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Impact of Unifine[®] Pentips[®] Plus on pen needle changing behaviour amongst people with diabetes medicating with injectable formats

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Abstract

Unifine® Pentips® Plus is a premium quality pen needle with a built-in remover designed to improve patient adherence by offering greater ease of use and convenience during patient self-injection.



Purpose: The study assessed the impact of Unifine® Pentips® Plus on pen needle changing behaviour over a period of eight weeks. The first 4 weeks with their existing pen needle, then with only a short introduction from their pharmacist, another 4 weeks with Unifine® Pentips® Plus.

Methods: Patients (n=59) with either Type 1 or Type 2 diabetes were involved in a semi-longitudinal study whereby they completed a short online diary entry each day to collect information about their pen needle changing behaviour.

Introduction

Experts agree that the safest, most accurate routine when using injection pens is the immediate removal of the pen needle after injection and replacement with a new needle just prior to injection^{1,2}.

In order to test this hypothesis, research was conducted with an independent healthcare market research company, Healthcare Research Worldwide. Owen Mumford hypothesise that Unifine® Pentips® Plus will improve pen needle changing behaviour; specifically, that patients using Unifine® Pentips® Plus will change their pen needles more frequently than they do using standard pen needle devices. In order to test this hypothesis, research was conducted with n=59 diabetes patients across the UK.

Results: The results showed that after using Unifine® Pentips® Plus, there was a 61% increase in the rate of adherence to using a new pen needle for each injection, also 86% stated Unifine® Pentips® Plus were 'as easy' or 'easier' to use compared to the current pen needle and 61% preferred Unifine® Pentips® Plus to their current pen needle.

Conclusions: Unifine® Pentips® Plus can help to improve pen needle changing behaviour. The unique design means that patients always have access to an empty chamber into which to dispose of a used pen needle, with the majority of patients finding the process of changing the pen needle easier or at least as easy as their current pen needle. Unifine® Pentips® Plus was intuitive to use as patients were given either little or no additional instruction compared to standard pen needles. Combined with a high level of appeal and a majority preference for Unifine® Pentips® Plus. In the eyes of the researcher, Unifine® Pentips® Plus device represents a step forwards in improving one element of the injection routine.

Methods

Study population

Potential participants to the study were initially contacted via local pharmacists supporting the research. Suitable participants were then provided with a study specific information and consent form and were screened via a short questionnaire to assess their eligibility to take part in the research. Participation in the research was purely voluntary and participants were free to withdraw from the study at any time without prejudice.

Inclusion criteria:

Only participants to whom all of the following conditions applied were included in the research:

1. Gave written informed consent
2. Male or Female volunteers aged 18-65 years
3. Previously diagnosed with Type 1 or Type 2 diabetes
4. Currently using an insulin pen needle device where the needle should be changed
5. Administering injections themselves (i.e. needles not changed by a carer who injects for them)
6. Inject using a diabetes pen device at least 3 times or more per day
 - a. OR if participant injects twice a day using a pen device they must inject their medication at least twice a week outside of the home environment
7. Existing "customers" within the pharmacy (i.e. have obtained a diabetes prescription product from the recruiting pharmacy)
8. Computer literate with internet access

Exclusion criteria:

Participants to whom any of the following conditions applied were excluded:

1. Current users of Unifine® Pentips® Plus
2. Participants who had previously participated in this, or any other, market research about needle pen devices in the previous three months
3. Those in the opinion of the Pharmacist who were not suitable
4. Those who inject less than twice a day
5. Those unable to give consent

Full participant demographics are shown in table 1.

Table 1: Study population details

Characteristic	Sub-group	Total	Total percentage
Gender	Male	n=42	71%
	Female	n=17	29%
Age	18-25	n=5	8%
	26-35	n=12	20%
	36-45	n=13	22%
	46-55	n=13	22%
	56-65	n=16	27%
Current pen needles	Unifine® Pentips®	n=4	7%
	BD Micro-Fine +	n=21	36%
	NovoFine	n=31	53%
	Penfine	n=2	3%
	Other	n=1	1%
Length of needles used	5 mm	n=15	25%
	6 mm	n=19	32%
	8 mm	n=25	42%
Number of injections per day	2 injections per day	n=17	29%
	3 injections per day	n=10	17%
	4 injections per day	n=18	31%
	5 injections per day	n=11	19%
	6 injections per day	n=3	5%

Study design

Participants completed a daily online diary, where they were asked to record their pen needle changing behaviour for a period of up to eight weeks. In the first four weeks, participants continued to use their current pen needle, but during the remaining four weeks, they injected using Unifine® Pentips® Plus.

Whilst the short daily questionnaire captured how often participants injected their diabetes medication and how often they changed their pen needles each day, additional questions were asked in order to ensure that the questionnaire did not purely focus on adherence to their current treatment regimen. Furthermore, the questionnaire was conducted over a four week period in order to mitigate against any atypical behaviour resulting from taking part in the research study. It is widely believed in market research that any behavioural research-effect occurs early on in the research and that behaviour normalises over a period of several weeks; thus any uncharacteristic behaviour is average out across the test period.

Figure 1: Daily questions asked both current and the Unifine® Pentips® Plus pen needles

Summary of daily question format:

- What has your day been like today?
- Proportion of time spent at home versus out and about
- How diabetes has affected your day?
- In the last 24 hours how many times have you injected yourself with medication to treat your diabetes?
- Whereabouts did you administer each injection today?
- In the last 24 hours, did you use a new pen needle?
- In the last 24 hours, how many new pen needles have you used on your injection pen device?
- Did you experience any problems changing your pen needles in the last 24 hours?
- What problems did you experience changing your pen needles in the last 24 hours?

During the first four weeks of the study participants continued to use their usual pen needles whilst completing the diary. Participants then returned to the pharmacist who supplied them with Unifine® Pentips® Plus. All pharmacists were trained how to use Unifine® Pentips® Plus and were provided with a dummy pen device so that they could demonstrate to participants how to use Unifine® Pentips® Plus.

Participants then completed the same daily questionnaire for a period of up to four weeks with Unifine® Pentips® Plus. Exactly the same questions were asked for both the current and Unifine® Pentips® Plus pen needle to ensure that no bias was introduced.

After both pen needle testing periods, a short online follow-up questionnaire was completed by participants to assess their overall preference and to directly compare their experiences of using both pen needles, including how easy to use they found Unifine® Pentips® Plus.

Figure 2: Follow-up questionnaire

Summary of the follow-up questionnaire format:

- Thinking about your experience of using Unifine® Pentips® Plus, how easy or difficult was it to change the pen needle? Please score on a scale of 1-10 where 1 = very difficult and 10 = very easy.
- And how easy was Unifine® Pentips® Plus to change compared to your usual? Please answer on a scale of 1-5 where 1 = is much more difficult and 5 = is much easier.
- To what extent do you agree or disagree that Unifine® Pentips® Plus: made it easier to change the pen needle when out and about; convenient to change when out and about; encouraged you to change your pen needle more often; made you more likely to change your pen needle; helped you avoid needle stick injuries. Please score on a scale of 1-5 where 1 = is completely disagree and 5 = is completely agree.
- If given a choice, would you prefer to use Unifine® Pentips® Plus or would you prefer to use your usual? Why did you say that?
- Please rate both your current and Unifine® Pentips® Plus pen needle on the below factors. Please rate them on a scale of 1-10 where 1 = completely disagree and 10 = completely agree: The pen needle is easy to handle; used pen needles are convenient to store; using these pen needles helped to reduce needle stick injuries; the pen needle is comfortable to use.
- Would you continue using Unifine® Pentips® Plus?

N.B. The study design as described above was submitted to and approved by Reading Independent Ethics Committee in the UK.

Statistical analysis

In order to compare the current pen needle testing period with that of Unifine® Pentips® Plus testing period, the total number of injections and the total number of pen needle changes were compared. Significance testing was conducted at the 95% level of confidence ($p < 0.05$) to ensure that any difference in the results was meaningful.

Further analysis was conducted to determine the number of participants who were fully adherent in terms of their pen needle changing behaviour (i.e. who changed the pen needle every single time they injected). Again, statistical significance testing was conducted at the 95% level of confidence ($p < 0.05$). T-Tests and Z-Tests were used to analyse the results.

Additional analysis included descriptive statistics gained from the follow-up interview, in which mean averages and percentage distributions were produced.

Results

A total of n=59 participants were included in the analysis. A total of n=5409 injection occasions were reported for current pen needles and n=5501 injection occasions for Unifine® Pentips® Plus.

Behaviour change

The results of this research showed that participants were significantly more likely to change their pen needle more frequently when using Unifine® Pentips® Plus compared to their current pen needles ($p < 0.05$).

Participants were also more likely to change their pen needle at least once a day when using Unifine® Pentips® Plus when compared to using their current needle (78% vs. 95%). The mean number of needle changes per day for Unifine® Pentips® Plus was 2.69, compared to only 1.95 for current needles.

In addition, when considering the proportions of participants who change their pen needle every time they inject, it was found that 31% of participants changed their pen needle after every injection when using their current needles; this figure increased to 49% for Unifine® Pentips® Plus ($p < 0.05$).

Participants taking part in the research were assessed in terms of their pen needle changing adherence with both pen needle types. Results show that n=13 participants (22%) exhibited non-adherent behaviour when using their current pen needle, but fully adherent when using Unifine® Pentips® Plus.

A breakdown of the levels of reported adherence is shown in table 2.

Table 2: Reported levels of adherence

	Current pen needle	Unifine® Pentips® Plus
Fully adherent pen needle changing behaviour (changed pen needle for every injection)	n=18	n=29
Non-adherence in pen needle changing behaviour	n=41	n=30

Of the n=13 participants whose non-adherent pen needle changing behaviour became fully adherent when using Unifine® Pentips® Plus, n=4 reported having dexterity issues, n=10 were aged over 36. More specifically, n=7 were current users of Novofine pen needles and n=4 were current users of BD Microfine Plus pen needles.

Ease of use

On a scale of 1-10 where 1 is very difficult and 10 is very easy, 80% of participants rated Unifine® Pentips® Plus between 8 and 10, demonstrating its ease of use. 43% of participants found Unifine® Pentips® Plus easier to use compared to their current pen needle, with a further 44% stating that it is at least as easy to use.

In addition, 61% of participants agreed that Unifine® Pentips® Plus made them more likely to change their pen needles.

Preference

61% of participants stated a preference for Unifine® Pentips® Plus. The key reasons driving this preference were: ease of use (38%); ease of disposal (28%); safe (19%); and less bulky or good when out and about (11%).

The remaining 39% of participants claimed to prefer their current pen needles. The key reported reasons behind this were difficulty disposing (43%); taking up too much space (39%); being bulky or not good when out and about (26%); some needles blunt (17%); not quick, fiddly or inconvenient (13%); and not being able to fit as many into pen case (13%).

Conclusion

The study results show that the frequency of pen needle changing behaviour improves when using Unifine® Pentips® Plus and it should be noted that 75% of patients in the study had been diagnosed for more than 6 years. In addition, the pen needles are seen to be easy to use, or at least as easy to use as current pen needles, with only brief additional instruction.

Many participants also prefer Unifine® Pentips® Plus above their current pen needles, and so the new pen needles not only improve pen needle changing frequency but also benefit from being both liked and accepted by participants.

References

1. Diabetes care in the UK, The First UK Injection Technique Recommendations, 2nd Edition.
2. Ginsberg B.H., J.L. Parkes, C. Sparacino: The kinetics of insulin administration by insulin pens. *Horm. Metab. Res.* 26: 584-587 (1994).