armstrong et al (2000)	1	1

PN = peripheral neuropathy

Table 2. Participant demographics.

		NEW ***n* = 80**	**EST** ***n* = 91**	**Comparison** ***n* = 73**	**p value**
Gender	**Male** **Female**	**44** **36**	**66** **25**	**38** **35**	**= 0.013***
Age	**Mean** **+/- SD**	**59.6** 8.4	**61.4** 8.4	**52.6*** 10.6	**<0.001***
Height	**Mean** **+/- SD**	**170.7** 9.1	**171.4** 8.7	**172.6** 9.5	**0.45**
Weight	**Mean** **+/- SD**	**94.8** 17	**89.2** 16	**76.6*** 1.6	**<0.001***
BMI	**Mean** **+/- SD**	**32.7**** 6.1	**30.5**** 5.5	**25.5*** 3.4	**<0.001*** **= 0.016****
HbA_1c	**Mean** **+/- SD**	**8** 1.4	**8.3** 1.6	**5.6*** 0.5	**<0.001***
Systolic	**Mean** **+/- SD**	**141** 17.2	**136** 18.3	**129*** 17.2	**<0.05***
Diastolic	**Mean** **+/- SD**	**82.7**** 7.9	**76.9**** 9.5	**79.5** 11.8	**<0.001****
Duration months	**Mean** **+/- SD**	**12.5** 7.4	**106.3** 78.2	**N/A**	**N/A**

Key: * denotes that the Comparison group was significantly different from diabetic groups

** denotes significant difference between 2 diabetic groups

N/A = not applicable

Table 3. The percentage of participants in each group, who perceived the monofilaments at all sites.

Monofilament	**NEW** ***n* = 80**	**EST** ***n* = 91**	**Comparison** ***n = 73***	**p value**
2-gramme	19%	9%	52%	<0.001
4-gramme	51%	33%	81%	<0.001
6-gramme	64%	48%	90%	= 0.003
8-gramme	75%	66%	99%	< 0.001
10-gramme	84%	79%	100%	= 0.004

Figure 1a. Percentage of sites perceived by each group with the 2-gramme monofilament.

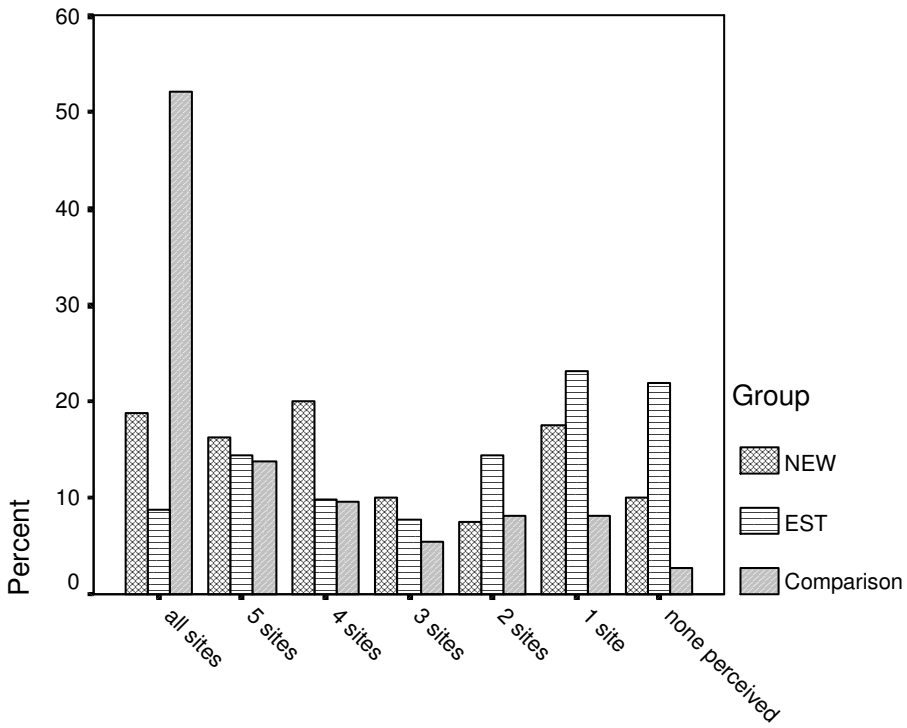

Figure 1b. Percentage of sites perceived by each group with the 4-gramme monofilament. (Note the vertical percentage scale has increased to 100)

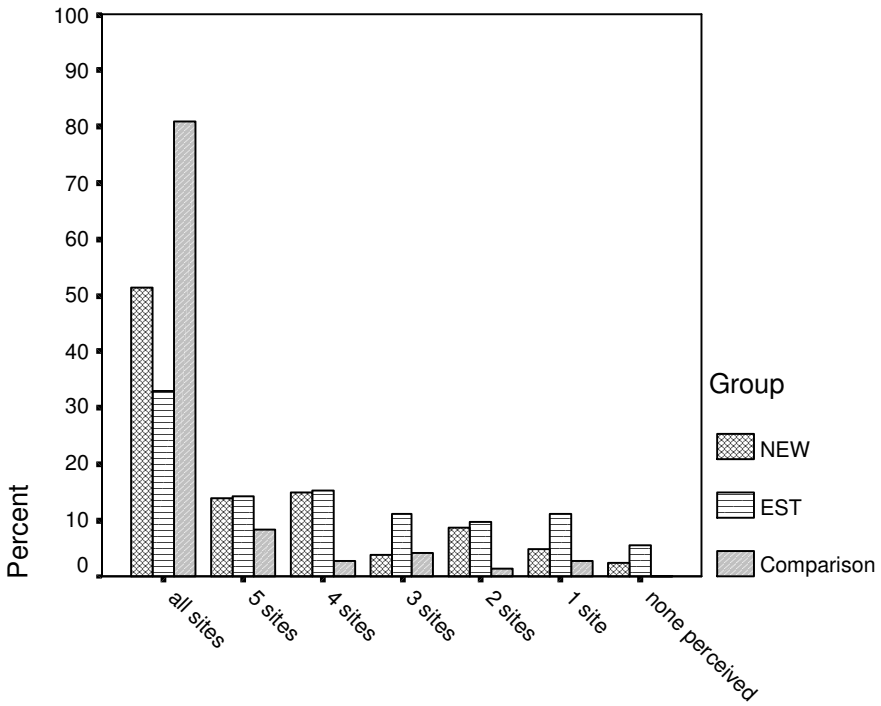

Figure 1c. Percentage of sites perceived by each group with the 6-gramme monofilament.

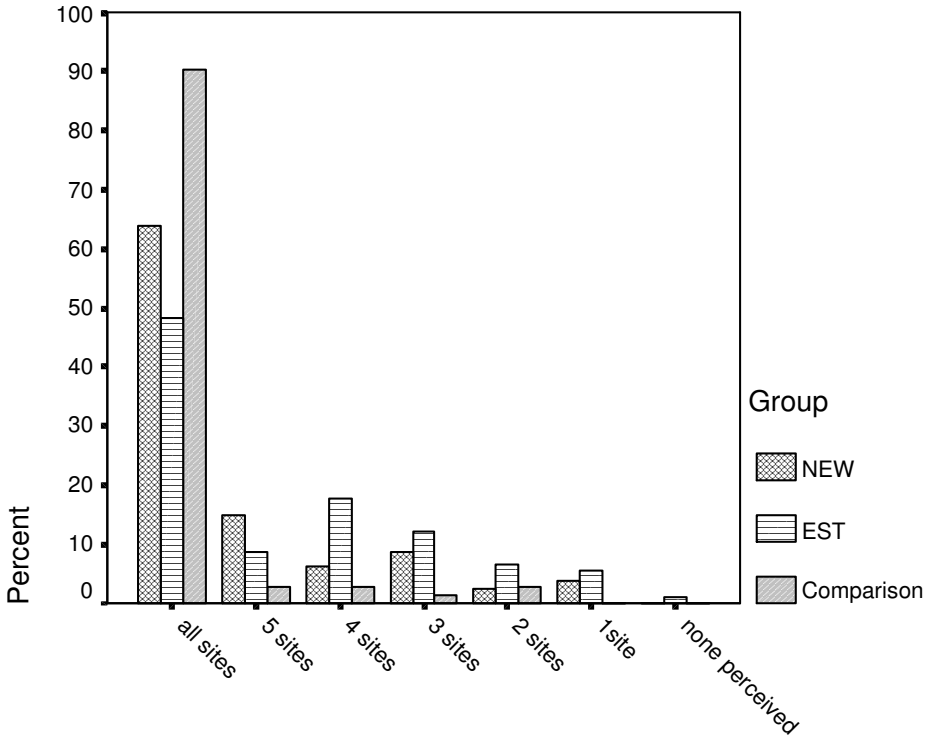

Figure 1d. Percentage of sites perceived by each group with the 8-gramme monofilament.

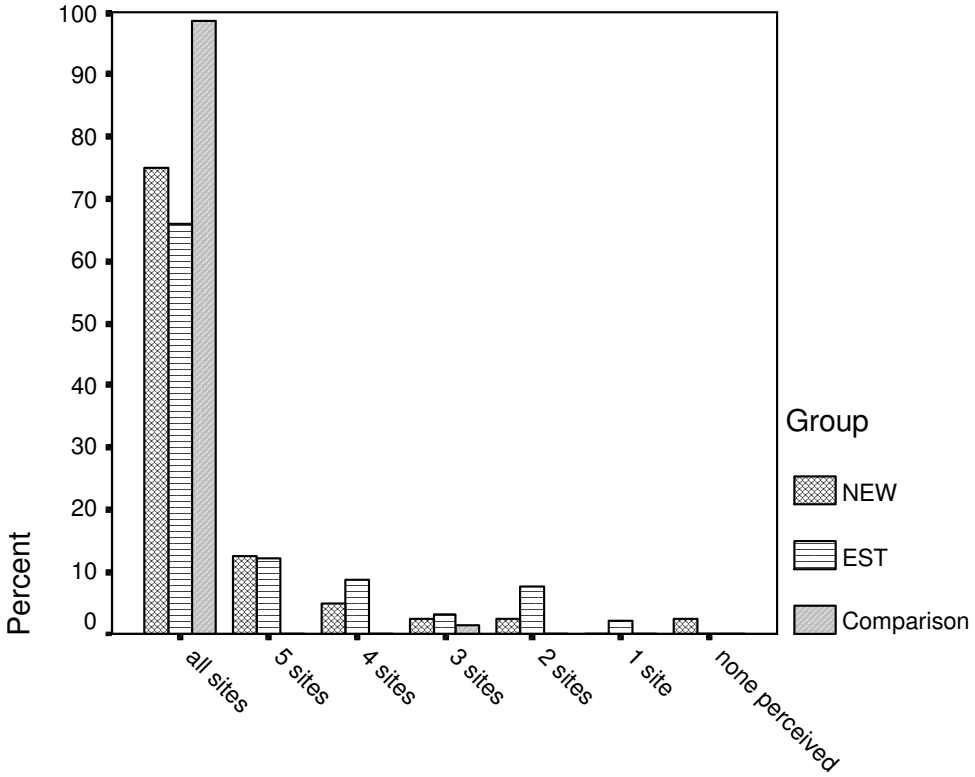

Figure 4

Figure 1e. Percentage of sites perceived by each group with the 10-gramme monofilament.

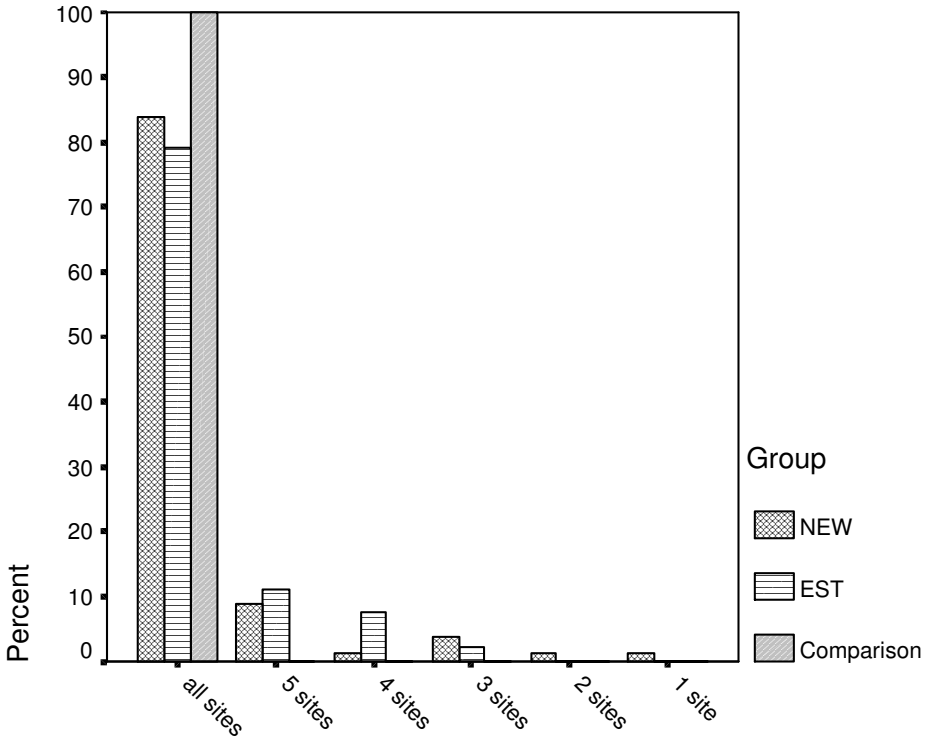

Figure 2. The percentage of participants in each group, who perceived the monofilaments at all sites, at each weight.

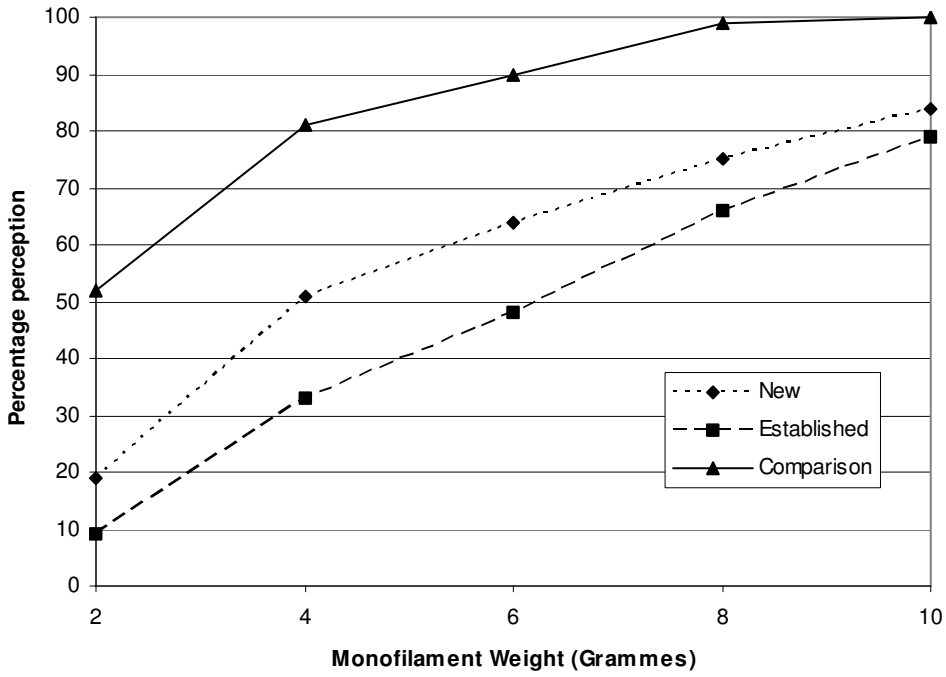

Figure 6