

“INCREMENTAL SYRINGE” A NOVEL INVENTION OF A USER FRIENDLY SYRINGE TO INJECT BOTULINUM TOXIN WITH IMPROVED ACCURACY, PRECISION, AND SPEED

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Introduction

Traditional syringes require users to visually estimate syringe volume, resulting in adverse effects on dosing accuracy, precision, and speed. This is especially problematic when the user must simultaneously focus on other visual information and deliver multiple small, accurate and precise volumes. Injecting Botox via cystoscope while observing the procedure on a monitor, often leads to unequal and non-accurate delivery in different spots in the bladder. We have designed an Incremental Syringe (IS) which provides an audible “click” and tactile resistance from the plunger feedback after each increment (1 ml) of injection. Here we compare the dosing accuracy, precision and speed of the incremental syringe to those of a traditional syringe.

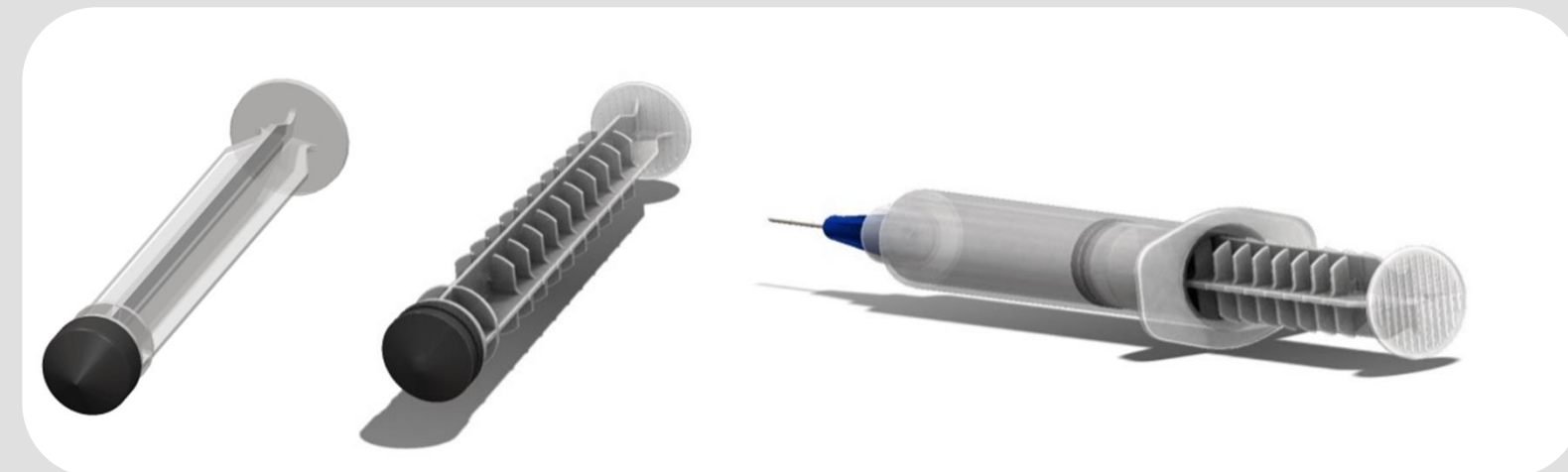


Figure 1. Original and Incremental syringe plunger design

Methods

We converted half of 10 ml traditional syringes to IS by replacing their plungers. Incremental plungers were prototyped with increments every 1.0 mL and to fit the 10 mL syringes. 14 graduate student volunteers tested syringes with three needle sizes (14, 18, and 23 gauges). Each operator tested all syringe type and needle size combinations by dispensing 1.0 mL at a time for 8 consecutive injections. Each injection was weighed on a balance and converted to volume using the specific gravity of water. Precision of dose volumes were compared using Bartlett’s Test for unequal variances. A standard one-way or Welch’s ANOVA was used to compare differences in accuracy depending on equality variances.

Results

Traditional and IS dose volumes were off by -3.2% and -2.5% respectively ($p=0.03$). Accuracy differences were identified between syringe types with 14 and 18 gauge needles, but not with 23 gauge. The coefficient of variation was 3.5% for traditional syringes and 1.2% for IS which was significantly different for all three needle sizes ($p<0.001$).



Figure 2. Test with multiple gauge needles

Accuracy and Precision of Syringes				
		Volume (mL)	Standard Deviation	
14 ga.	Traditional	0.9682 (-3.2%)	0.0346 (3.6%)	$p < 0.001$
	Incremental	0.9739 (-2.6%)	0.0109 (1.1%)	$p < 0.001$
18 ga.	Traditional	0.9720 (-2.8%)	0.0461 (4.7%)	$p < 0.001$
	Incremental	0.9774 (-2.3%)	0.0282 (2.9%)	$p < 0.001$
23 ga.	Traditional	0.9708 (-2.9%)	0.0443 (4.6%)	$p < 0.001$
	Incremental	0.9762 (-2.4%)	0.0181 (1.9%)	$p < 0.001$
Traditional	14 ga.	0.9682 (-3.2%)	0.0346 (3.6%)	$p = 0.603$
	18 ga.	0.9720 (-2.8%)	0.0461 (4.7%)	
	23 ga.	0.9708 (-2.9%)	0.0443 (4.6%)	
Incremental	14 ga.	0.9739 (-2.6%)	0.0109 (1.1%)	$p = 0.094$
	18 ga.	0.9774 (-2.3%)	0.0282 (2.9%)	
	23 ga.	0.9762 (-2.4%)	0.0181 (1.9%)	

Table 1. Accuracy and Precision

Statistically different variation in dose volumes were not found to be significantly different between needle sizes and between users for traditional syringes ($p=0.603$) or IS ($p=0.094$). However, 13/14 individuals were more accurate and 13/14 were more precise with the IS. Also pilot data suggests ISs are approximately 50% faster.

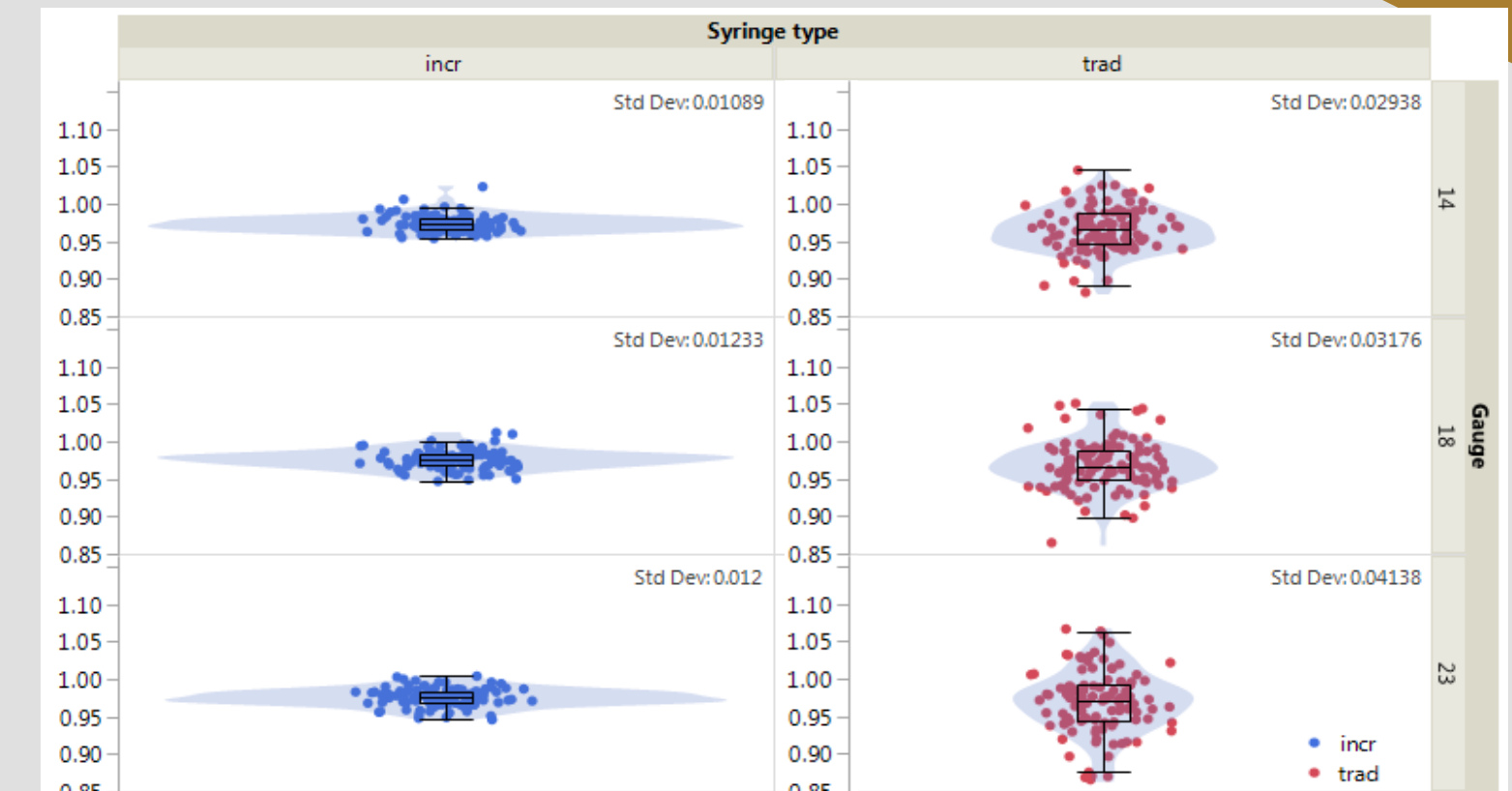


Figure 3. Scatter plot showing precision and accuracy

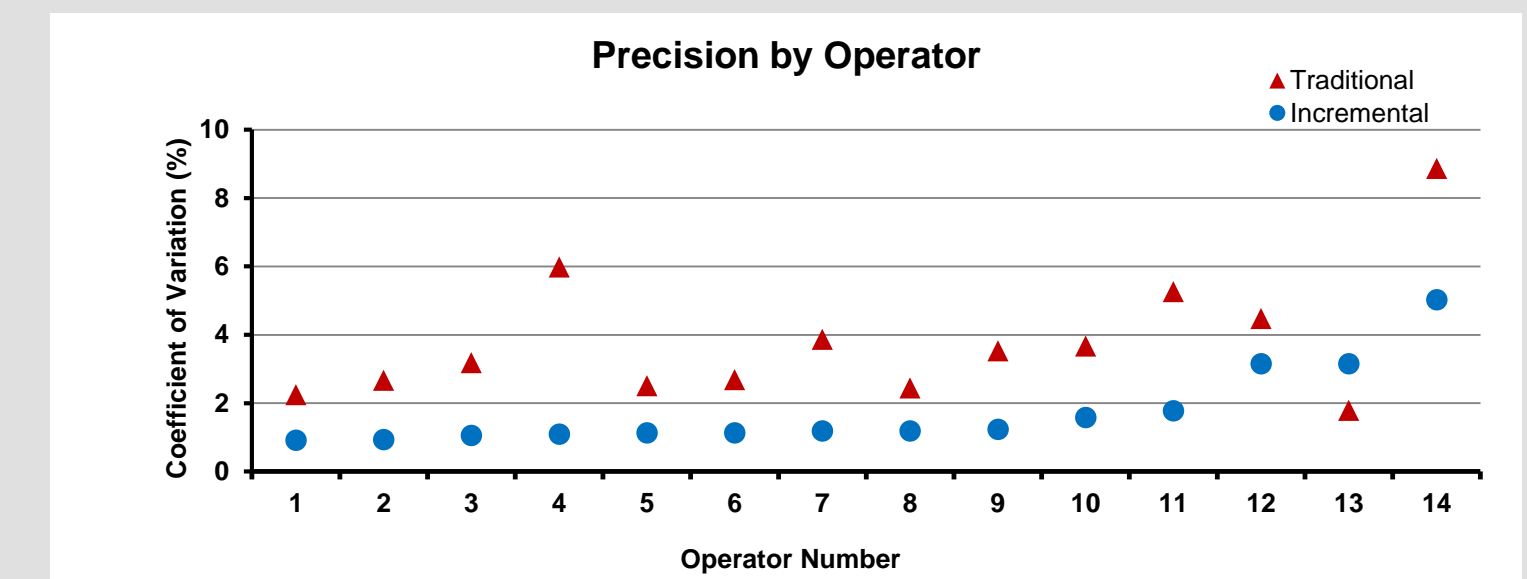


Figure 4. Precision by user and syringe type

Conclusions

While the Incremental Syringe’s main advantage lies in simple handling, it is also more accurate, reducing dosing variation within individuals, across individuals, and across needle sizes. IS is a promising medical device for difficult situations like Botox injections when multiple precise injections and monitoring the screen are needed at the same time.