NEW YORK STATE OF OPPORTUNITY. Department of Health

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DATE: April 13, 2022

TO: All Licensed Practitioners

RE: New York State Department of Health (NYSDOH) Guidelines for Performing Liposuction with and without Fat Grafting in the Office-Based Surgery Setting.

From: Office of Quality and Patient Safety, Clinical Center, Office-Based Surgery Program

Purpose of the Guideline

This guideline for performing liposuction with and without fat grafting in the Office-Based Surgery setting was developed by the New York State Department of Health (NYSDOH) Office-Based Surgery Program based on recommendations of a Plastic Surgery Expert Workgroup and the Office-Based Surgery Advisory Committee. This guideline aims to achieve the following goals:

- Improve safety in the performance of liposuction with and without fat grafting procedures in the office-based surgery setting.

- Reduce adverse events and deaths related to office-based surgery procedures of liposuction with and without fat grafting.

The NYSDOH Office-Based Surgery Program is publishing these guidelines in relation to the following:

- In recent years, liposuction and gluteal fat grafting/augmentation procedures have become some of the most frequently performed plastic surgery procedures in the United States.[1,2]

- The NYSDOH Office-Based Surgery Program has recently experienced an increase in reported deaths related to liposuction and liposuction with fat grafting.

- Recommendations to improve safety in the performance of liposuction and liposuction with fat grafting procedures include that subfascial or intramuscular injection should not be performed.[1,3] All injections should be performed exclusively into the subcutaneous tissue.

- Anatomical studies have found that the injection of fat subjacent to the fascia of the gluteus maximus muscle can migrate deep through the muscle into the submuscular

space, possibly causing tears in the gluteal veins, leading to fat embolisms to the heart and lungs.[3]

These guidelines are in addition to and supplement other standards or guidelines for office-based procedures inclusive of liposuction with or without fat grafting.

Office-Based Surgery in New York State:

- New York State Public Health Law (PHL) Section 230-d defines Office-Based Surgery (OBS) as any surgical or other invasive procedure accompanied by general anesthesia, deep sedation, or moderate sedation; any liposuction procedure with removal of greater than 500 ml; or any liposuction procedure with removal of less than 500 ml under supplemented local, minimal or moderate sedation, or inhalational nitrous oxide in any concentration; where the procedure is performed by a physician, physician assistant (PA), specialist assistant (SA), or podiatrist privileged to perform ankle surgery by the State Education Department in a location other than an Article 28 hospital or ambulatory surgery center.

- In accordance with PHL § 230-d, all physicians, PAs, SAs, and podiatrists must report specific adverse events occurring in relation to the performance of OBS to the Office of Quality and Patient Safety (OQPS) of the NYSDOH. Such reportable adverse events shall be reported to OQPS within three business days of the occurrence of the event; suspected transmission of bloodborne pathogens must be reported within three business days of becoming aware of a suspected transmission.

- Failure to report this information falls within the definition of professional misconduct identified in Section 6530(48) of NYS Education Law.

Adverse Events that must be reported according to PHL § 230-d:

1. Patient death within thirty (30) days of the procedure;
2. Unplanned transfer to a hospital for reasons related to the office-based surgery encounter;
3. An emergency department visit within seventy-two (72) hours of office-based surgery for reasons related to the office-based surgery encounter;
4. Unscheduled hospital admission or assignment to observation services within seventy-two (72) hours of the office-based surgery, for longer than twenty-four (24) hours;
5. Any other serious or life-threatening events: The NYSDOH has adopted those events identified and defined as Serious Reportable Events by the **National Quality Forum** as meeting the definition of "other serious or life-threatening events" involving OBS patients.
   In addition to the National Quality Forum Serious Reportable Events, the NYSDOH has identified the following events as meeting the OBS law definition of an "other serious or life-threatening event":
   - Unplanned return to the Operating Room after discharge from an OBS practice for a procedure related to the OBS procedure;

- Delayed admission to the hospital for actual or potential OBS-related complications occurring between seventy-three (73) hours and thirty (30) days after an OBS procedure.

6. Any Suspected Health Care Transmission of a Bloodborne Pathogen (BBP): a suspected transmission of a bloodborne pathogen (BBP) from a healthcare practitioner to a patient or between patients originating in an OBS practice as a result of improper infection control practices. BBP include but are not limited to Hepatitis B virus, Hepatitis C virus, and Human Immunodeficiency Virus.

Who Must Report Adverse Events:

- It is the personal responsibility of each mandated reporter to ensure that an adverse event has been reported.

- A mandated reporter includes ANY physician, PA, SA, and/or podiatrist in an OBS practice, hospital, or other setting who believes or becomes aware of a patient complaint, complication, condition, emergency department visit, hospital admission, or death that occurred related to an OBS procedure.

The Adverse Event Report can be found at: https://obsaer.health.ny.gov.

Guidelines for Performing Liposuction with and without Fat Grafting in the Office-Based Surgery (OBS) Setting

I. Proceduralist Graduate Medical Education/Board Certification

a. Proceduralist must be a NYS-Licensed physician (MD or DO) who is certified or eligible for certification by a board recognized by the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) in Plastic Surgery, Plastic Surgery within the Head and Neck, Plastic and Reconstructive Surgery, or Dermatology.
b. Physicians planning to perform procedures of liposuction with removal of greater than 500 ccs with or without fat grafting in the OBS setting must have privileges in their specialty for the same procedure at a licensed Article 28 acute care hospital and/or ambulatory surgery center.

II. Patient selection for OBS setting vs. hospital

a. Patients should be under the care of a licensed practitioner (physician performing procedure and/or patient's primary care provider), who should evaluate the condition of the patient, including specific comorbidities that may complicate performance of the procedure and/or anesthetic management, and identify and discuss with the patient the potential risks associated with treatment options.
b. A patient who, due to pre-existing medical or other conditions, is at undue risk for complications, should be referred to an appropriate specialist for a preoperative consultation, and to another treatment setting/facility for performance of the surgery and administration of the anesthesia as deemed necessary by the evaluation.
c. Preoperative evaluation should include, but may not be limited to:

i. Review of patient's medical status to include medical history, surgical history, anesthetic history, social history, allergies, height, weight, current medications, hematological or bleeding disorders, and psychological status.
ii. Review of previous medical records and interview of the patient or family to identify:
    1. Abnormalities of the major organ systems (e.g., cardiac, renal, pulmonary, neurologic, sleep apnea, metabolic, endocrine).
    2. Adverse experience with sedation/analgesia, as well as regional and general anesthesia.
    3. History of a difficult airway.
    4. History of previous surgical procedures with potential of scar tissue or herniations within the planned surgical site locations.
    5. Current medications (e.g., prescription, over the counter, herbals, supplements, or other), potential drug interactions, drug allergies, and nutraceuticals.
    6. Prior experience with post-operative pain, current and previous use of pain medications, and expectation of post-operative pain management plan.
    7. History of tobacco, alcohol, or substance use or abuse.
    8. History of hematological disorders and/or use of medications such as antithrombotics (anticoagulants/antiplatelet) or herbal supplements which may increase risk of bleeding or thrombosis.
iii. Performance of a physical examination of the patient to include vital signs, auscultation of the heart and lungs, evaluation of the airway, and evaluation of other organ systems where abnormalities have been identified.

d. Document preprocedural evaluation, including the review of findings and decision to perform procedure.

III. Preprocedural testing

a. Perform pertinent preprocedural testing based upon findings of the preprocedural evaluation.
    i. Review available laboratory test results; order additional laboratory tests guided by the patient's medical condition, physical examination, and the potential that results will affect the management of moderate sedation/analgesia.
    ii. Document review of preprocedural testing in the medical record.

IV. Anticoagulation for prevention of thromboembolism (i.e., blood clots)

a. Evaluate patient for history of, or potential for, venous thromboembolism and perform risk stratification as part of preprocedural evaluation.
    i. Utilize a venous thromboembolism risk assessment tool (e.g., Modified Caprini Scale).
    ii. Document evaluation of risk stratification and venous thromboembolism risk assessment tool utilized in the medical record.

b. Discuss risks of hormone therapy and consider discontinuing. When hormonal therapy is prescribed, consult with the ordering physician prior to discontinuing.
c. Utilize intermittent pneumatic compression devices for mechanical prophylaxis, early mobilization, chemical prophylaxis based on venous thromboembolism risk assessment findings/score, and limit Operating Room times (recommended Operating Room time limit of 2-3 hours).

V. Maximum amount of fluid removed by liposuction in office-based setting (Total Aspirate)

a. Large volume liposuction (greater than 5,000 ccs total aspirate) and/or large volume liposuction combined with other procedures should be performed in an Article 28 facility i.e., acute-care hospital or an Ambulatory Surgery Center.
b. No more than 5,000 ccs of aspirate should be removed while performing liposuction unless the patient is monitored overnight in an appropriate Article 28 facility with minimum of a registered nurse (RN) with ACLS certification in attendance.

VI. Post-op care/follow-up

a. Immediate postoperative care considerations:
    i. Identify length of required patient monitoring/recovery time in facility post procedure (number of hours) or if overnight monitoring needed, arrange transport and stay in an Article 28 facility.
    ii. Assess fluid and electrolyte requirements and plan for administration of replacement fluids to assure fluid and electrolyte balance.
        1. Fluid replacement recommendations:
            a. Replace preoperative fluid deficit as needed.
            b. Administer maintenance fluid, adjusting for changes in patients' clinical situation, e.g., vital signs, intake & output.
            c. Account for infiltration solution (super wet or tumescent technique).
            d. For patients undergoing greater than 4,000 ccs of liposuction:
                i. follow all fluid replacement recommendations as above, and
                ii. administer 1 cc of crystalloid solution for every 4 ccs of lipoaspirate greater than 4,000 ccs.
b. With longer procedures, 4 to 6 hours in length, patient should not be discharged after less than a 1-2 hour monitored observation in a Post Anesthesia Care Unit (PACU).
c. Post discharge considerations: early ambulation and chemical prophylaxis based on patient venous thromboembolism risk assessment.

VII. Maximum hours of procedures allowed in OBS setting (Length of Procedure)

a. Recommended Operating Room time of 2-3 hours; not to exceed 6 hours in length. If the Operating Room time is expected to exceed the maximum of 6

hours, the patient should be referred to an alternative facility (i.e., Article 28 acute-care hospital or an Ambulatory Surgery Center) for performance of the surgery and administration of the anesthesia.

b. If the intended procedure which, under usual circumstances would not exceed the maximum 6 hours in the Operating Room, should go beyond 6 hours the following processes should be in place prior to the start of the case:
    i. a written emergency transfer procedural plan for transferring patients to a hospital and
    ii. a transfer agreement with a local acute-care hospital within thirty (30) minutes of the OBS facility in which the surgeon has privileges to admit patients.

VIII. No intramuscular/submuscular injection of fat

a. When performing gluteal fat grafting procedures, fat should be injected into the subcutaneous space only and never cross the gluteal fascia. Intramuscular or submuscular fat injections are contraindicated.
b. If the aesthetic goal requires a greater amount of fat than can be placed in the subcutaneous layer, the surgeon should stage the procedure rather than injecting below the subcutaneous layer.

References:

1. Wall, S., Delvecchio, D., Teitelbaum, S., Villanueva, N. L., Dayan, E., Durand, P., Sanniec, K., & Rohrich, R. J. (2019). Subcutaneous Migration: A Dynamic Anatomical Study of Gluteal Fat Grafting. *Plastic and Reconstructive Surgery, 143(5),* 1343-1351. Doi: https://doi.org/10.1097/prs.0000000000005521

2. Teven, C. M., TerKonda, S. P., Martinez-Jorge, J., Mardini, S., & Rebecca, A. M. (2021). Liposuction and Patient Safety: Appropriately Credentialing Providers. *Plastic and reconstructive surgery*, *147*(6), 1087e–1088e. https://doi.org/10.1097/PRS.0000000000007970

3. American Society of Plastic Surgeons. (2018, January 31). *Gluteal Fat Grafting Advisory.* Retrieved from: https://www.plasticsurgery.org/for-medical-professionals/advocacy/key-issues/gluteal-fat-grafting-advisory