

DBA Design Effectiveness Awards 2009

SoloSTAR®

A disposable pen injector for insulin



Category:	Product
Sub category:	Consumer
Client company:	Sanofi Aventis GmbH
Design consultancy:	DCA Design International Ltd
Current date:	2nd June 2009

Executive summary

Pen injectors were introduced over 20 years ago to deliver liquid medication. They allow users to select a dose of medication and inject this via a needle connected to a small reservoir within the pen.

In Europe, Japan and the US, pen injectors are commonly used to deliver insulin for the treatment of diabetes mellitus. In many countries they have largely replaced the traditional vial and syringe because they benefit patients by allowing accurate and easy dosage, whilst being convenient and discrete.

Lantus[®], a new once a day basal insulin, was originally offered in a licensed injector device but in order to sustain the development of the new insulin, Sanofi Aventis decided to begin developing its own pen in 2003. The new device could not be a 'me too' product; it had to offer significant improvements over all other disposable insulin devices on the market.

The design brief was suitably ambitious. In order to satisfy the needs of patients requiring high dose volumes of insulin, the new pen injector had to be capable of delivering a single dose of 80 insulin units (over 30% larger than all comparable devices on the market) with no penalty for comfort and convenience. In addition to being extremely robust, the device also had to satisfy the very high accuracy standards outlined in ISO-11608.

The solution is SoloSTAR[®]. SoloSTAR[®] meets all of these requirements and exhibits significant advantages over previous devices in terms of comfort, safety and ease of use¹. Since its launch in 2007, SoloSTAR[®] has rapidly established itself as a leading disposable pen injector for insulin, accounting for 41% of all growth in the global injectable insulin market in 2008².

(277 words)



Project overview

Outline of project brief

To develop a 'best-in-class' disposable pen injector with the following key features:

- Maximum selectable dose up to 80 units in 1 unit increments.
- Dose correction without penalty, i.e. the possibility to dial back without expelling liquid.
- The lowest injection force in its class.
- User interface design based on good ergonomic principles.
- Simple, obvious operation with no additional steps beyond selecting and dispensing a dose.
- Suitable for extremely high volume manufacture at low cost.
- Safe, robust and reliable.
- Maximum differentiation for devices containing different insulins.

Description

SoloSTAR[®] contains 3ml of insulin, dispensable in single unit increments (0.01ml). The user selects a dose by rotating a dial and injects this volume by simply depressing the dose button.

Improvements over predecessor devices have been achieved in all key areas (from initial learning through to daily usage) and together they provide genuinely important advantages for users. SoloSTAR[®] is the first disposable insulin pen to combine very low injection force (which provides a smooth injection experience for patients) with 80 units maximum dose capability, an important breakthrough.

Overview of market

Measured by the number of insulin units (IU) prescribed worldwide, the total market for injectable insulin grew from 217 Billion IU in 2003 to 302 Billion in 2008.

Of the different methods of injecting insulin available, disposable pen injectors form the fastest growing sector, up from approximately 20% of the market in 2003 to 31% in 2008³.

In 2003, Sanofi Aventis held just 6.1% of the total disposable insulin pen market, well behind its two main rivals Novo Nordisk (60.2%) and Eli Lilly (29.2%)⁴.

Project launch date

April 2007 in Germany.

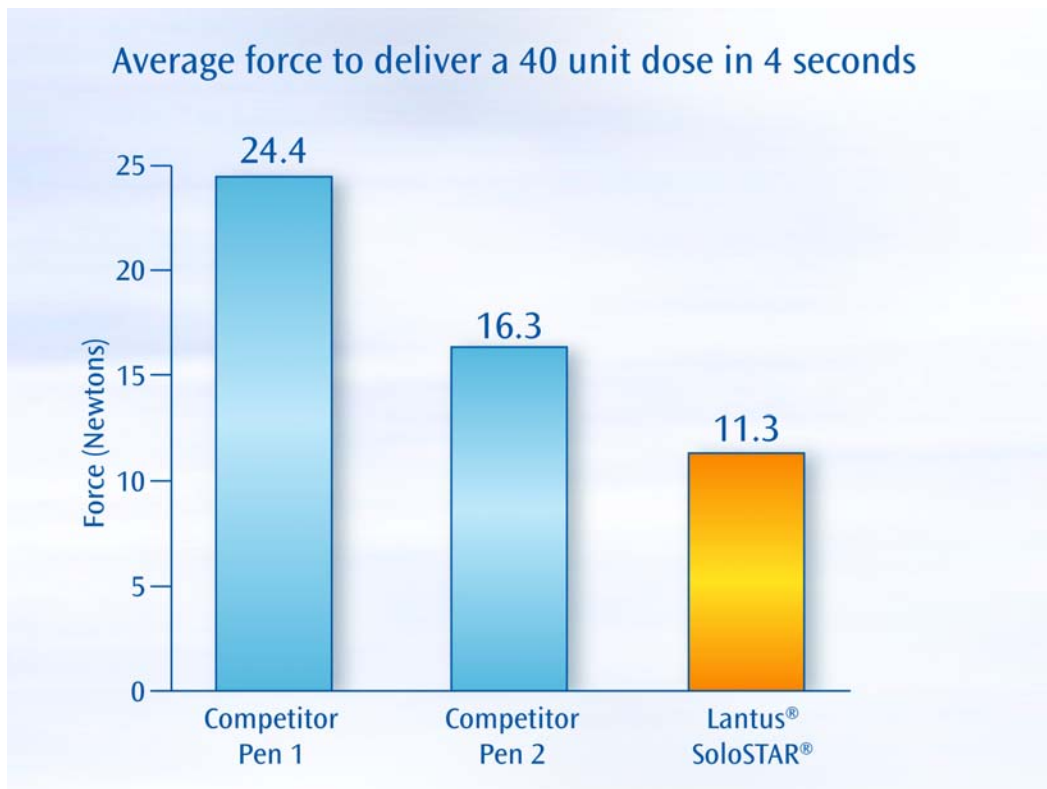
Size of design budget

Not available

Outline of design solution

The key technical challenges faced in developing SoloSTAR[®] resulted from worldwide research, which indicated that users strongly desire low injection force together with a large selectable dose range.

A fundamentally new operating mechanism was needed to resolve this problem. The highly efficient mechanism at the heart of SoloSTAR[®] is the product of a rigorous, evidence-based engineering design process. This innovative mechanism gives SoloSTAR[®] the lowest injection force in its class (over 30% less than key competitor devices)⁵.



During the development of SoloSTAR[®], the design team held the needs of users in primary focus and careful consideration was given to visual design. SoloSTAR[®] has a discretely appealing form that helps to neutralise any stigma that may be attached to its use in public.

Colour is used to enhance safety by minimising the risk of a misidentification. In fact SoloSTAR[®] Lantus and Apidra have a total of five differentiation features for improved safety: body colour, dial colour, button colour, label design and a tactile feature on the injection button of the Apidra pen.

As many diabetic sufferers experience vision deficiencies, a very clear, high-contrast dial number display with magnification was also developed.

(480 words)



Summary of results

Increase in sales

Analysis of the market growth during 2008 shows that SoloSTAR[®] is highly successful. Around the world, SoloSTAR[®] has become the engine for growth in sales of Lantus[®]. Between October 2007 and October 2008, the Lantus[®] SoloSTAR[®] device alone captured:

- 41% of the total growth in the injectable insulin market⁶,
- and accounted for 89% of Sanofi Aventis' annual consumption growth in the injectable insulin market⁶.

Reductions in manufacturing costs

SoloSTAR[®] has few components and is designed to facilitate very high speed automated manufacture and assembly. Careful attention to these aspects means that greatly improved functional performance is gained with no cost penalty over previous devices.



Increases in market distribution

Before the launch of SoloSTAR[®], Sanofi Aventis did not market disposable insulin pen injectors in the US and Japan. The disposable devices available at the time simply did not meet the particular needs and expectations of these important markets.

SoloSTAR[®] has been launched into both of these markets and is proving very successful, as can be seen in the sales evolution graphs shown on the previous page.

Increases in market share

The worldwide sales evolution in the first 15 months after launch clearly shows that Lantus® SoloSTAR® has overtaken the closest basal insulin competitor⁷. In fact, in the last quarter of 2008 Lantus® SoloSTAR® achieved almost 45% more sales (by volume) than this competitor. This success demonstrates the markets' preference for a device designed with the patient's needs at the heart of its development.

In 2008, Sanofi Aventis' share (volume share) of the total disposable insulin pen market grew to 22.7%, with Novo Nordisk taking 61.8% and Eli Lilly 14%⁸. This represents a significant improvement on the position in 2003, when Sanofi held just 6.1% of this key market, indicating just how successful SoloSTAR® has been.

Improvements in staff morale

DCA have been working alongside a dedicated device department set up at Sanofi Aventis to develop injection devices. All members of the team involved in the project are very proud to have helped create such a globally successful product.

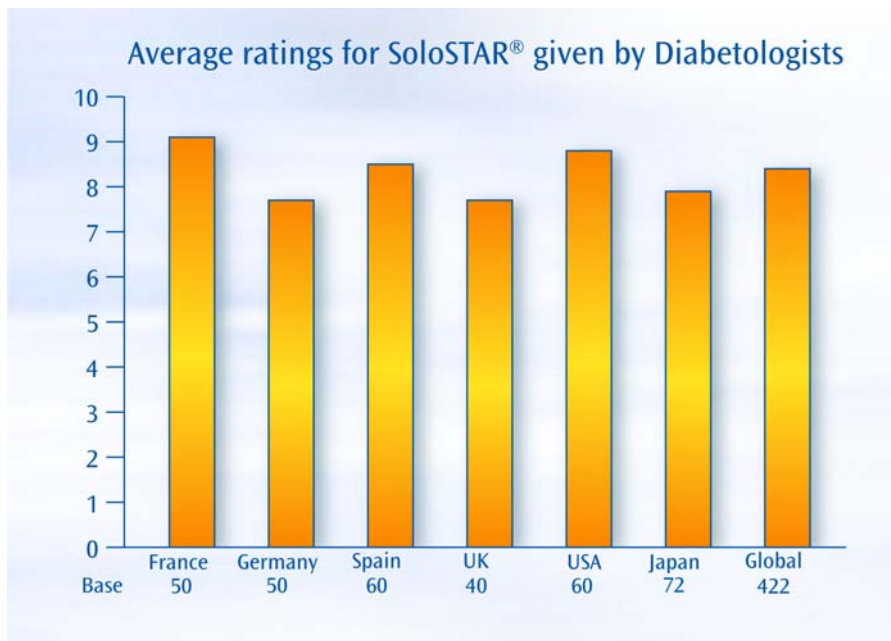
A great deal of positive feedback has also been given by the Sanofi Aventis global sales teams who are delighted that they are now able to offer their best-in-class insulin (Lantus®) within a best-in-class device.

Improvements in consumer attitudes or behaviour

In September 2008, Sanofi Aventis commissioned market research agency Ipsos Health to undertake interviews with over 2000 health-care professionals, who are involved in the initiation of treatment for patients with diabetes in eight major countries around the world⁹.

One of the questions that this group were asked was whether SoloSTAR[®] has changed attitudes towards prescribing Lantus[®]. 69% of physicians responded that the availability of the SoloSTAR[®] pen increases their likelihood of prescribing Lantus[®] to patients.

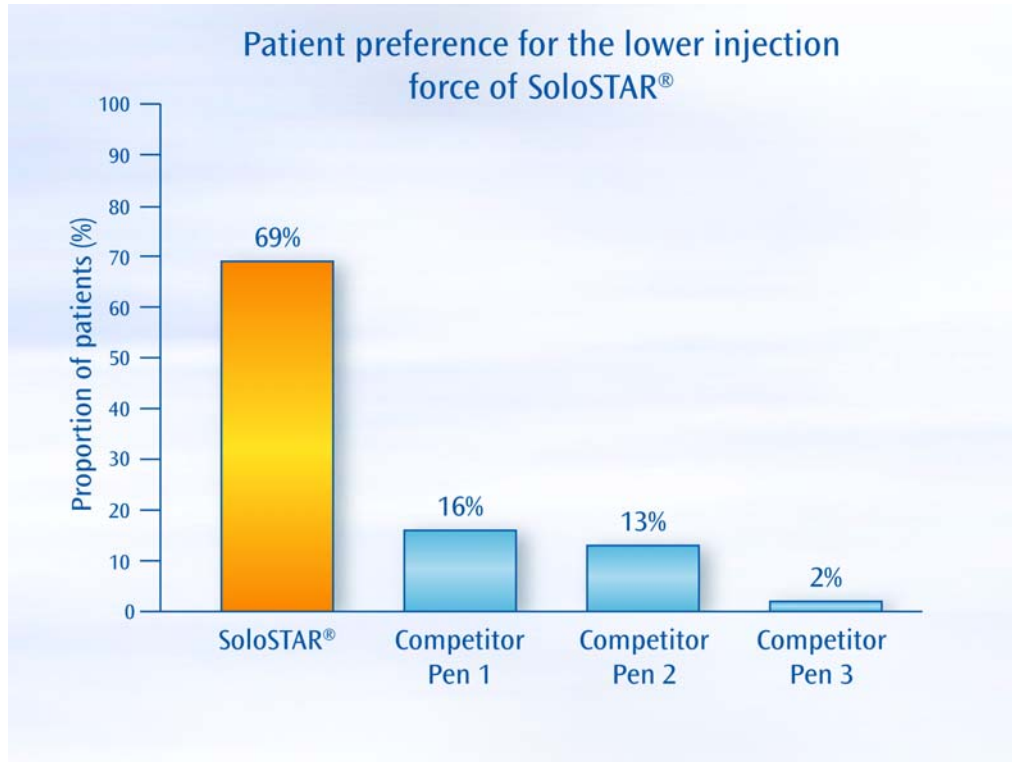
Within the same study 422 specialist Diabetologists were asked how they would rate the SoloSTAR[®] device overall, on a scale from 1 to 10. The chart below shows the average ratings given by Diabetologists from the six largest markets, as well as the result for all responses globally.



“SoloSTAR takes very little time to teach... we can teach more patients and teach them more quickly. And that is a huge advance.”

Maureen Bancroft (Diabetes Nurse, UK)

Market studies¹⁰ undertaken by Sanofi Aventis have also shown high acceptance of SoloSTAR[®] by patients. The graph below illustrates one key element of this.



"I have got rheumatoid arthritis and my fingers are buckled, but I can manage the pen. I think it's fantastic, the Lantus SoloSTAR. ... If I can do it, anyone can do it!"

Wendy Tait (Diabetic patient, Australia)

Research sources

- 1 - Clinical Therapeutics 2007. Haak T, et al.
- 2 - IMS Health 2008. The world's leading provider of market intelligence to the pharmaceutical and healthcare industries.
- 3 - IMS Health 2008. The world's leading provider of market intelligence to the pharmaceutical and healthcare industries.
- 4 - IMS Health 2008. The world's leading provider of market intelligence to the pharmaceutical and healthcare industries.
- 5 - Expert Opinion on Drug Delivery (2007) 4(2) pages 165-174, Clarke and Spollet. Comparison is made for the mean force of the total dose between SoloSTAR[®], Novo Nordisk Flexpen[®] and Eli Lilly Humalin[®]/Humalog[®].
- 6 - IMS Health 2008. The world's leading provider of market intelligence to the pharmaceutical and healthcare industries.
- 7 - IMS Health 2008. The world's leading provider of market intelligence to the pharmaceutical and healthcare industries.
- 8 - IMS Health 2008. The world's leading provider of market intelligence to the pharmaceutical and healthcare industries.
- 9 - Ipsos Health. Help pharmaceutical, biotech and medical device businesses around the world understand patients, prescribers and influencers.
- 10 - Clinical Therapeutics 2007. Haak T, et al.

Other influencing factors

A number of PR events for press/ doctors/ nurses were held to increase awareness of the new product; a number of publications have also featured articles which challenge the competition on dispense force, importance of dose accuracy for the therapy, etc.