

Analysis of the Injection Force of SoloStar[®] Compared with Other Disposable Insulin Pen Devices at Constant Volume Flow Rates

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Abstract

Insulin pen devices have greatly enhanced the portability and accessibility to insulin therapy for millions of people with diabetes. Comparison research data should be reviewed thoroughly.

In this issue of *Journal of Diabetes Science and Technology*, the study presented by Thomas van der Burg is balanced in number of samples tested, same tensile meter, and identical units per second delivery rate into an open beaker. Mean plateau force of SoloSTAR[®] and KwikPen[™] were significantly lower. KwikPen and SoloSTAR utilized 5-mm length 31-gauge (G) needles vs 6-mm 31G needles for FlexPen[®] and Next Generation FlexPen[®], perhaps skewing results in favor of shorter needles instead of device design.

Individual understanding of correct insulin use, appropriate self-monitoring of blood glucose, vision and dexterity capability, and affordability of therapy must be considered first. SoloSTAR holds one unique market advantage, delivery of up to 80 units of insulin per injection.

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Insulin pen devices have greatly enhanced the portability and accessibility to insulin therapy for millions of people with diabetes. Availability of both short-acting and basal insulin in pen devices makes diabetes management more convenient for the individual and improves their chances of achieving tight glycemic control. Given that there are no obvious clinical differences in outcome between similar action insulin compounds, the only marketing differences become out-of-pocket cost, ease of use, and proper identification of insulin product before injecting. An informal survey of wholesale prices and insurance formulary preferences implied that out-of-pocket cost should be similar for all devices

tested, leaving ease of use and identification as the two critical marketing points to consider. Injection force could be a factor in selecting one product over another, but comparison research data sponsored by a specific manufacturer touting one product's benefit over another should be reviewed thoroughly before conclusions are made.

In an article entitled *Injection Force of SoloSTAR[®] Compared With Other Disposable Insulin Pen Devices at Constant Volume Flow Rates* in this issue of *Journal of Diabetes Science and Technology*, Thomas van der Burg's study methods appear to be balanced in number of samples tested (20 each), same tensile meter, and identical

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Abbreviations: (G) gauge, (NGFP) Next Generation FlexPen[®], (SMBG) self-monitoring of blood glucose

Keywords: affordability, compliance, ease of use, glycemic control, injection force

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units per second delivery rate into an open beaker.¹ Unstated but assumed to be equivalent are temperature of insulin compound, room temperature, and atmospheric pressure for each test sequence. It is also assumed that the fluid viscosity of insulin glargine, insulin detemir, and insulin lispro remains identical between products at temperature and pressures tested. Manufacturer recommended needles were used to replicate home use, but needle length would affect injection force given the same 31-gauge (G) bore size. It is interesting to note that the mean plateau force of SoloSTAR® (sanofi-aventis, Bridgewater, NJ) and KwikPen™ (Eli Lilly and Company, Indianapolis, IN) was significantly lower than that of the FlexPen® (Novo Nordisk Inc., Princeton, NJ) products. In this test both KwikPen and SoloSTAR utilized 5-mm length 31G needles vs 6-mm 31G needles for FlexPen and Next Generation FlexPen® (NGFP), perhaps skewing results reported in favor of shorter 31G needles instead of injection device design.

While injection force is a valid point in evaluating ease of use for self-injection, another factor not discussed is indwelling time of needle in tissue. KwikPen directions for use state that the needle must remain *in-situ* for a slow 5 count, FlexPen and NGFP require a slow 6 count, while SoloSTAR instructions are for a slow 10 count before needle removal. When used according to manufacturer supplied instructions, persons with impaired dexterity may have difficulty in maintaining less pressure for a longer duration, negating the advantage of lower injection force needed for actuation. Variance in tissue composition will also affect pressures needed, but is best evaluated by the individual and their health care provider.

SoloSTAR holds one unique market advantage, the ability to deliver up to 80 units of insulin in a single injection. For some, this may be a key point for selecting SoloSTAR devices over competitors. Decision of what insulin compound to use should be the primary concern for the prescribing practitioner; lower injection force and shorter push-button travel may be less of a concern than out-of-pocket cost for the product prescribed.

While appropriate therapy selection is most important to the prescriber, *affordability* is the primary concern of the individual for compliance to the prescribed therapy. Many life-saving medications are being abandoned at the pharmacy counter as the health care consumer struggles to cope with lower income, high-deductible insurance, and rising copayment. Recently a Consumer Reports survey found that 27% of individuals questioned did not

take prescriptions as directed in order to save money. Cost-saving tactics include skipping doses, not getting prescriptions filled, sharing prescriptions, and taking expired medication. Reusing pen needles and lancets along with skipping self-monitoring of blood glucose (SMBG) tests to cut expenses are occasional admissions during detailed therapy review. Increasingly, diabetes specialists must choose lower cost therapy options to assist their patients with compliance.

New insulin products, both basal and short acting, are expensive. Human recombinant insulin may not be the latest "drug of choice" given current therapeutic options, but it costs less. Failure to maintain reasonable glycemic control due to out-of-pocket expense is unacceptable. Practitioner assessment of individual understanding about correct insulin use and appropriate SMBG, vision and dexterity capability, and affordability of therapy are important factors to consider before a treatment plan is finalized. Other considerations, such as less injection force needed, become of secondary importance.

References:

1. Van der Burg T. Injection force of SoloSTAR® compared with other disposable insulin pen devices at constant volume flow rates. *J Diabetes Sci Technol* 2011;5(1):150-7.