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General & Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

The Use of Dermal Fillers in the Neck and Décolletage

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Financial Disclosure

Revance Therapeutics, Inc.

- Lead investigator for a clinical trial involving Revance's neurotoxin product



The American Academy of Dermatology Association (AADA)

- Nearly 17,500 members nationwide
- Committed to excellence in the medical and surgical treatment of skin disease
- Advocating for high standards in clinical practice, education, and research in dermatology





Current Regulatory Status

Off-label disclaimer: There are currently no FDA-approved indications for soft-tissue fillers in the neck or décolletage.



Dermal Fillers are Trending

- In 2024, soft tissue fillers or hyaluronic acid (HA) fillers were considered one of the top 5 cosmetic minimally invasive procedures.¹
- Demand for noninvasive dermatological procedures for cutaneous rejuvenation is on the rise.²
- At times, these procedures are done on an off-label basis.



¹ American Society of Plastic Surgeons (ASPS) 2024 Complete Plastic Surgery Statistics Report. <https://www.plasticsurgery.org/documents/news/statistics/2024/plastic-surgery-statistics-report-2024.pdf>

² Cassuto D, Bellia G, Schiraldi C. An Overview of Soft Tissue Fillers for Cosmetic Dermatology: From Filling to Regenerative Medicine. Clin Cosmet Investig Dermatol. 2021 Dec 22;14:1857-1866. doi: 10.2147/CCID.S276676. PMID: 34992400; PMCID: PMC8710524. Copyright American Academy of Dermatology Association. All Rights Reserved. Proprietary materials for AAD/A use only. Reproduction or distribution of this material is strictly prohibited without prior permission.

Fillers Most Commonly Used in the Neck & Chest³



Hyaluronic Acid (HA)

(Volumizing)

Short-acting



Calcium Hydroxylapatite (CaHA)

(Biostimulatory)

Long-lasting



Poly-L-Lactic Acid (PLLA)

(Biostimulatory)

Long-lasting

Disclaimer: There are currently no FDA-approved indications for soft-tissue fillers in the neck or décolletage.



Studies Demonstrate the Clinical Safety of Dermal Fillers in the Neck and Décolletage^{4,5,6,7}

Dermal fillers are used in the neck and décolletage to improve:

- Skin texture & crepiness
- Skin thickness
- Fine lines and wrinkles
- Skin tightening

Adverse events for dermal fillers in the neck & décolletage are generally mild and transient, which include:^{4,5,6,7}

- Redness
- Swelling
- Minor Bruising
- Lumpiness post-injection

****Additional long-term studies are recommended to further evaluate their safety.**



⁴ Christen MO. Collagen Stimulators in Body Applications: A Review Focused on Poly-L-Lactic Acid (PLLA). Clin Cosmet Investig Dermatol. 2022 Jun 21;15:997-1019. doi: 10.2147/CCID.S359813.

⁵ Siperstein, Robyn M; Cotofana, Sebastian MD, PhD; Barnes, Megan MS†; Nestor, Elizabeth MD†; Meran, Suzanne DO; Grunebaum, Lisa MD§. A Randomized, Placebo-Controlled, Split-Neck Trial of Hyaluronic Acid Filler for Static Horizontal Neck Rhytides Using Either a Cannula or Needle. Dermatologic Surgery 48(4):p 423-428, April 2022. doi: 10.1097/DSS.0000000000003391.

⁶ Goldie, Kate MBChB*; Peeters, Wouter MD; Alghoul, Mohammed MD, FACS; Butterwick, Kimberly MD§; Casabona, Gabriela MD; Chao, Yates Yen Yu MD; Costa, Joana MD; Eviatar, Joseph MD, FACS; Fabi, Sabrina Guillen MD, FAAD, FAACS; Lupo, Mary MD; Sattler, Gerhard MD; Waldorf, Heidi MD; Yutskovskaya, Yana MD; Lorenc, Paul MD. Global Consensus Guidelines for the Injection of Diluted and Hyperdiluted Calcium Hydroxylapatite for Skin Tightening. Dermatologic Surgery 44():p S32-S41, November 2018. | doi: 10.1097/DSS.0000000000001685.

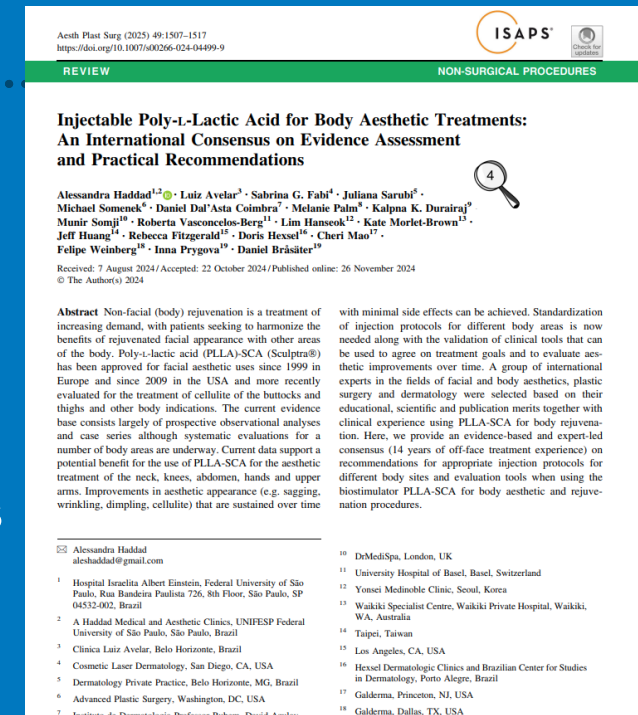
⁷ Haddad A, Avelar L, Fabi SG, Sarubi J, Somenek M, Coimbra DD, Palm M, Durairaj KK, Somji M, Vasconcelos-Berg R, Hanseok L, Morlet-Brown K, Huang J, Fitzgerald R, Hexsel D, Mao C, Weinberg F, Prygova I, Brásater D. Injectable Poly-L-Lactic Acid for Body Aesthetic Treatments: An International Consensus on Evidence Assessment and Practical Recommendations. Aesthetic Plast Surg. 2025 Mar;49(5):1507-1517. doi: 10.1007/s00266-024-04499-9.



Less Common Risks and Adverse Events

- Research shows intravascular complications are uncommon in the neck and décolletage compared to other applications.^{8,9,10,11,12}

There is a lower risk of nodules with higher dilutions of biostimulatory fillers and massage after injection.^{8,9,11}



⁸ Haddad A, Avelar L, Fabi SG, Sarubi J, Somenek M, Coimbra DD, Palm M, Durairaj KK, Somji M, Vasconcelos-Berg R, Hanseok L, Morlet-Brown K, Huang J, Fitzgerald R, Hessel D, Mao C, Weinberg F, Prygova I, Bråsåter D. Injectable Poly-L-Lactic Acid for Body Aesthetic Treatments: An International Consensus on Evidence Assessment and Practical Recommendations. *Aesthetic Plast Surg*. 2025 Mar;49(5):1507-1517. doi: 10.1007/s00266-024-04499-9. Epub 2024 Nov 26.

⁹ Massidda E. Starting Point for Protocols on the Use of Hyperdiluted Calcium Hydroxylapatite (Radiesse®) for Optimizing Age-Related Biostimulation and Rejuvenation of Face, Neck, Décolletage and Hands: A Case Series Report. *Clin Cosmet Investig Dermatol*. 2023 Nov 29;16:3427-3439. doi: 10.2147/CCID.S420068.

¹⁰ Rongthong A, Wanitphakdeedecha R, Maiprasert M, et al. Efficacy and safety of hyaluronic acid filler on the treatment of horizontal neck lines. *J Cosmet Dermatol*. 2023; 22: 433-438. doi:10.1111

¹¹ Christen MO. Collagen Stimulators in Body Applications: A Review Focused on Poly-L-Lactic Acid (PLLA). *Clin Cosmet Investig Dermatol*. 2022 Jun 21;15:997-1019. doi: 10.2147/CCID.S359813.

¹² Machado RA, Oliveira LQ, Martelli-Júnior H, Pires FR, Carvas JB, Rogerio VE, Rabelo VD, Coletta RD. Adverse reactions to the injection of face and neck aesthetic filling materials: a systematic review. *Med Oral Patol Oral Cir Bucal*. 2023 May 1;28(3):e278-e284. doi: 10.4317/medoral.25713. PMID: 36565218; PMCID: PMC10181027.



The Use of Dermal Fillers in Combination with Other Procedures

- Research shows that many neck rejuvenation techniques can be combined safely.^{13,14,15}
- Additional long-term studies may be needed for combination procedures of dermal fillers.
- Literature recommends that maintaining high safety protocols, meticulous use of proper injection techniques, and the employment of FDA-approved high-quality dermal fillers is imperative to successful combination procedures.^{13,14,15}



¹³Vanaman M, Fahi SG, Cox SE. Neck Rejuvenation Using a Combination Approach: Our Experience and a Review of the Literature. Dermatol Surg. 2016 May;42 Suppl 2:S94-S100. doi: 10.1097/DSS.0000000000000699. PMID: 27128251.

¹⁴Casabona G, Nogueira Teixeira D. Microfocused ultrasound in combination with diluted calcium hydroxylapatite for improving skin laxity and the appearance of lines in the neck and décolletage. J Cosmet Dermatol. 2018 Feb;17(1):66-72. doi: 10.1111/jocd.12475.

¹⁵Aleisa, Abdullah MD*; Lu, Jasmine Thai BS†; Al Saud, Aljohara MD‡; Veldhuizen, Inge J. MD, PhD§; Rossi, Anthony M. MD||; Lee, Kachiu C. MD MPH. The Differences in the Practice of Cosmetic Dermatologic Procedures Between Physicians and Nonphysicians. Dermatologic Surgery 49(12):p 1165-1169, December 2023. doi: 10.1097/DSS.0000000000003948.

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Post-Market Study Assessments

Post-Market Study Assessments

- *Hyaluronic Acid*¹⁶

Consensus Recommendations

- *Calcium Hydroxylapatite (CaHA)*^{17,18}
- *Poly-L-Lactic Acid (PLLA)*¹⁹

These recommendations support the use of the above biostimulatory fillers for use in the body (i.e., the neck and décolletage) and provide best practices.^{16,17,18,19}

AADA's Key Message:

Dermal filler injections, specifically those administered in the neck and décolletage, should be administered under the direct supervision of or by an experienced physician, given the importance of injection technique, depth, patient age, location, and ongoing assessment and monitoring after filler administration.

¹⁶ Siperstein, Robyn M; Cotozana, Sebastian MD, PhD; Barnes, Megan MS†; Nestor, Elizabeth MD†; Meran, Suzanne DO; Grunebaum, Lisa MD§. A Randomized, Placebo-Controlled, Split-Neck Trial of Hyaluronic Acid Filler for Static Horizontal Neck Rhytides Using Either a Cannula or Needle. *Dermatologic Surgery* 48(4):p 423-428, April 2022. doi: 10.1097/DSS.0000000000003391

¹⁷ de Almeida AT, Figueredo V, da Cunha ALG, Casabona G, Costa de Faria JR, Alves EV, Sato M, Branco A, Guarnieri C, Palermo E. Consensus Recommendations for the Use of Hyperdiluted Calcium Hydroxylapatite (Radiesse) as a Face and Body Biostimulatory Agent. *Plast Reconstr Surg Glob Open*. 2019 Mar 14;7(3):e2160. DOI: 10.1097/GOX.0000000000002160.

¹⁸ Massidda E. Starting Point for Protocols on the Use of Hyperdiluted Calcium Hydroxylapatite (Radiesse®) for Optimizing Age-Related Biostimulation and Rejuvenation of Face, Neck, Décolletage and Hands: A Case Series Report. *Clin Cosmet Investig Dermatol*. 2023 Nov 29;16:3427-3439. doi: 10.2147/CCID.S420068.

¹⁹ Haddad A, Avelar L, Fabi SG, Sarubi J, Somenek M, Coimbra DD, Palm M, Durairaj KK, Somji M, Vasconcelos-Berg R, Hanseok L, Morlet-Brown K, Huang J, Fitzgerald R, Hexsel D, Mao C, Weinberg F, Prygova I, Bråsåter D. Injectable Poly-L-Lactic Acid for Body Aesthetic Treatments: An International Consensus on Evidence Assessment and Practical Recommendations. *Aesthetic Plast Surg*. 2025 Mar;49(5):1507-1517. doi: 1007/s00266-024-04499-9. Epub 2024 Nov 26.



Removal of Dermal Filler Implant Material and Patient Preference

A. Removal of Dermal Fillers

- Injectable HA fillers can be dispersed and dissolved with hyaluronidase, however, there is no precise way to dissolve CaHA or PLLA.²⁰
- The exact usage of hyaluronidase to dissolve HA filler is not an FDA-approved indication for hyaluronidase.
- Patients should be informed of the off-label use of hyaluronidase for dissolving HA fillers, potential adverse effects, and the inability to dissolve CaHA or PLLA.²¹

B. Patient Preference²¹

- Patients receiving filler injections should be educated about common and serious adverse events.
- Severe complication rates can be mitigated by detailed knowledge of neck and chest anatomy, correct patient selection, correct filler selection, proper injection technique, and post-care.



²⁰ Siperstein, Robyn M; Cotozana, Sebastian MD, PhD; Barnes, Megan MS†; Nestor, Elizabeth MD†; Meran, Suzanne DO; Grunebaum, Lisa MD§. A Randomized, Placebo-Controlled, Split-Neck Trial of Hyaluronic Acid Filler for Static Horizontal Neck Rhytides Using Either a Cannula or Needle. *Dermatologic Surgery* 48(4):p 423-428, April 2022. doi: 10.1097/DSS.0000000000003391.

²¹ AADA Position Statement on Medical Spa Standards of Practice. <https://server.aad.org/forms/policies/Uploads/PS/PS-Medical%20Spa%20Standards%20of%20Practice.pdf>

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Removal of Dermal Filler Implant Material and Patient Preference (cont.)

- The AADA maintains that removal of filler injections should be performed by appropriately trained physicians or non-physician personnel under the direct supervision of a physician.²⁵
- Physicians and supervised non-physicians have the training and expertise to minimize the risk of severe complications, identify impending complications, and manage them effectively.^{22,23}
- For the safety of the public, do-it-yourself administration of fillers by laypersons or by non-physician providers without direct physician supervision should not be permitted.

Dermatologists are the Preferred Provider for Cosmetic and Surgical Procedures²²

- One study found that the public preferred dermatologists and plastic surgeons for filler injections.²³
- Another study found that primary care physicians **considered fellowship-trained dermatologists the most qualified specialists** for various procedures, including filler injections, laser treatments, skin biopsies, and skin cancer surgeries.²⁴

Primary care physicians found dermatologists to be the most qualified specialist for:

- Filler injectables
- Botulinum toxins
- Laser procedures



²² Aleisa A, Lu JT, Al Saud A, Veldhuizen IJ, Rossi AM, Lee KC. The Differences in the Practice of Cosmetic Dermatologic Procedures Between Physicians and Nonphysicians. *Dermatol Surg*. 2023 Dec 1;49(12):1165-1169. doi: 10.1097/DSS.0000000000003948.

²³ Bangash HK, Ibrahim OA, Green LJ, Alam M, Eisen DB, Armstrong AW. Who do you prefer? A study of public preferences for health care provider type in performing cutaneous surgery and cosmetic procedures in the United States. *Dermatol Surg*. 2014 Jun;40(6):671-8. doi: 10.1111/dsu.0000000000000016.

²⁴ Ibrahim OA, Bangash H, Green L, Alam M, Armstrong AW, Eisen DB. Perceptions of expertise in cutaneous surgery and cosmetic procedures: what primary care physicians think. *Dermatol Surg*. 2012 Oct;38(10):1645-51. doi: 10.1111/j.1524-4725.2012.02577.x. Epub 2012 Sep 7. PMID: 22958115.

²⁵ AADA Position Statement on Medical Spa Standards of Practice. <https://server.aad.org/forms/policies/Uploads/PS/PS-Medical%20Spa%20Standards%20of%20Practice.pdf>

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AADA Resources: Filler FAQs

- The AADA is committed to equipping the public with resources to support patient-centered decision-making.
- Informed consent is critical to ensuring patients understand the risks associated with dermatologic cosmetic procedures.
- Educational materials help patients engage in informed discussions with their dermatologist and collaboratively shape their treatment plan.

Public / Cosmetic treatments / Wrinkles / **FILLERS: FAQs**

Advertisement

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FILLERS: FAQs

OVERVIEW

FAQS

PREPARATION

FILLERS GIVING PATIENTS BETTER, LONGER-LASTING RESULTS

Fillers are popular. To help you decide whether this treatment is right for you and to have the treatment performed safely, the AAD provides the following facts.

Warning

If you decide that fillers are right for you, it is important to know that injecting a filler is a medical procedure. Having a filler injected in a non-medical setting can be extremely dangerous. To protect your health, you should never get a filler injected at a:

- Non-medical spa.
- Party.
- Salon.
- Someone's home.

The AAD recommends that you see a doctor who has expertise injecting fillers and many satisfied patients. The results you see depend largely on the experience of the person performing this procedure. A dermatologist has the knowledge and experience required to inject fillers safely and effectively.

AADA Dermal Filler FAQs: <https://www.aad.org/public/cosmetic/wrinkles/fillers-faqs>



Conclusion

Expertise in Body Dermal Filler Injections

Dermatologists, plastic surgeons, and other specialty physicians are highly trained in minimally invasive cosmetic procedures, including dermal filler injections in the neck and décolletage.²⁶

Complications Decrease with Experienced Physicians

Complication rates are lower when procedures are performed by or under the direct supervision of experienced physicians.²⁶

Informed Decision Making, Patient Education, and Physician Oversight

Dermal filler patient safety for the neck and décolletage relies on clear and informed-decision making and patient education, physician oversight, and adherence to evidence-based clinical practices.²⁷

The AADA welcomes the opportunity to collaborate with the FDA to ensure fillers are safely administered to patients and remain under the supervision of qualified physicians who can appropriately oversee other medical personnel.

²⁶ Alam M, Kakar R, Nodzenski M, et al. Multicenter Prospective Cohort Study of the Incidence of Adverse Events Associated With Cosmetic Dermatologic Procedures: Lasers, Energy Devices, and Injectable Neurotoxins and Fillers. *JAMA Dermatol*. 2015;151(3):271–277. doi:10.1001/jamadermatol.2014.2494

²⁷ AADA Position Statement on Medical Spa Standards of Practice. <https://server.aad.org/forms/policies/Uploads/PS/PS-Medical%20Spa%20Standards%20of%20Practice.pdf>

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