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FEATURE ARTICLE

Are You Missing the Point?

The Evolution of Syringes & Injectable Delivery Systems

Feature Article

Are You Missing Point?
The Evolution of Syringes & Injectable Delivery Systems

The word syringe comes from the Greek word ‘syrinx’ meaning tube.

In its most basic form this is exactly what it is, a tube or barrel into which a plunger fits, which can be pulled and pushed along the tube to draw in, and push out an injectable substance. At the other end of the tube is an opening which can be fitted with a hollow needle, cannula or other attachment, these days via a Luer lock fitting, develop by Fairleigh S. Dickinson of Becton Dickinson fame in 1930 (trade-marked Leur Lok™).

The use of syringes dates back to the Romans, with the invention of the hollow needle to attach to a syringe coming about in the mid-1800s. It has been a staple in medicine ever since and to be honest has not really changed beyond all recognition in that time. We still have a barrel and a plunger – albeit plastic and rubber have mostly replaced glass tubes in metal housings, making them ‘disposable’ and safer than devices which needed autoclaving, but the principle design and application is still the same, we have just developed the materials and the ergonomics.

Which leads to the age old saying - ”*If it ain’t broke, don’t fix it*”- so why develop the concept yet further?

Cynics would say that if you always took that attitude then we would have not seen any research and development and innovation is many of the areas of our everyday lives, just because a concept works, doesn’t mean it can’t be improved upon.

But conversely, when an advancement is just done for the sake of advancement, and not really improving the original concept and function, then you have to question whether it should just have been left alone. Sometimes we can be guilty of simply over-engineering a concept and just making things more costly.

This is what I am seeking answers to – are we just missing the point – do we really need to improve on the humble hypodermic syringe, beyond the comfort and feel in the hand?

Of course, the concept of pen injectors or auto-delivery injection devices is nothing new in many areas of medicine, so learning and evolution has certainly come from everyday solutions such as epi-pens and diabetic insulin self-injector pens.

Technological advancements, led by the rise in the market for facial injectable treatments, has led to a number of recent innovations coming to market as alternatives for the pre-packed syringes shipped with most dermal filler brands, or the insulin syringes favoured by practitioners delivering botulinum toxins. So called smart needles or motorised pen injectors control the flow of the product being delivered, provide accurate dose delivery and offer audible or tangible feedback to the user (the practitioner administering the injection) to aid the practical experience.

This article will look at some of the concepts now available to medical aesthetic practitioners for the smart assistance in the delivery of soft tissue fillers or botulinum toxin products. It will not include so called ‘meso-guns’ such as the U225 or larger scale automated injection systems such as Artiste.

The Claims

Dose Delivery Accuracy

Many syringe systems are now available with either pre-defined (according to the product recommendations) or customisable dose delivery settings either built-in or on the barrel of the syringe.

These provide an audible and tangible feedback system in the form of a click, and some resistance to alert the practitioner to the successful delivery of a predefined dose of product.

The claimed benefit from such systems is that it allows the practitioner to concentrate on injection technique and interaction with the patient, without the need to constantly refer back to the dose markings on the barrel of the syringe which may or may not be easily visible at the time of delivery. Similarly, avoiding the need to make sure the barrel is in the correct orientation to be visible at the point of insertion and product delivery. Practitioners can literally 'take their eye off' it and rely on a 'click' to let them know they have given the dose.

It could be argued that this sounds like a lazy option, or perhaps even a 'dumbing down' in the skill set requirements for delivery of the treatment. Yet, many converts to such systems are quick to point out, in no uncertain terms, that such devices should no longer be viewed as something for novices, but as serious devices for accurate dosing which can be used by all levels of practitioner.

Reduced Pain

Many of the devices on the market claim that more automation and less reliance on direct extrusion force by the practitioner results in less pressure on the syringe and ultimately less pain for the patient. Creating a controlled delivery with a constant pressure of product delivery is claimed to increase patient satisfaction due to the reduction in pain and potential for bruising.

Devices For Use With Dermal Fillers

PPI® Injector – Restylane Vital White Pen Injector

Back in the mid- to late- 2000s, the first true pen injector to hit the aesthetic marketplace, came as an option for delivery of the Restylane Vital and Vital Light products, now referred to as Skinboosters.

Each disposable pen injector came preloaded with 2mls of product in a glass syringe and also included three needles. It required manual winding by the practitioner before its trigger mechanism could be used to release a precise amount of product (10 µl) into the skin, via a 'clicker' button press on the side, meaning uniform injection and results.

This **Precise Pen Injector (PPI)** system, which was branded specifically for Restylane, comes from the seasoned, Swedish auto and pen injector designer and manufacturer, the SHL (Scandinavian Health Ltd) Group, known for their diabetic solutions.

It worked well, but as an early innovation, it still needed improvements and many practitioners found flaws, including its cumbersome nature when in small hands, and the need to constantly wind it up, which became a nuisance.

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Restylane SmartClick™

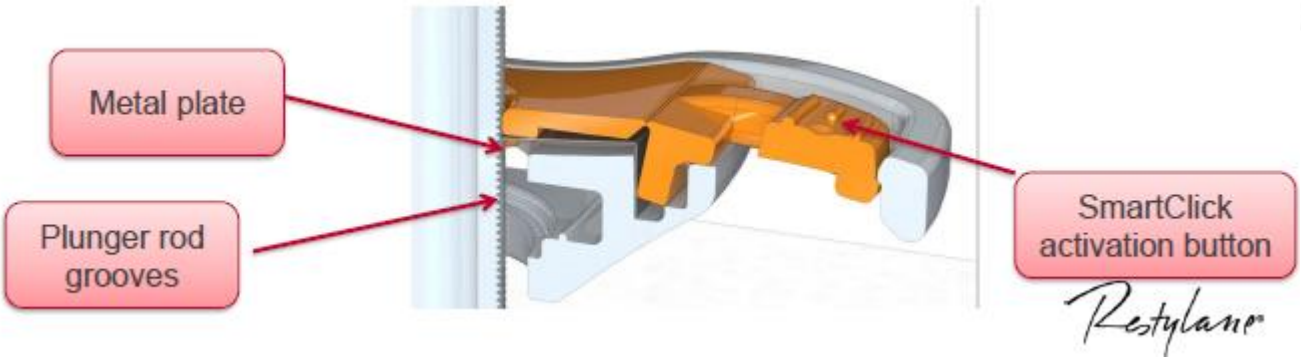
The SmartClick™ system introduced by Galderma on the Restylane Skinboosters™ (Vital and Vital Light) products back in 2014 has a built in audible dose control which dispenses 10µL microdroplets of product on each 'click'. A 1ml syringe delivers 100 doses, although you can expect to lose between 20 and 40 µL as you prime the SmartClick system. It does not control the flow of the product.

The company claim to have developed and brought this device to the marketplace because their Skinboosters product has been shown in a paper by **Streker M et al** to give better results when small amounts are distributed evenly in the skin using the precise delivery offered by the SmartClick system.

The system has also been designed, alongside a new syringe for the other main Restylane range, to feel lighter and be more ergonomically shaped for a comfortable grip and sculpted thumb rest. It also includes a tamper-proof seal to guarantee product authenticity and improvements to the Luer lock system.

The SmartClick system consists of a finger grip with a built in metallic plate and a plunger rode with grooves. The dose is indicated by a clicking sound which is generated when the metallic plate is pressed over the grooves on the plunger rod by the practitioner.

The SmartClick option can also be turned on and off via an activation button on the finger grip, which will push the metallic plate against the grooves. Once deactivated, the syringe will function just as a normal syringe, offering practitioner versatility. When the SmartClick is activated the extrusion force of the syringe is higher than when deactivated, although the difference is minimal (3 newtons) and said to be unlikely to be noticed by the practitioner.



Galderma note in their documentation that: "*This new delivery system is an intuitive solution designed so that minimal training is required for clinicians experienced with injectables. For clinicians new to injectables, the new delivery system was designed to lower the required training time.*" The Restylane Skinboosters SmartClick™ System also received the Red Dot Award for high design quality in 2014, where it was in competition with over 1,800 other international entrants looking to scoop the award for innovation.

Cosmetic Nurse, Claudia McGloin said; "*I've used both of the Restylane solutions - the old pen injector was a bit of a nightmare as you had to constantly wind it up and there were times during a treatment that I'd forget! I much prefer the new SmartClick one. It's easy to use and less painful for the patient. These devices are good for even distribution of product and in some cases you may use less product.*"

TEOSYAL® PEN

Launched to the UK aesthetic marketplace in 2015, the TEOSYAL® PEN from Teoxane UK, became the first motorised and cordless device specifically created for the injection of hyaluronic acid (HA) for soft tissue filling indications to be marketed to the sector. It is a European CE marked Class IIa device which is manufactured by JuvaPlus and licenced to **Teoxane Laboratories** for worldwide distribution and commercialisation (apart from in the USA) for this indication.

The device facilitates the injection of HA using two programmes (a linear or droplet – small, medium or large - delivery style) and three different speeds (slow, medium or fast) within an ergonomic and light weight design. This, according to the makers, provides complete control over pressure, speed and product quantity delivered. It is claimed to be especially beneficial for treatments in the oral, peri-oral and peri-oribital regions where more precise and homogeneous injections of HA are required for a natural result. The manufacturers also claim that it is less painful then manual injection, with a smoother delivery and increased patient satisfaction. With little comparative data to go on, other than anecdotal user feedback and manufacturer backed trials, it is difficult to determine if it really is better than using a manual syringe, especially given the cost differential to the practitioner and patient.

The main data available comes from a 2014 study by Kantar Health, known as the European TEOSYAL®PEN trial which included 30 physicians and 236 patients. 42 patients had never received manual injection with a hyaluronic acid-based filler. Results from this claimed a 50% reduction in pain intensity versus manual injections, as reported by the physicians. As well as faster recovery and more natural results, with 9 out of 10 patients saying they would prefer to have their next injections with the TEOSYAL® PEN versus manual injections.

Another study carried out by Teoxane Laboratories which looked at 2,000 patients who had previously been injected manually, found that 95% reported that the TEOSYAL® PEN was at least 60% less painful than the manual injections.

Using the flow mode, an average of 7µL per second can be delivered on the slow rate, 19µL per second on medium speed and 40µL per second on fast. Using the droplet mode for a 1ml syringe, an average of 1,429 x 0.7µL small droplets can be delivered, 454 x 2.2µL medium droplets or 251 x 4µL of large droplets. Slow speed is recommended for superficial wrinkles and delicate areas such as tear troughs, medium speed for superficial to moderately deep wrinkles and lips, and fast speed for deep injections.

Users note that it is easy to assemble and use. It is provided with single use syringe holders (called Teolink) to ensure sterile product delivery, and is compatible with most of the hyaluronic acid brands available on the market, coming with pre-set, colour coded modes for precise deliver of each product, plus it is compatible with all Luer Lock needles and cannulas. It is compatible for use with various products (but not all) within the following brands, (a full list is available from Teoxane UK): Stylage, Juvéderm (Ultra and Vycross), Perfectha, Belotero, Princess, Restylane, Emervel and Teosyal. Some product derivatives have a syringe shape which stops them fitting through the Teolink, something which Teoxane say they are working on.

The TEOSYAL® PEN weighs in at 40 grams and its dimensions are 130mm x 24mm. As a motorised device, it produces an electronic whirring noise as it delivers the HA – which some patients may find disconcerting. Battery life allows for the use of approximately 50 syringes between running out. The device will also automatically switch itself off after approximately 4 minutes of inactivity to save on battery. With each box of 25 Teolink syringe holders

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a new battery is also provided. An 18-month manufacturer's guarantee is provided, with the option to take out extended cover.

Appropriate care must be taken with cleaning the TEOSYAL® PEN, in between each use, ideally as soon as practically possible after use. This means that you remove the needle, the syringe and the syringe holder. You press the return or rewind button, this is so the lead screw goes to its original configuration, and then you wipe the system with a damp cloth and 1:100 dilution of 5.25%-6.15% sodium hypochlorite to remove viable organic residues. You should not immerse or soak the device in other liquids or place it in an autoclave.

The Teosyal Pen has won the Anti-Aging & Beauty Trophy for Best Aesthetic Device Trophy at the 2nd Anti-Aging Medicine European Congress (AMEC).

Dr Kieren Bong, Medical Director of Essence Medical Cosmetic Clinic in Glasgow, is Key Opinion Leader and International Trainer for the Teosyal range of dermal fillers. He says; "*The fear of pain and side effects are leading factors holding back a significant proportion of my patients from having dermal filler procedures. One of the advantages of TEOSYAL PEN is that it delivers a smooth and consistent flow with minimised pain.*"

The device is not without some criticism though. One cosmetic doctor told me that he was concerned that the device has no cut off mechanism when pressure increases. An increase in the pressure required to inject a dermal filler product can indicate an intravascular injection, thus no safety cut off was, he felt, a weak point in its mechanism of action.

In fact, the risk of intravascular injection is something that the company also feel the need to address, and devote a section to it within their user manual documentation, looking at issues related to whether it is possible to aspirate with the TEOSYAL® PEN to check if the needle has been placed in a blood vessel. It is not possible to aspirate with the device and this is what the company say to justify it:

> "*One of the biggest fears of the physicians who inject HA fillers is indeed to block a vessel with the gel which will lead to embolism and a subsequent necrosis. As a prophylactic measure, blood aspiration is thought to be needed to see whether the needle is in a vessel and several physicians often aspirate before injecting for reinsurance to be outside of a vessel to avoid necrosis.*
>
> *In a recent paper published in Clinical, Cosmetic and Investigational Dermatology, Dr. De Boule suggests that in highly vascularized areas, an aspiration should be done with a new needle (without priming it with a filler) prior to deep bolus injection.*
>
> *A work that will be published soon in a special edition of Journal of Dermatologic Surgery by Dr. Wayne Carey clearly demonstrates that:*
>
> > *- it's indeed possible to aspirate blood when the needle is not primed but,*
> > *- it's impossible to aspirate blood into a syringe when the needle is primed for up to 90% of available fillers.*
>
> *Only the very light fillers designed for very superficial injections could allow blood to be aspirated but at this depth, no vessels are present. This ex vivo work (with an aspiration of blood into a tube) shows that when gel is into the lumen of a needle (the gel is extruded before injection in most of the cases), the plunger has to be pulled back for at least 4 cm and you have to wait few seconds for the gel to move back in the syringe (even with very "light gels") and the blood to be aspirated. It will be nearly impossible to stay that long and with this high force to pull back the plunger when the needle is in the dermis of a patient.*
>
> *This work thus clearly demonstrates the uselessness of blood aspiration when the needle is primed. On a daily basis it will also be very tricky, unrealistic or even impossible to change the needle at each injection point in order to check by aspiration whether the needle is in a vessel.*
>
> *Dr. Carey also states that with the well-controlled flow delivered with the pen, the risk of necrosis and other side effects is highly reduced (these side effects often arise because of a too quick injection under high pressure). With Teosyal Pen, the pressure is constant and the speed is well controlled – the physicians can also concentrate on the injection and not on the pressure to apply, making the injection safer for the patients. And it is not possible to aspirate with Teosyal Pen.*"

The TEOSYAL® PEN is available direct from Teoxane UK priced at £1,500 +VAT. On purchase of the device one box of 25 TeoLink syringe holders, and a spare battery, is included free of charge. Replacement packs cost £60.00 +VAT.

For Use With Botulinum Toxins

Juvapen

Following the successful launch of their partnership product with Teoxane Laboratories, the TEOSYAL® PEN, Swiss company **JuvaPlus** is now embarking on launching another European CE marked Class IIa motorised and cordless device specifically for the injection of botulinum toxins (BoNTA), the **Juvapen**. The device was officially launched to the European marketplace in October 2015, and was featured at IMCAS in Paris and the AMWC in Monaco earlier in 2016. The general concept and design is very much the same, using a 40g, lithium battery powered device. The device is patent pending.

Compatible with all dilutions of approved botulinum toxins, the Juvapen comes with 6 pre-set doses - 0.0125ml, 0.020ml, 0.025ml, 0.050ml, 0.100ml and 0.125ml - and has 2 constant flow modes, slow and high speed.

The method of operation is to unpack the syringe, and fill it with diluted toxin to the desired volume. Then break the syringe rod and insert the syringe into the syringe holder.

You then need to connect the syringe holder to the Juvapen, select the desired dose from the options on the device handle and then inject by pressing the activation button via depressing the arm on the syringe holder. The Juvapen motor whirrs into action and the spring guided plunger at the end of the device is pushed forward (the distance depending on the dose selection) and will then inject just the preselected dose by pushing the plunger within the syringe.

See this **video** for exact details on how to use the device.

Product waste is said to be minimised due to the increased control over dosage. The increased dose accuracy (said to be +/- 2%) also allows for a high concentration dilution. Peak injection pressure is said to be controlled through the motorised flow management and the size of the needle used can thus be reduced, which has an effect on reducing pain for the patient.

As with other dose control mechanisms, patient follow-up and treatment optimisation is better managed as the exact dose delivery is known and the treatment is repeatable.

Those practitioners who offer so called ‘baby botox’ or ‘tiny toxin’ treatments which use many, small dose injection points are said to like this controllable, automated delivery solution.

Currently, the Juvapen is distributed outside of the USA by Swiss company Medical Development and Marketing Services (MDMS) SA. The manufacturers JuvaPlus note that regional distribution channels for the Juvapen will be available soon. The device is set to be demonstrated at many European conference events being held this summer.

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TSK 3Dose™ & Unit Dose Injector

TSK Laboratory Europe BV, based in The Netherlands, introduced the 3Dose™ BoNT syringe to the UK aesthetic marketplace following initial launch at the AMWC in 2014. Designed to deliver an accurate dose of botulinum toxin via an audible and tactile clicker system, it is compatible with all the available botulinum toxin dilutions to give precise unit delivery. It also combines a low dead space needle hub to reduce the wastage of product, which can typically be up to 0.08ml. The system is designed to deliver a precise dose injection of 0.025ml, 0.04ml and 0.05ml.

As with other dose delivery systems, the aim is to take away the need to constantly look at the markings on the barrel of the syringe to assess how many units of product have been delivered at each injection point.

It is claimed, that this method of more accurate dose delivery, rather than simply the practitioner gauging their view of units delivered by the syringe markings which can lead to a 10-20% inaccuracy rate both under and over-dosing, allows for improved control and traceability on exactly how many units of toxin were actually injected. Inaccurate dosing can lead to an increase chance of a debilitating or unsightly (perhaps unbalanced) result and a dissatisfied patient, claim the company, thus 100% accurate quantities placed in each injection site removes this problem. The use of accurate dosing can benefit both experienced and more novice, or less frequent injectors of botulinum toxins. A more predictable outcome is achieved and the results are more reproducible for the patient each time that they visit for repeat treatment.

Fast forward two years and the company, and its core manufacturer, Vlow Medical are about to launch a second generation product design to the marketplace this summer.

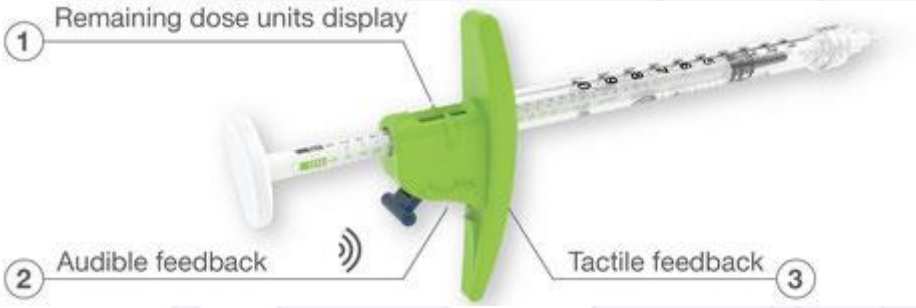
The new 3Dose™ Unit Dose Injector, is firstly being targeted for use with botulinum toxins, as its predecessor, but is being developed for use in other medical applications.

The new 3Dose™ injector claims to make calculating units per ml more simplified and will eliminate calculation errors for botulinum toxins in cosmetic practice. The injector is available in a green (125) and orange (100) version, each with different user preferred dose unit settings related to the various NaCl (saline) solutions used to dilute the botulinum toxins.

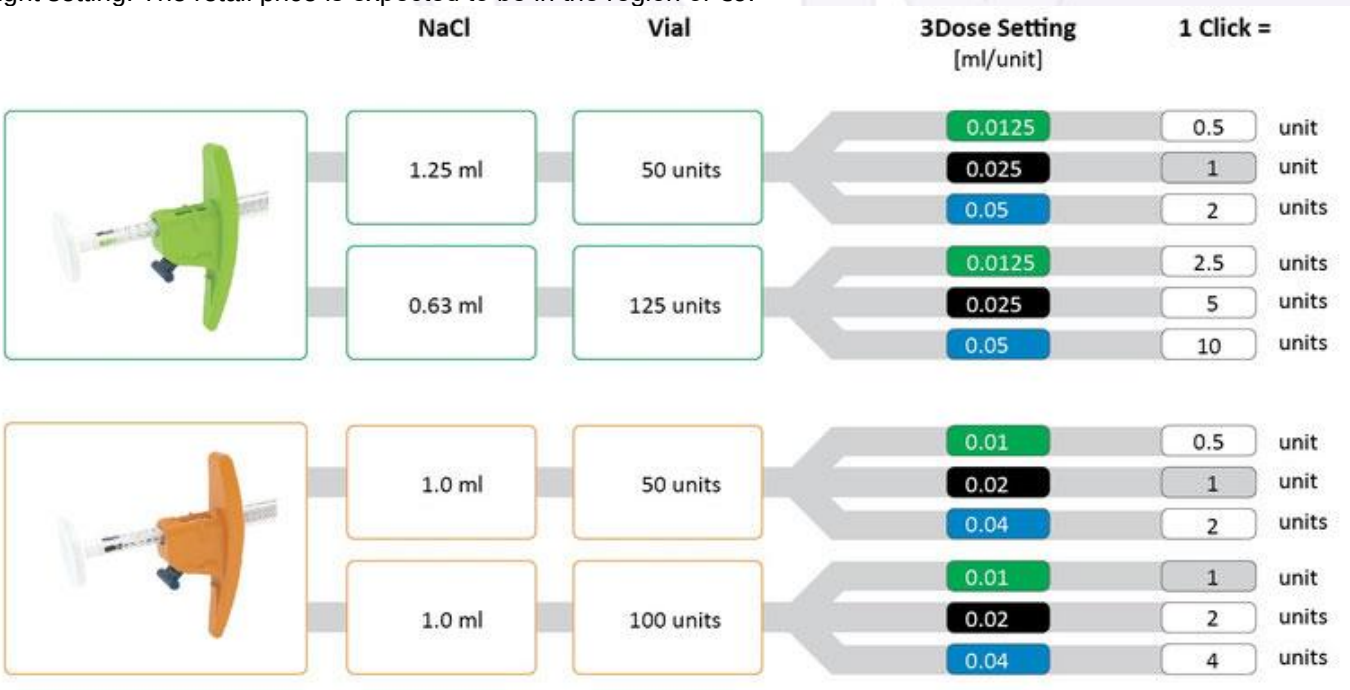
The green syringe features the 3 dose unit setting options 80 x 0.0125ml, 40 x 0.025ml and 20 x 0.05ml for the dilution

amounts 0.63ml and 1.25ml. The orange syringe features the 3 dose unit setting options 100 x 0.01ml, 50 x 0.02ml and 25 x 0.04ml for the dilution amounts 1.0ml and 2.0ml.

The 3Dose™ now also features a more ergonomic handling design, with an improved plunger and thumb rest. It continues to have a low dead space design to eliminate product loss, alongside a Luer Lock connection for compatibility with all needles – including the new INViSIBLE NEEDLE™ from TSK, which is said to provide a significant reduction in pain compared to standard 30G needles. The window on the finger grip window displays, at a glance, the remaining available units, at the reconstituted dilution, for easy viewing of what is left as the treatment progresses.



Available in a sterile blister pack for single use with a dilution table printed on the box to assist with choosing the right setting. The retail price is expected to be in the region of €5.



Mr Dalvi Humzah FRCS (Plast) from Midland's based clinic **PDS**, is a Key Opinion Leader for TSK, but holds no financial interest. In his opinion, from having used the first generation 3Dose injector extensively and tested the new generation device and INViSIBLE NEEDLE, it is indispensable and priceless in his practice.

He told me; "*Injecting small doses of toxin in small volumes (0.1, 0.05 & 0.025 mls) requires accuracy and to do so means parallax errors and positioning of the syringe barrel is important. The patient, at the other end of the needle sees the practitioner injecting them and concentrating hard on the markings of the syringe. Often the facial expressions of the practitioner show the tension as they are being injected. The practitioner has to multi-task (not easy for all) - concentrating on reassuring the patient, maintaining the needle depth and also watching the position of the plunger on a small area of the syringe.*

Using the first generation 3Dose, and more recently looking at the new Unit Dosing Injector, I can fully concentrate on the patient and maintain the position of the needle. Keeping my head in a comfortable position and not having to look at the marking or position of the plunger I get a tactile and audible click as the appropriate dose is delivered. All the time I can interact with my patient and be assured I always deliver the exact dose in whatever lighting condition or position the syringe and needle is placed in. Using this system, I never have to look at the markings of the barrel and as the syringe also calibrates the amount of "shots" left in the syringe I don't have to work out if I have enough left in the syringe to treat the patient. Finally, the syringe is a no dead space syringe so there is no wastage of toxin (combined with a low dead space needle hub saves even more toxin)."

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Conclusion

I am a layperson, not a medic, but I have sat and watched a huge variety of native and global aesthetic professionals give demonstrations on injecting a variety of dermal fillers and botulinum toxins over the last 13 years. This puts me in a unique position. I have probably absorbed much more knowledge on practical injection technique than many medics in fact, (particularly those new to facial aesthetics), and certainly more than most non-medics now embarking on training courses within the specialty.

I have been on the receiving end of treatment, but I have never (of course!) tried to 'have a go' at delivering treatment myself. I have 'played' with needles and have taken great joy from delivering drops of hyaluronic acid out onto a table to get a feel for the many syringes offered within filler blister packs. In theory there is nothing to really stop me from setting up shop – apart from the fact that I'm not a medic and I don't know what I'm doing!! Thankfully I know this, perhaps because I have gained so much knowledge that my ignorance gene has been well and truly squashed.

When I started looking at the concept of smart syringes and automated pen systems, my ignorance gene woke up a little, and I found myself wondering if such systems were in danger of making it too easy for novices and non-medics to join the sector and 'click and go' with ease. But when I sat back and thought about it, and whether I could do that, I remembered that the dose delivery syringes and then motorised pen injectors are still lacking in one thing which would make that possible…they don't come with one added feature…there is no NPS – or Needle Positioning System!

You STILL need to know, and understand, WHERE and how deeply to place the needle in the first place to achieve an optimised and safe treatment outcome. So what if the dose is managed, that doesn't make it much easier for the practitioner to achieve correct needle and product placement, and thus cannot be really considered to be dumbing down or making it easy for novices. Giving me one of these solutions cannot make me better able to deliver a botulinum toxin or dermal filler treatment – I still don't really know what I'm doing. Best case, the dose response will mean that I would do a little less harm, but that's where it stops.

So, if you think these are not for you, but for 'learners', then I urge you to think again. What you do need to decide on is – is it right for you, can you get on with it, and can you justify or accommodate any additional costs involved.

Most areas of our daily lives highlight development in the tools that we use to do common, everyday tasks and mean that we are constantly changing the items that we see in our homes, cars, workplaces etc. Take the humble can opener. I recently broke one which I had owned for almost a decade, and promptly entered a cookware shop in my local town centre looking for a replacement. This proved more of a challenge than I ever imagined, such that when confronted with a display unit with upwards of twenty styles, I genuinely didn't know what to choose. But what it came down to is whether the £25 ergonomically shaped, over-sized plastic design icon would open my tins any better than the £2 basic metal can opener, beloved of Scout camps up and down the country.

The same can be said for the humble hypodermic syringe. As medical professionals, you need to decide if the comfort afforded by some of the new design concepts, the dosing controls and delivery style warrants the extra costs of use. Some, such as the TSK 3Dose adds not much more than the cost of a high street cappuccino to each patient treatment, almost a no-brainer if you like it. Other solutions, such as the automated pens, are a much bigger initial investment and ongoing patient expense based on consumables. This needs much more trial and thought before considering it as a permanent addition to your armamentarium. Plus, deciding how to cover the costs.

Speaking to one aesthetic nurse who has booked to trial a motorised solution, she said; "*I'm looking forward to trying it, to see how it compares to other pen injectors that I have used, but I know in my heart that I'll probably just inject the old fashioned, reliable way in the end!*". I guess that's the thing – "*If it ain't broke…*"

Lorna Jackson
Lorna has been Editor of Consulting Room, the UK's largest aesthetic information website since 2003. She has become an industry commentator on a number of different areas related to the aesthetic industry, collating and evaluating statistics, plus researching, investigating and writing feature articles, blogs, newsletters and reports for Consulting Room and various consumer and trade publications, including *Cosmetic News, Journal of Aesthetic Nursing, Body Language*, *PMFA News*, *Aesthetic Medicine* and *Aesthetic Dentistry Today.* Lorna has also been asked to present at various industry events, including Smart Ideas, FACE and the CCR Expo. She was awarded *Journalist of the Year* at the MyFaceMyBody Awards 2014.

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The CPD Certification Service, The Coach House, Ealing Green, London W5 5ER. Tel: 020 8840 4383 Fax: 020 8579 3991
E-mail: info@cpduk.co.uk Web: www.cpduk.co.uk