RETRACTION OF THE PLUNGER ON A SYRINGE OF HYALURONIC ACID BEFORE INJECTION: ARE WE SAFE?

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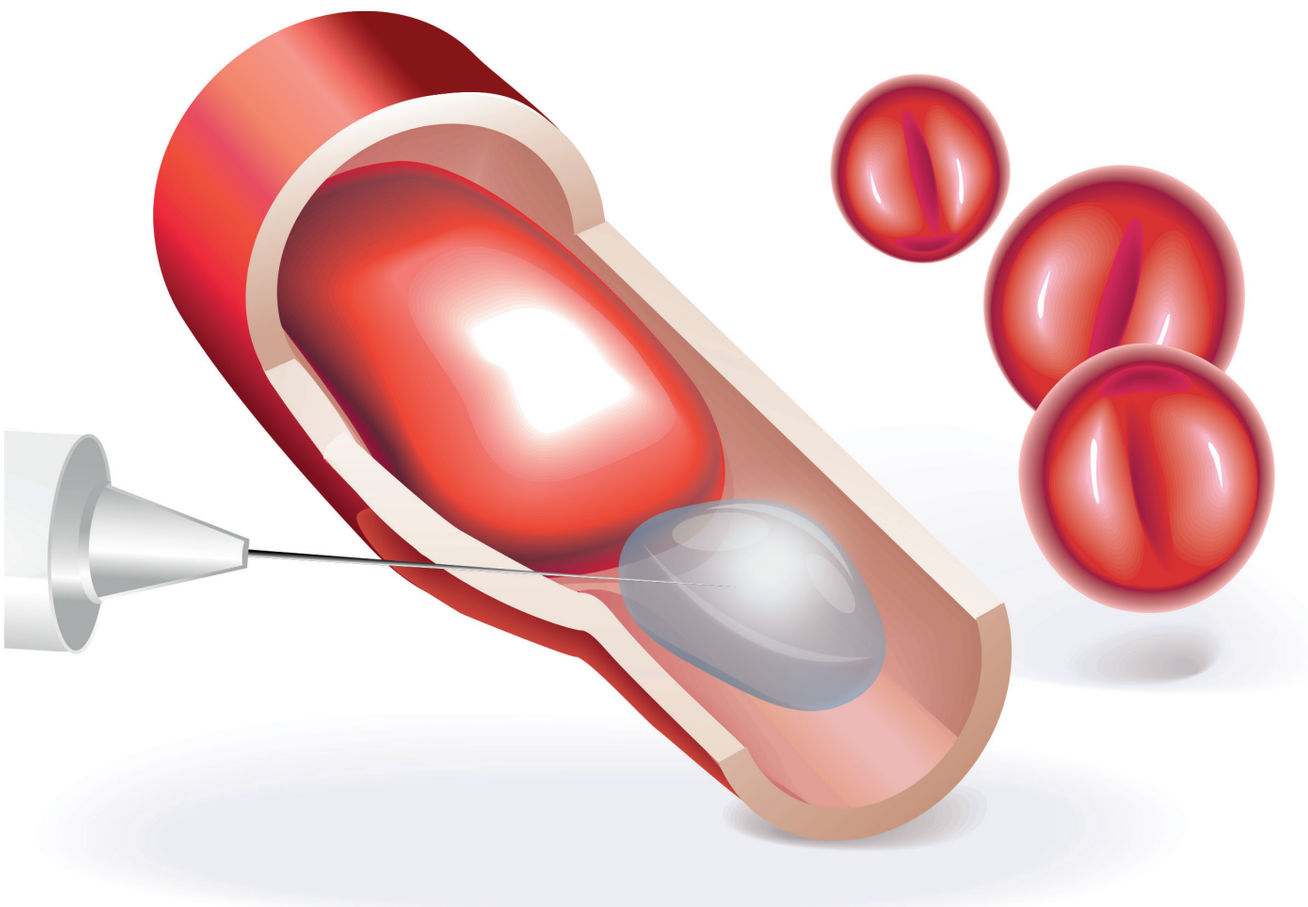
Dermatologic Surgery 2015; 41:S340-S346



IS IT NECESSARY TO ASPIRATE BEFORE HA FILLER INJECTION TO AVOID NECROSIS?

Findings in this new released paper

IS IT NECESSARY TO ASPIRATE BEFORE HA FILLER I

Findings in this new released paper

BACKGROUND

Some controversy exists concerning the need for aspiration before injection with hyaluronic acid (HA) fillers:

- **Aspiration is common in medical procedures prior to giving injections** to **avoid** the potential of material being injected into the **intravascular space.**
- But **HA fillers** used for cosmetic procedures have a **gel-like** consistency which **may impede the flow of blood back into the syringe**.
- Before HA injections, there is a tendency to **pullback the plunger with a quick accelerated movement**, which **does not allow** enough time **to empty the needle lumen, or may even collapse the vessel giving a false negative result of intravascular placement**.

PROBLEMATIC

- Could the blood be aspirated back into a syringe of HA using the usual clinical technique?
- Is the aspiration test always reliable to avoid necrosis risk?

METHODOLOGY

Main goal: Determine if or when blood could be withdrawn from a heparinized fresh tube of blood into the HA syringe* (*in vitro*) via a slow-pull test or a snap test.

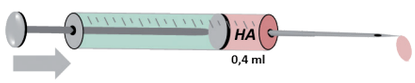
Tested techniques: Two different techniques were tested: one using a slow-pull retraction of the plunger and up to a 5-second waiting time before release *versus* a rapid pullback of the plunger and a quick release, replicating the usual clinical technique.

Tested products: Products used in this study are from four major HA manufacturers: TEOXANE, MERZ, GALDERMA/MEDICIS & ALLERGAN.

Snap test

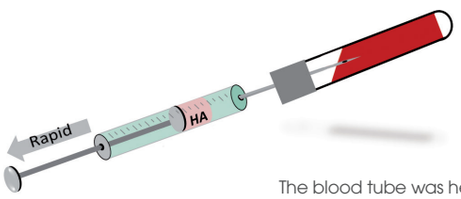
Priming the needle

HA gel was initially extruded and discarded from the syringe, leaving 0.4 mL of material, to create a significant negative pressure estimated to 0.5 atm when the plunger was retracted



Rapid pullback

The plunger was pulled back promptly to replicate the usual clinical technique used by many of the injectors



The blood tube was held at approximately a 20° incline

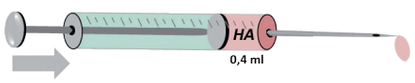
Plunger fast release

The plunger was immediately released after retraction using the thumb of the injecting hand

Slow-Pull test

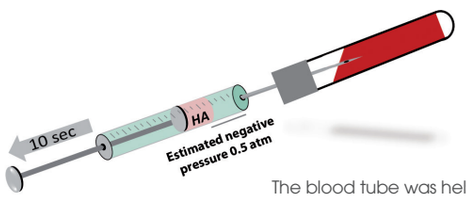
Priming the needle

HA gel was initially extruded and discarded from the syringe, leaving 0.4 mL of material, to create a significant negative pressure estimated to 0.5 atm when the plunger was retracted



Slow pullback

The plunger was retracted very slowly using approximately 10 seconds to reach the 0.8 mL marking of the syringe if needed representing a negative pressure of 0.4 mL



The blood tube was held at approximately a 20° incline

Plunger retention (5 Sec) & release

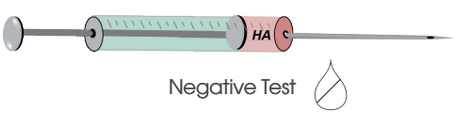
The plunger was retained in place up to a maximum of 5 seconds before release

Results

Blood in the syringe

Positive Test

No blood in the syringe



Negative Test

* A schematic representation of the 2 mL syringe was used to illustrate the two retraction methods.

RESULTS OF THE SNAP TEST

Usual clinical technique

Results are represented in two ways: presence of blood in the syringe is indicated by a red drop & absence of blood in the syringe is indicated by a crossed drop

SNAP TEST

COMPANY	PRODUCT	PROVIDED NEEDLE
GALDERMA	Perlane	29 G
	Restylane	29 G
	Fine Lines	29 G
MERZ	Fortelis FE	27 G
	Modelis Lido MS	25 G
	Esthelis Basic Lido EB	30 G
	Esthelis Basic Lido EB	27 G
	Esthelis Soft Lido	30 G
ALLERGAN	Juvederm Ultra	30 G
	Ultra Plus	27 G
	Ultra XC	30 G
	Ultra XC Plus	27 G
	Forma	27 G
	Voluma	27 G
	Volift	30 G
	Refine	30 G
TEOXANE	Ultimate	27 G
	Ultra Deep	25 G*1"
	Deep Lines	27 G
	Global Action	30 G
	Kiss	27 G
	First Lines	30 G
	Redensity I	30 G
	Redensity II	30 G
	RHA4	27 G
	RHA3	30 G
	RHA2	30 G
	RHA1	30 G

Blood in the syringe

No blood in the syringe

A series of needles were used starting with the company-supplied 30 G, 29 G (GALDERMA / MEDICIS only), 27 G, company-supplied 27 G (larger lumen), and finally 25 G and 25 G (TEOXANE supplied).

The authors used a series of increasing diameter needles until blood was obtained. However, in the table above only results obtained with needles supplied with each of the products are shown.

- **Factors affecting the removal of HA from the needle** will be the consistency and cohesivity of the material, length of the needle, force of suction applied, and the time under negative pressure during withdrawal.
- The **usual clinical method**, which involves quick withdrawal and instant release of the syringe plunger **does not allow for sufficient release of the filler** in the needle and **may give rise to false negative results** *in vitro* and likely *in vivo*.

RESULTS OF THE SLOW-PULL TEST

Results are represented in two ways: presence of blood in the syringe is indicated by a red drop & absence of blood in the syringe is indicated by a crossed drop

SLOW-PULL TEST

COMPANY	PRODUCT	PROVIDED NEEDLE
GALDERMA	Perlane	29 G
	Restylane	29 G
	Fine Lines	29 G
MERZ	Fortelis FE	27 G
	Modelis Lido MS	25 G
	Esthelis Basic Lido EB	30 G
	Esthelis Basic Lido EB	27 G
	Esthelis Soft Lido	30 G
ALLERGAN	Juvederm Ultra	30 G
	Ultra Plus	27 G
	Ultra XC	30 G
	Ultra XC Plus	27 G
	Forma	27 G
	Voluma	27 G*
	Volift	30 G
	Refine	30 G
TEOXANE	Ultimate	27 G
	Ultra Deep	25 G*1"
	Deep Lines	27 G
	Global Action	30 G
	Kiss	27 G
	First Lines	30 G
	Redensity I	30 G
	Redensity II	30 G
	RHA4	27 G
	RHA3	30 G
	RHA2	30 G
	RHA1	30 G

Blood in the syringe

No blood in the syringe

A series of needles were used starting with the company-supplied 30 G, 29 G (GALDERMA only), 27 G, company-supplied 27 G (larger lumen), and finally 25 G and 25 G (TEOXANE supplied).

The authors used a series of increasing diameter needles until blood was obtained. However, in the table above only results obtained with needles supplied with each of the products are shown.

*For the Juvederm® Voluma (ALLERGAN) product, the result of the slow-pull test was positive when using the 30G needle.

- Using a slow withdrawal rate then holding the syringe under a negative pressure for up to 5 seconds demonstrates that there is a **variability in the blood aspiration, between different product lines and different companies**.
- **The rapid pull and release technique is significantly less effective than the slow-pull technique** in demonstrating blood withdrawal, especially with cohesive HA materials.

CONCLUSION

- In the case of HA fillers the usual clinical technique of aspiration, which involves **pulling back quickly** with a short wait time before release, in most cases leads to **false negative results**.
- Withdrawal of the syringe plunger with no visible blood in the syringe does not eliminate the possibility of intravascular placement of the syringe.
- For **the majority of the HA fillers, retraction of the plunger** when using smaller gauge needles or those supplied with the particular product do not allow for cleansing of the needle lumen or hub and thus subsequent **entry of the blood**.
- The other point to be made is that it is **unlikely with the maneuvers required to pullback and release a viscous gel** that the **needle remains absolutely in the exact same cutaneous position** during the withdrawal and release of the syringe plunger.
- The only way that **guarantees a positive aspiration test is to change the needle each time one injected a bolus with a HA - free non primed needle.** However, this method would be **impractical because** it creates a significant loss of product with a **slight potential risk of an air embolism** because the empty needle contains air.

RECOMMENDATIONS

- Therefore, the aspiration test is not always reliable in HA filler injection and does not avoid the necrosis factor.

- A slow, prudent «**stop and go**» technique should **limit the damage**.
- Need for a **long injection duration of 2 minutes per 0.3 mL** particularly when injecting **susceptible areas**.
- For **physicians who wish to continue** using a **pullback technique** before injection, **authors' recommendations** are: using a large bore needle, maximum negative pressure fixation of the plunger position, and extended waiting time while the syringe is under negative pressure.

TEOSYALPEN

The controversy surrounding the safety of motorized delivery equipment such as the TEOSYAL®PEN, which do not allow for retraction of the plunger, is negated.

TEOSYAL®PEN*

- Reduces injection risks because it has as a feature a controllable flow rate, and continuous low pressure that can be evenly delivered in drops.
- Enables multiple controlled micro boluses delivery, and optimizes the control of the procedure.
- Allows the physician to maintain their concentration on observing the patient without having to concentrate on the injecting hand and the volume delivered. This may enable physicians to recognize immediately and accurately if an embolism occurs (immediate whitening of the skin, and a subsequent bluish hue).

*TEOSYAL®PEN is a motorized and cordless device for hyaluronic acid injections in order to correct wrinkles and depressions. Manufactured by JuvaPlus SA. This medical device (class IIa), is a regulated health product which bears, under this regulation, the CE mark (CE0434). For more information, please consult your doctor and TEOSYAL®PEN's instructions for use.

500349/00 – March 2016