


Juvéderm™ Lose the Lines – Not the Smile



Michelle D. Lesé, PharmD
PGY1 Pharmacy Practice Resident
West Palm Beach VA Medical Center
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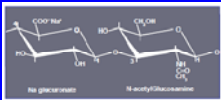
Objectives



- Describe what dermal fillers are
- Provide education on adverse reactions and complications of Juvéderm™
- Analyze clinical trial evidence

What is Juvéderm™?

- A sterile, biodegradable, non-pyrogenic, clear, colorless, gel implant
- Consists of hyaluronic acid (HA)
- Derived from *Streptococcus equi* bacteria




Types of Dermal Fillers


	Synthetic	Synthetic	Natural	Natural
Major Component	Hydroxyl-apatite	Poly (L-lactic acid)	HA	Collagen
Brand Name	Radiesse®	Sculptra®	Restylane® Perlane® Hylaform® Juvéderm™ Eleveess™	Zyderm® Zyplast® Cosmoderm® Cosmoplast® Evolve®

Intended Use/Indications

- Injection into the mid to deep dermis
- Correction of moderate to severe facial wrinkles and folds



Dosage Forms



- Intradermal injectable gel
- Supplied as 24mg/mL prefilled syringes
- Juvéderm™ 24HV (Juvéderm™ Ultra)
- Juvéderm™ 30HV (Juvéderm™ Ultra Plus)
- Juvéderm™ 30 – not FDA-approved in the US

Adverse Events



- Redness (90%)
- Pain/Tenderness (90%)
- Firmness (88%)
- Swelling (86%)
- Lumps/Bumps (82%)
- Bruising (60%)
- Itching (35%)
- Discoloration (33%)

Contraindications



- Known sensitivities to the filler material
- History of severe allergy or anaphylaxis
- Bleeding disorders

Warnings



- Not for IV injection
- Use at sites of active inflammatory processes
- Bleeding disorders

Precautions



- Risk of infection
- Safety during pregnancy or breastfeeding not established
- Safety in patients <18 years not established
- Reactivation of herpes
- Patients susceptible to keloids, hyperpigmentation, & hypertrophic scarring

Juvéderm™ Procedure

- Wash treatment area and swab with alcohol
- Inject directly into the skin
- Physician may anesthetize treatment area
- Optimal correction is 1.6mL per treatment site
- Correct to 100% of desired volume effect
- Gently massage treatment site







Efficacy – Before and After



Accessed at: http://beauty-redefined.com/yahoo_site_admin/assets/images/juv1.54204838.jpg, January 14, 2006.

Post-procedure Counseling

- Avoid strenuous exercise 
- Avoid extensive sun/heat exposure 
- Avoid alcoholic beverages 
- May experience localized swelling 

Benefits of Juvéderm™

- No requirement for skin testing
- Duration of action
- Fewer allergic side effects
- Better pliability
- Overcorrection can be reversed

Baumann LS et al: Comparison of Smooth-Gel Hyaluronic Acid Dermal Fillers with Cross-linked Bovine Collagen: A Multicenter, Double-Masked, Randomized, Within-Subject Study

- **Three treatment arms:**
 - Juvéderm™ Ultra vs. Zyplast®
 - Juvéderm™ 30 vs. Zyplast®
 - Juvéderm™ Ultra Plus vs. Zyplast®
- **Objective:** compare the effectiveness & safety of these smooth-gel HA dermal fillers with bovine collagen for nasolabial fold (NLF) correction
- **Outcome Measures:** Wrinkle Assessment Scale (WAS) & photographic documentation

Baumann LS, et al. *Dermatol Surg* 2007;33(S2):S128-S135

Baumann et al: Dermal Fillers Study

- **Subjects:** 439
- **Mean age:** 49 years
- **Demographics** comparable in all treatment groups
- **Baseline NLF severity score** 2.5-2.6 across all groups; $p \leq 0.001$

Baumann et al: Dermal Fillers Results

- All the dermal fillers resulted in a clinically significant improvement from baseline; $p \leq 0.001$
- Juvéderm™ provided longer-lasting wrinkle correction than Zyplast® at 24 weeks
 - Clinically significant improvement of 81-90% of HA dermal fillers vs. 36-45% of bovine collagen filler; $p \leq 0.001$
- Treatment site reactions similar for all fillers

Pinsky MA et al: Juvéderm™ Injectable Gel: A Multicenter, Double-Blind, Randomized Study of Safety and Effectiveness

- **Two treatment arms:**
 - Juvéderm™ Ultra vs. Zyplast®
 - Juvéderm™ Ultra Plus vs. Zyplast®
- **Objective:** determine the long-term effectiveness & safety of Juvéderm™ Ultra and Ultra Plus injectable gel
- **Outcome Measures:** 5-point WAS & photographic documentation

Pinsky MA et al. *Aesthetic Surg J* 2008;28(1):17-23.

Pinsky et al: Dermal Fillers Study

- **Subjects:** 292
- **Mean age:** 50 years (Ultra) 48 years (Ultra Plus)
- Demographics similar between treatment groups
- Baseline NLF severity score 2.6 for both treatment groups

Pinsky et al: Dermal Fillers Results

- Mean NLF severity reduced by ~2 points after initial treatment; $p \leq 0.001$
- Clinically significant wrinkle correction at end of trial & during posttrial follow-up; $p \leq 0.001$
- Treatment site reactions similar for all fillers

Summary

- HA considered the gold standard in dermal fillers
- Longer duration of action
- Require no skin testing
- Fewer side effects
- Better pliability
- Excellent results & greater patient satisfaction



Self Assessment True/False questions



1. Juvéderm™ is a colorless hyaluronic acid gel that is injected into facial tissue to smooth wrinkles & folds around the nose or mouth.
2. Juvéderm™ permanently adds volume to facial tissue & restores a smoother appearance to the face.
3. Exposure to sun or heat should be avoided for at least 24 hours following treatment with Juvéderm™ injectable gel.

References

- Juvéderm™ Ultra [package insert]. Santa Barbara, Ca: Allergan Inc.; 2007.
- Juvéderm™ Ultra Plus [package insert]. Santa Barbara, Ca: Allergan Inc.; 2007.
- [FDA] Food and Drug Administration. 2006. Summary of safety and effectiveness data. Rockville (MD) [online]. Accessed 2009 Dec 23. URL: http://www.accessdata.fda.gov/cdrh_docs/pdf5/p050047b.pdf.
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- Allemann IB, Baumann L. Hyaluronic acid gel (Juvéderm™) preparations in the treatment of facial wrinkles and folds. [Review]. *Clin Interv Aging* 2008;3(4):629-634.