The Aesthetic Surgery Education and Research Foundation

Culture of Safety

Body Contouring

Report on Mortality from Gluteal Fat Grafting: Recommendations from the ASERF Task Force

M. Mark Mofid, MD, FACS; Steven Teitelbaum, MD, FACS; Daniel Suissa, MD, MSc, FRCSC; Arturo Ramirez-Montañana, MD; Denis C. Astarita, MD; Constantino Mendieta, MD, FACS; and Robert Singer, MD, FACS

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Abstract

Background: Gluteal fat grafting is among the fastest growing aesthetic procedures in the United States and around the world. Given numerous anecdotal and published reports of fatal and nonfatal pulmonary fat embolism resulting from this procedure, the Aesthetic Surgery Education and Research Foundation (ASERF) formed a Task Force to study this complication.

Objectives: To determine the incidence of fatal and nonfatal pulmonary fat embolism associated with gluteal fat grafting and provide recommendations to decrease the risks of the procedure.

Methods: An anonymous web-based survey was sent to 4843 plastic surgeons worldwide. Additional data on morbidity and mortality was collected through confidential interviews with plastic surgeons and medical examiners, public records requests for autopsy reports in the United States, and through the American Association for the Accreditation of Ambulatory Surgical Facilities (AAAASF).

Results: Six hundred and ninety-two (692) surgeons responding to the survey reported 198,857 cases of gluteal fat grafting. Over their careers, surgeons reported 32 fatalities from pulmonary fat emboli as well as 103 nonfatal pulmonary fat emboli. Three percent (3%) of respondents experienced a patient fatality and 7% of respondents reported at least one pulmonary fat embolism in a patient over their careers. Surgeons reporting the practice of injecting into the deep muscle experienced a significantly increased incidence rate of fatal and nonfatal pulmonary fat emboli. Twenty-five fatalities were confirmed in the United States over the last 5 years through of autopsy reports and interviews with surgeons and medical examiners. Four deaths were reported from 2014 to 2015 from pulmonary fat emboli in AAAASF facilities.

Conclusions: Despite the growing popularity of gluteal fat grafting, significantly higher mortality rates appear to be associated with gluteal fat grafting than with any other aesthetic surgical procedure. Based on this survey, fat injections into the deep muscle, using cannulae smaller than 4 mm, and pointing the injection cannula downwards should be avoided. More research is necessary to increase the safety of this procedure.

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Dr Mofid is an Associate Clinical Professor of Plastic Surgery (Voluntary), University of California, San Diego (UCSD), San Diego, CA; and is Chairman of the ASERF Gluteal Fat Grafting Task Force. Dr Teitelbaum is an Associate Clinical Professor (Voluntary), David Geffen School of Medicine at the University of California, Los Angeles (UCLA), Los Angeles, CA; and is President of ASERF. Dr Suissa is a plastic surgeon in private practice in Los Angeles, CA. Dr Ramirez-Montañana is a plastic surgeon in private practice in Monterey, Mexico. Dr Astarita is a Surgical Consultant, Department of Medical Examiner-Coroner, County of Los Angeles, CA. Dr Mendieta is a plastic surgeon in private practice in Miami, FL. Dr Singer is a Clinical Professor of Plastic Surgery (Voluntary), UCSD, San Diego, CA; and is a Past President of ASERF.

Corresponding Author:
Dr M. Mark Mofid, University of California San Diego, Department of Surgery, 4150 Regents Park Row Suite 300, La Jolla, CA 92037, USA.
E-mail: drmofid@mofidplasticsurgery.com

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The demand for gluteal augmentation with autologous fat has increased dramatically over the last five years. According to statistics from the American Society for Aesthetic Plastic Surgery (ASAPS), "core physicians" (plastic surgeons, dermatologists, and facial plastic surgeons) performed 18,487 of these procedures in 2015 compared to 7382 in 2011.[1] For the purposes of tabulation of procedural statistics, the number of cases performed by nonplastic surgeons is included in estimates provided by ASAPS (however, the Task Force believes that nonplastic surgeons should not be considered "core" specialists for this procedure.) It is estimated that as many as 25% more of these procedures are performed by non-core physicians, resulting in a total of approximately 23,108 procedures performed last year in the United States. The popular consumer website RealSelf (Seattle, WA) reported that in 2015 there were 7.2 million visits to buttock augmentation pages, a 32% increase from 2014. This number of visits was exceeded only by inquiries into breast augmentation, the most popular aesthetic surgical procedure.[2] The online forum reports high patient satisfaction and a general unawareness by patients and surgeons of the risk of severe complications.

There have been anecdotal and published reports of mortality from this procedure including a retrospective survey and autopsy-based study documenting 22 deaths over 10 and 15 years respectively in Mexico and Colombia from pulmonary fat emboli (PFE).[3] As the total numbers of cases performed in those countries over the study period was not provided, the incidence of fatal PFE was undetermined. The very first case report of a fatal PFE from gluteal fat grafting was published in the pathology literature in 2015.[4] Because of its concern and commitment to patient safety and given the significance of these findings and news reports in the lay press,[5-9] the ASERF formed a Task Force of 11 surgeons, pathologists, and statisticians to study the risks of both fatal and nonfatal PFEs from gluteal fat grafting as well as any potential variables affecting these risks.

METHODS

A 15 question survey (Sogo Survey, Herndon, VA) was created by the Task Force to query surgeons about numbers of cases performed, depth and angulation of injection, size and type of cannulae used for grafting, access and approach used, and the number of fatal and nonfatal PFEs occurring over the last 12 months and over their career. Additional questions were asked about geographic location. The survey was sent in July 2016 to 4843 active members of the American Society of Aesthetic Plastic Surgeons (ASAPS, 1963 members) and the International Society of Aesthetic Plastic Surgery (ISAPS, 2880 members) and results collected over 14 days with three separate email reminders to survey recipients. All duplicate ASAPS/ISAPS members were excluded from mutual member roster rolls so that individuals would be counted in either one or the other membership society only. All responses were anonymous and imported into an Excel (Microsoft, Redmond, WA) spreadsheet. In order to assure physicians of absolute privacy, it was unknown whether an individual surgeon had filled out the survey and it is possible that a surgeon may have completed it more than once. A variable was defined as each potential answer for every closed-ended question. Surgeons had the option of selecting more than one answer per question and the variables were consequently not mutually exclusive.

Individual rates of complications were calculated for each of the variables. Since each variable was either selected or not as an answer to each question, the rates of complication (fatal and nonfatal PFEs) were calculated for both "yes" and "no" answers for each variable. To account for the varying number of cases per surgeon, the rates of "yes" and "no" answers were then analyzed using a Poisson rate test to obtain a *P* value for each variable. In addition, incidence rate ratios (IRRs) were calculated for each variable in order to assess their unadjusted effect on the rate of complications. Finally, to tease out the independent contribution of each variable on the risk of PFEs, we used a backwards selection Poisson multivariate regression analysis to estimate the adjusted incidence rate ratio of fatal and nonfatal PFEs associated with each variable, along with the corresponding *P* value and 95% confidence interval. Other descriptive statistics were calculated such as surgeon experience, risk of complications for any surgeon who reported at least one case, and overall rates of PFE or death.

Email inquiries were sent to the International Association of Coroners and Medical Examiners (www.theiacme.com) and The National Association of Medical Examiners (www.thename.org) for autopsy reports consistent with fatal PFEs resulting from gluteal fat grafting. Confidential surgeon interviews were performed by Task Force members of self-reported and anecdotally identified surgeons with known fatal PFEs as well as of coroners with identified cases from 2011 onwards. A data request was made to the American Association for the Accreditation of Ambulatory Surgical Facilities (AAAASF) for all cases over the previous 24 months of a fatal PFE as a result of gluteal fat grafting. Additional inquiries were made to several medical malpractice carriers, state medical boards, and other outpatient surgical accreditation organizations. These other entities did not provide information citing either that the data had not been collected, the data were not indexed or in a searchable format, that the data were proprietary, or that they were unavailable for some other reason. CosmetAssure (Birmingham, AL), a surgical

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Table 1. Geographic Practice Location

Region	Percentage of respondents
USA/Canada	38%
South America	24%
Europe	15%
Mexico/Central America	11%
Middle East/North Africa	5%
Asia Pacific/Indian Subcontinent/Australia	4%
Other	3%
Sub Saharan Africa	1%

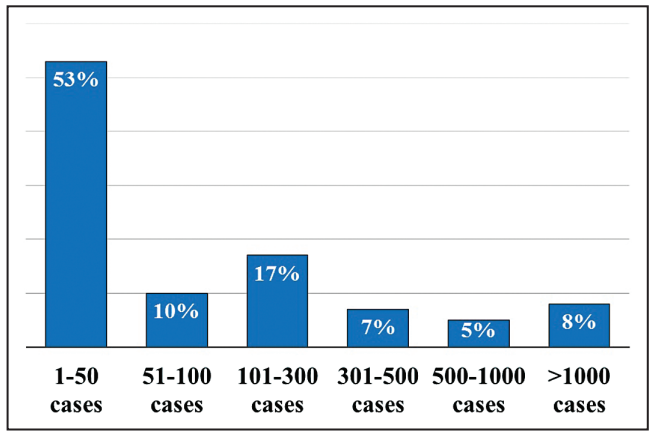

Figure 1. Percentage of surgeons stratified by surgical experience.

complications insurance corporation was queried about any known PFEs amongst insured patients.

RESULTS

Six hundred and ninety-two (692) responses were received from the 4843 email surveys sent to members of ISAPS and ASAPS (14.3% response rate). Of these responses, 612 surgeons (88.4% of respondents) reported at least one gluteal fat grafting procedure performed over a career for a total of 198,857 cases. The Task Force elected to exclude two surgeons whose unusually high outlier responses were most likely due to an erroneous entry while completing the survey. Thirty-two fatal PFEs were reported for a career mortality rate of 1:6214 cases of gluteal fat grafting. One hundred and three nonfatal PFEs were reported for a career PFE rate of 1:1931. The calculated total rate of having either a fatal or a nonfatal PFE over a career is therefore 1:1473. Over the previous 12 months, 574 surgeons reported performing 17,519 cases. Five fatal PFEs were reported over this period for an annual mortality rate of 1:3448 and 12 nonfatal PFEs were reported for an annual PFE rate of 1:1449. The calculated total rate of both fatal and nonfatal PFEs in the last year is therefore 1:1030 cases.

Three percent (3%) of respondents to the survey (18 individuals) who reported at least one gluteal fat grafting procedure experienced a patient fatality over their career. Seven percent of respondents reporting at least one case (43 individuals) experienced a patient with nonfatal PFE over their career. The mean number of buttock fat grafting surgeries performed by a surgeon reporting a death over his or her career was 605. The mean number of buttock fat grafting surgeries performed per surgeon never having a patient fatality was 283. No association was identified between surgeon experience and PFE. The geographic practice location of respondents is provided in Table 1. More than half of all respondents reported having done fewer than 50 cases over their careers and 8% of respondents (49 individuals) reported having performed over 1000 cases (Figure 1).

Surgeons were asked into which of the three planes (subcutaneous, mid to superficial muscle, and deep muscle) they typically injected fat. Respondents could indicate any or all of the three options. The reported plane of injection was found to be highly statistically correlated with both fatal and nonfatal PFEs. On multivariate analysis, the adjusted IRR for deep muscle injection was found to be 4.03 ($P < 0.0001$) for fatal PFE and 6.15 ($P < 0.0001$) for nonfatal PFEs. Angling of the cannula tip downwards during fat grafting was also found to be highly statistically correlated with fatal (IRR, 3.90; $P < 0.0001$) and nonfatal PFEs (IRR, 3.70; $P < 0.0001$). Large fat grafting cannulae over 4.1 mm were found to reduce both fatal (IRR, 0.2; $P < 0.0002$) and nonfatal PFEs (IRR, 0.14; $P < 0.0001$). Multiple hole cannulae (as opposed to single hole cannulae) were found to increase the risk of both fatal (IRR, 2.46; $P < 0.0001$) and nonfatal PFEs (IRR, 2.41; $P = 0.003$) (Tables 2 and 3).

Confidential Task Force interviews were conducted with surgeons identified anecdotally or self-reported to have had fatal PFEs. In association with surgeon interviews, autopsy reports and coroner interviews confirmed a total number of 25 unique cases over a 5 year and 9 month period from 2011 to September 2016 (Table 4). Through a public records request from the Medical Examiners offices in South Florida, seven deaths were identified. The Los Angeles County Medical Examiner-Coroner confirmed five deaths during the study period including three deaths in 2016. ASAPS procedural statistics from 2011 to 2015 estimate the total number of gluteal fat grafting cases performed by board certified plastic surgeons, facial plastic surgeons, and dermatologists to be 65,068 over a 5-year period with

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Table 2. Adjusted Incidence Rate Ratio (IRR) of Mortality from Pulmonary Fat Embolism in Association with Surgical Factors

Variable	IRR	*P* value	95% Confidence interval
Deep muscle injection	4.03	<0.0001	2.44, 6.66
Mid to superficial muscle injection	0.18	<0.0001	0.11, 0.27
Tip angled downwards	3.90	<0.0001	2.36, 6.46
Tip angled parallel	0.58	0.0255	0.36, 0.94
Cannula size ≥4.1 mm	0.20	0.0002	0.09, 0.47
Multiple hole cannula	2.46	<0.0001	1.63, 3.71

Table 3. Adjusted Incidence Rate Ratio (IRR) of Variables of Non-Fatal Pulmonary Fat Embolism in Association with Surgical Factors

Variable	IRR	*P* value	95% Confidence interval
Deep muscle injection	6.15	<0.0001	3.37, 11.24
Mid to superficial muscle injection	0.20	<0.0001	0.12, 0.33
Tip angled downwards	3.70	<0.0001	2.13, 6.43
Tip angled parallel	0.42	0.0010	0.25, 0.70
Cannula size ≥4.1 mm	0.14	<0.0001	0.06, 0.35
Multiple hole cannula	2.41	0.0003	1.49, 3.90

Table 4. Confirmed Deaths by Region

Region	Number of Deaths
South Atlantic/Southeast Central (FL, GA, NC, SC, VA, WV, AL, KY, MS, TN)	10
Pacific (AK, CA, HI, OR, WA)	7
Mid-Atlantic (MD, DE, NJ, NY, PA, DC)	6
West and Central South (TX, OK, LA, AR)	2
Midwest (IA, KS, MN, MO, NE, ND, SD, IL, IN, MI, OH, WI, AZ, CO, ID, MT, NV, NM, UT, WY)	0
New England (CT, ME, MA, NH, RI, VT)	0
Total	25

a margin of error of 30%.[1,10-13] Based upon the impression of Task Force members in their own communities, it was estimated that an additional 25% of cases were performed by noncore physicians not accounted for in ASAPS procedural statistics for a total of roughly 100,000 cases over this 5¾ year time frame. This suggests that the mortality rate may have been 1:4000 from 2011 to the present. The AAAASF data for the period of 2014 to 2015 showed that there were four reported fatal PFEs arising from gluteal fat grafting procedures.[14] It is estimated that 25% of all aesthetic procedures are performed in AAAASF facilities by core physicians that make up ASAPS procedural statistics making the total number of gluteal fat grafting cases performed in AAAASF facilities during this period 9407.[15] Four deaths from PFEs suggests an overall mortality rate in AAAASF facilities of 1:2351. AAAASF reports an overall mortality rate for all procedures in accredited facilities of 1:55,000 from 2001 to 2011.[16] This closely approximates previously published mortality rates of approximately 1:55,000 in AAAASF facilities.[17] AAAASF is the only nationally recognized accrediting organization of ambulatory surgery that has published statistics and requires reporting of all untoward sequelae.[18] The highest known mortality rate associated with an aesthetic procedure prior to this paper was abdominoplasty with a mortality rate of 1:13,147, nearly all from pulmonary embolisms.[19]

AAAASF has data on over 732,707 operations with liposuction, many of which had other simultaneous procedures. There were two deaths among the 285,921 cases in which the only procedure was liposuction, and the cause(s) of death were not specified.[20] This paper refers only to patients who had a PFE after the initiation of the gluteal fat injection portion of the procedure, so it can be concluded that it was the injection of fat and not the retrieval that contributed to the PFEs in this paper. It is important to distinguish that the phenomenon of PFE discussed here is a completely different problem than fat embolism syndrome, which is a systemic inflammatory response that results from pulmonary microemboli from a long list of causes, the most frequent of which is blunt trauma. It has also been reported with liposuction.[21,22] But the PFEs reported herein were macroscopic and caused catastrophic cardiopulmonary events. The Task Force found no descriptions of this entity occurring with other aesthetic operations.

CosmetAssure is an insurer of complications following aesthetic surgery. From March 2015 to February 2016 they covered approximately 700 gluteal fat grafting procedures with no reported deaths. Within this group, eight major complications occurred including one pulmonary embolism, one confirmed deep venous thrombosis, and one suspected deep venous thrombosis. Six of the eight major complications occurred in patients undergoing multiple procedures for an overall major complication rate of 1.1%.[23] Since CosmetAssure covers hospitalization costs, it is possible that a death without hospitalization in one of those cases was not reported.

DISCUSSION

Buttock augmentation using fat grafting techniques is among the fastest growing procedures performed in the United States with a 280% increase for the 5 year period from 2011 to 2015.[1] The origin of this procedure and its common reference as the "Brazilian Butt Lift" is generally attributed to the pioneering

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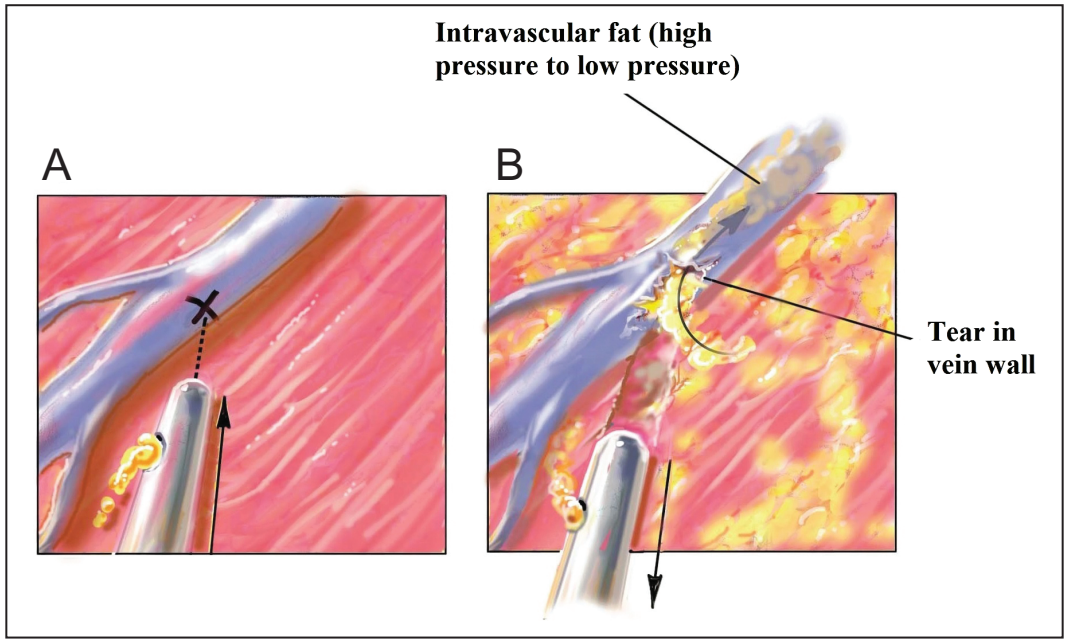

Figure 2. Illustration of injury to a gluteal vein wall by fat grafting cannula and transit of macroscopic fat particles from within the extravascular space into the lumen of the vein. (A) Depiction of a preinjury schematic of the gluteal vein wall and (B) depiction of an injury to the vein wall allowing intraluminal entry of fat.

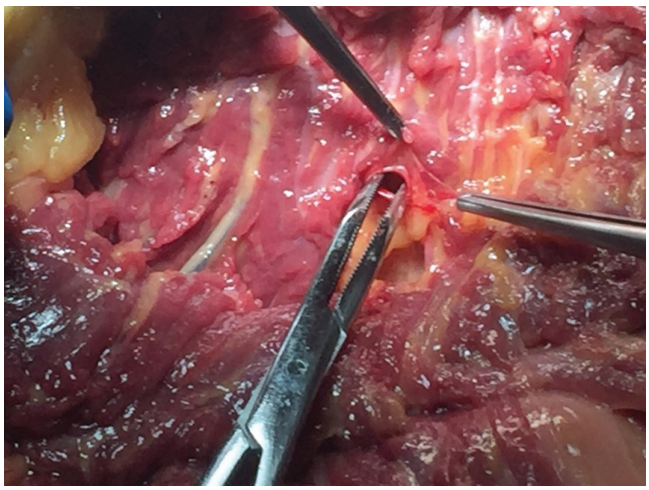

Figure 3. Middepth, midbody intramuscular dissection at the interface of the gluteus maximus and medius of the superior gluteal vein in a cadaver demonstrating a 4 mm in diameter vessel. The superior and inferior gluteal veins are even larger than this intramuscular tributary.

work of Toledo beginning in 1985.[24] Recent published and anecdotal reports of mortality from pulmonary fat embolism have not yielded the incidence of mortality and morbidity from this procedure.[25] Despite its great significance there is no all-inclusive local, state, or federal database for surgical deaths or complication and for this reason, multiple metrics were used to ascertain the safety of gluteal fat grafting relative to other common aesthetic surgical procedures. Recent reports in the lay press about how deaths from "superbug" infections are not reported in a consistent and searchable manner by medical examiner offices underscore the public's interest in better reporting throughout the medical industry.[26]

Instructions for gluteal fat grafting often include injections into the deep plane to possibly enhance fat graft survival[27,28] and the use of needles or small 2 mm cannulae for injection of the fat.[29,30] Generally low perioperative complication rates have been published with this procedure although serious complications including sciatic nerve injury have been reported with deep injections of fat.[31] In 2016 Sinno et al published a comparison of satisfaction and complications between silicone implants and lipoinjection.[32] They identified a total of 3567 gluteal augmentation patients in the studies that fulfilled their search criteria. They concluded that the rate of complications was lower with lipoinjection, although there were deaths in their review of gluteal augmentation with fat but not with silicone buttock implants. Also in 2016, Conde-Green et al published a systemic review of the literature and meta-analysis, and found 19 articles made up of 17 case studies and two retrospective studies for a total of 4105 patients (these include the cases in the Sinno review).[32] They found that 46.7% of the articles recommended fat injections into both the subcutaneous and intramuscular planes, 26.7% into only the intramuscular planes, and 26.7% into the subcutaneous or subfascial planes.[25] Cárdenas-Camarena first reported on nonfatal PFE in 1999 and Astarita first

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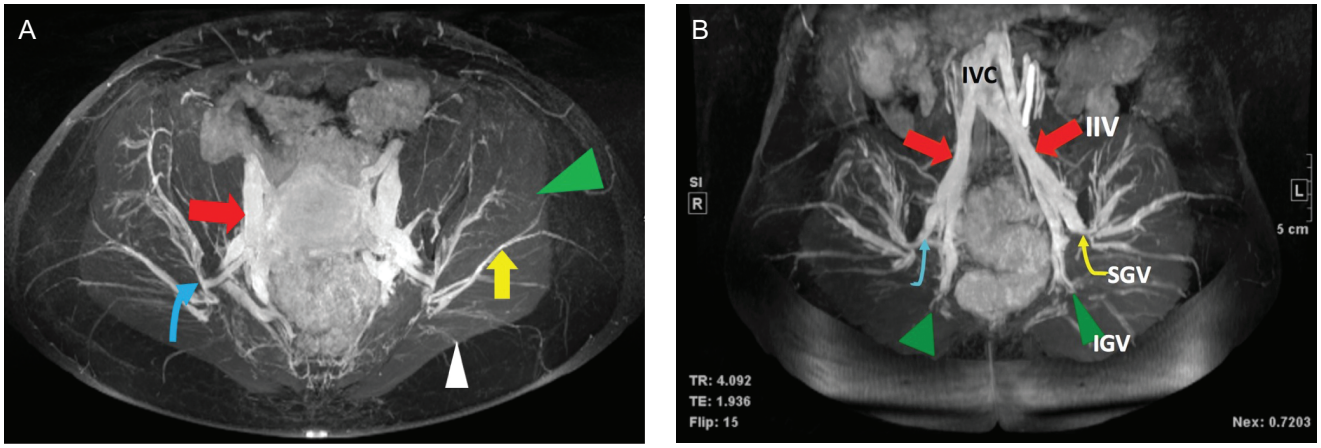

Figure 4. (A) Axial maximum intensity projection (MIP) from a blood pool MR angiogram following 10 mL gadofosveset in a 37-year-old female. The curved blue arrow indicates the typical large gluteal artery/vein bundle traversing in the plane between gluteus maximum (white arrowhead) and gluteus medius (green arrowhead) supplying multiple smaller perforating vessels through gluteus maximus to supply subcutaneous tissues. The superior gluteal vein travels between the gluteus medius and minimus toward the iliac wing. The superior gluteal vein (straight yellow arrow) and inferior gluteal vein drain into iliac veins (red arrow). Courtesy of Martin Prince, MD, PhD Columbia University. (B) A coronal oblique view shows how the superior gluteal veins (curved yellow arrow) and inferior gluteal veins (green triangles) flow directly into iliac veins (red arrows) and inferior vena cava (IVC).

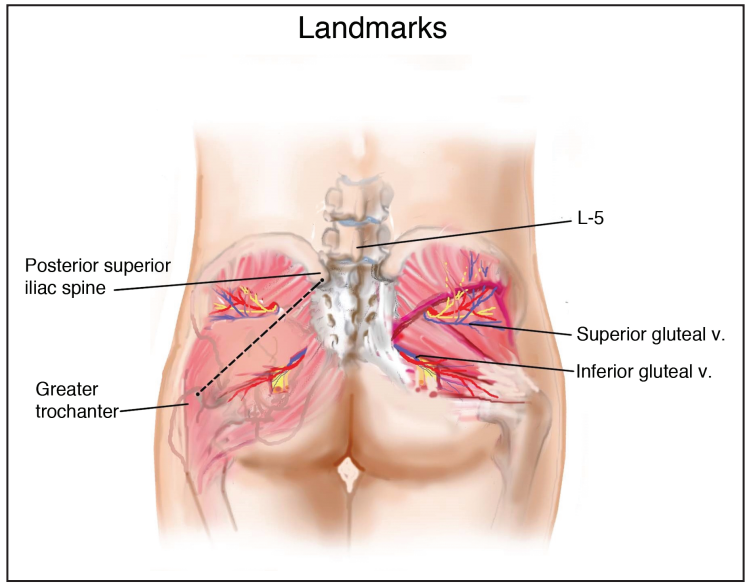

Figure 5. Posterior coronal illustration of superior and inferior gluteal vessels relative to bony anatomic landmarks.

described a fatal PFE in a 2015 case report.[4,33] A retrospective survey of Mexican plastic surgeons and the Colombian autopsy registry by Cárdenas-Camarena reported a total of 22 deaths from PFEs over a period of 10 and 15 years respectively.[34] It was hypothesized by these authors that macroscopic fat embolization was the result of migration of large fat particles from the high pressure extravascular space into the low pressure venous system due to venous injury. Two patients in their study had undergone postmortem examination of the gluteal region; one had a complete transection of the superior gluteal vein and the other an injury to the inferior gluteal vein (Figure 2). All postmortem exams revealed fat within the gluteal muscles. It is possible that a vein is cannulated and the injection is made directly into it, but it is more probable that extravascular fat follows a pressure gradient through a vessel wall injury into the venous system. The volume of fat grafted was not found to be associated with PFE in their study and the mean amount of fat injected in fatal PFE was 214 cc. The volumes of fat grafted in cases of nonfatal and fatal

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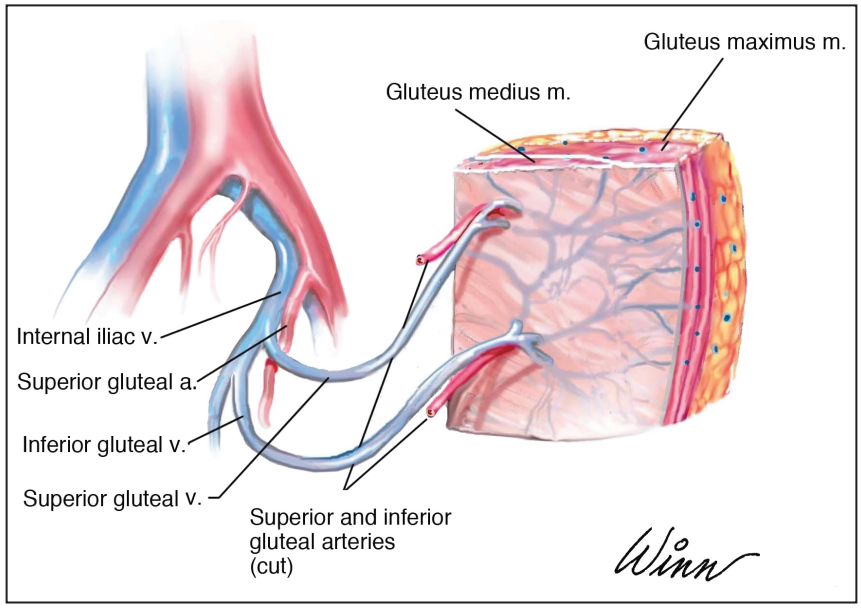

Figure 6. Illustration of superior and inferior gluteal vessels and their tributaries leading into the internal iliac vein and inferior vena cava.

PFE were not studied in our survey and has never been found to be associated with this complication. Deep muscle injections were discouraged due to the theoretical risks of injury to larger venous channels located deep in the muscle. Our study seems to support these recommendations in that surgeons who reported injecting into the deep muscle experienced higher rates of both fatal and nonfatal PFEs with IRRs of greater than 4 and 6, respectively. Some surgeons with PFE complications who were interviewed by the Task Force were emphatic that they injected only into the subcutaneous layer. It is impossible to ever determine whether they unknowingly injected deeper since careful gluteal dissections were not done or the results are unavailable. It is also possible that subcutaneous injections may track between a muscle plane or along a vascular pedicle deep and into an area of large veins or a venous plexus.

We also found that large and single hole cannulae (≥4.1 mm) are highly protective against fatal and nonfatal PFEs possibly due to a blunter tip reducing the likelihood of injury to vessels, or perhaps a stiffer cannula which may make it less likely to bend and follow an unintentionally deeper path. It may also be that larger diameter cannulae deposit larger parcels of fat that are less likely to enter the circulation.

The superior and inferior gluteal veins that drain into the internal iliac system are large caliber vessels that can be 4 mm or more as they transit the interface of the gluteus maximus and medius towards the iliac wing (Figures 3-7). Near the sciatic notch, large caliber veins that are 6 mm or larger may appear as venous lakes or varices. These delicate veins can be seen to noticeably fill and collapse with ventilation during surgical dissection. At the level of the gluteal muscle fascia they frequently split into smaller tributaries in the subcutaneous tissue.

The three methods in this study to estimate mortality spans between 1:2351 (AAAASF data) and 1:6241 (career reported mortality rate through the survey). The Task Force stresses that none of these estimates be construed as the actual rate. Each estimate has significant limitations in its methodology. It deserves special emphasis that the 25 documented US deaths are absolutely unequivocal, and it is almost certain that there are additional cases of which the Task Force was unaware or could not confirm. The Task Force believes that while it is desirable to know the exact number in order to track improvements from changes in technique, it is nonetheless clear that the rate is unacceptably high and the approach to this procedure must be improved. Given the tendency for surgeons to overestimate the total numbers of cases performed over a career and the reluctance to report complications in survey-based studies, it is possible that the mortality rate is higher than the survey suggests. It is interesting to note that the mortality rate over the previous 12-month period reported in the survey of 1:3448 is closer to data reported by AAAASF and from data generated through autopsy reports and surgeon and coroner interviews. Furthermore, it is nearly certain that the Task Force interviews and coroners' reports did not capture all deaths over the 5¾ year period from 2011 to September 2016, and that the actual mortality rate is likely higher than the 1:4000 estimated

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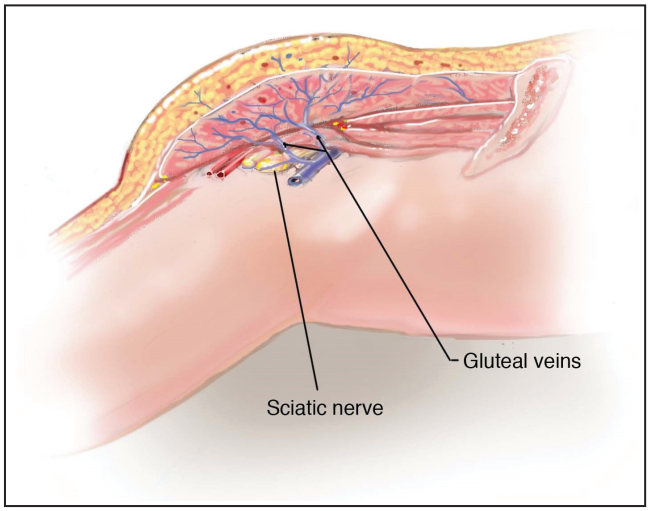

Figure 7. Sagittal illustration of the sciatic nerve and superior and inferior gluteal veins with perforators through the gluteus musculature.

using ASAPS procedural statistics and deaths identified by the Task Force. Several individuals contacted by the Task Force refused to participate with an interview or did not respond to emails and phone calls, and those anecdotally identified deaths were not counted in the study as they could not be confirmed. It is therefore likely that the actual mortality rate from PFEs is significantly greater than 1:4000 and possibly as high as 1:2351 or more. This puts the mortality risk from gluteal lipoinjection possibly 10-20 times greater than the average mortality rate for aesthetic surgery procedures in AAAASF facilities of 1:55,000. And it is possibly three to five times higher than the risk from abdominoplasty, which until this paper was thought to have the highest risk of any aesthetic procedure at 1:13,5000 in AAAASF facilities.

Even surgeons who have a done a few thousand gluteal augmentation procedures are urged to recognize that statistically speaking they have not done enough procedures to know that their own preferred technique will result in a lower rate of PFEs than the estimates in this paper.

Interviews with surgeons who have had cases of nonfatal PFE reveal that this is not a benign complication. Many of these patients require prolonged intensive care unit stays and suffer from chronic and in some cases permanent pulmonary morbidity and incomplete recovery. Our study reveals the risk of nonfatal PFEs to be between 1:1931 (career reported survey response) and 1:1449 (prior 12 month survey response). These numbers are lower than the previously reported incidence of 1:833 by Condé-Green.[25] Our survey is likely limited by the tendency of surgeons to overestimate the total numbers of cases performed which would falsely lower the actual incidence of this complication and by the retrospective nature of the survey which relies on surgeon recall of cases and events that may have occurred in the distant past. Surgeons reported a higher PFE rate in the year prior to the study than over their careers; the likely explanation is that surgeons were more likely to overestimate their career experience relative to what they could credibly report for a single year.

It is unknown whether surgeons actually injected into the plane in which they thought they were injecting. For instance, intraabdominal injuries have been described as a complication of subcutaneous abdominal liposuction and there are multiple clearly defined fascial layers beneath that level.[35] If that can happen with abdominal liposuction then it is certainly plausible that it can happen with this procedure. It therefore cannot be stressed enough that it is impossible to know whether the deaths in the subcutaneous or the midsuperficial muscle group were due to injections into those layers or inadvertent injection into the deep muscle. The only way to ultimately resolve this would be careful postmortem dissections or perhaps high resolution computerized tomography (CT) scans to identify the location of the fat and of the entry point(s) into the venous circulation. The survey failed to define the difference between deep, mid, and superficial muscle injections as there are no precise anatomical delineations of these arbitrarily ascribed injection planes during this nonvisualized procedure, leaving it up to respondents to each subjectively provide their responses. This terminology was used in the questionnaire because these are the common terms surgeons colloquially use to describe the level of injection. Surgeons were asked to report the planes in which they "typically" inject but were not asked what they did in the specific instances of each death, leading to the possibility that a typical practice was not necessarily representative of what occurred in the case(s) of death. Furthermore, it is not known if surgeons who answered the survey are representative of all surgeons who perform gluteal augmentation, whether they answered honestly, or whether all nonfatal and fatal PFEs were accurately reported. It is not known whether surgeons who had a death were more likely to ignore the study or participate in order to inform other surgeons. Many important factors including fat harvest techniques, volume of fat grafted, the use of pump vs syringe or mechanical fat grafting techniques, fat preparation techniques and the size of fat particles were not evaluated by our survey and could be of significant relevance. Patient positioning and incision location would profoundly affect the possible trajectories a cannula might follow and could be very important. Thoroughly investigating all of these relevant issues in a future survey would substantially lengthen the time to complete the survey and likely reduce the already low response rate. And in all likelihood there would still be a recall bias and many surgeons may not even remember all these details. Given privacy issues the survey was designed so that it would be impossible to trace any answers back to a surgeon. This means that surgeons who had already completed it were sent reminders

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Table 5. Recommendations from the ASERF Task Force on Gluteal Fat Grafting

1. Avoid injecting into the deep muscle.
2. Use ≥4.1 mm diameter single hole injection cannula.
3. Avoid downward angulation of the cannula.
4. Position patient and place incisions to create a path that will avoid deep muscle injections.
5. Maintain constant 3-dimensional awareness of the cannula tip.
6. Only inject when cannula is in motion.
7. Consider pulmonary fat embolism in unstable intra- and postoperative patients.
8. Review gluteal vascular anatomy.
9. Include the risk of fat embolism and surgical alternatives in the informed consent process.

and there was no way to be certain they did not fill it out a second time. This is a conundrum for which there is no clear solution other than to create a registry. Even a registry would still suffer from the potential of surgeons not reporting deaths out of concern for reputation, privacy, and legal issues. Routine audits such are done with AAAASF reaccreditation visits would likely increase compliance. The rate of PFEs is low enough so that tens of thousands of patients would need to be enrolled to achieve a statistically significant outcome, which would take at least a few years to achieve meaningful enrollment given the number of procedures done annually. There are potentially a great number of contributing issues that are as yet unknown, and so a great amount of data would need to be captured. Despite this daunting prospect, the Task Force encourages the plastic surgery societies to consider creating such a registry. A high-level collaboration should also be developed between the plastic surgery societies and coroners' offices in the largest cities. This will bring cases to light that may have not been recorded in the registry. Indeed, this relationship should be developed whether or not a registry is created. The central issue to understand is the exact mechanism of death. This relationship may also allow investigation into the location of the grafted fat and of the vessel injury. Many coroners have CT scanners and it is possible that a thin-cut scan would reveal these answers. Or perhaps the pathologists may be willing to allow plastic surgeons to assist in the dissection of the buttock region, ideally a surgeon experienced with gluteal perforator flaps.

Even if these recommendations are followed, the data still predict there will be deaths because there were deaths reported in the survey and in surgeon interviews with injection into the subcutaneous level. Perhaps the combination of several of the recommendations will diminish the risk of death to near zero, but the survey does not provide any data upon which such a conclusion can be made. It is unknown whether the rare patient may have veins in the subcutaneous tissue or superficial muscle of sufficient caliber to allow a catastrophic load of fat to embolize. It is not known whether with proper positioning and constant vigilance a specific plane can be reliably maintained or whether there will inevitably be a rate of unintended deeper passes of the cannula into the deep muscle. It is also not understood whether superficial injection might possibly cause distraction injuries to the larger and deeper veins or whether superficially injected fat can travel along a tissue plane towards that disrupted vessel. There are many hundreds or even thousands of cannula passes during a typical case, so even the very slightest rate of accidental deeper passes could present a significant risk. It is impossible to ascertain whether with ideal instrumentation, positioning, and constant vigilance unintended deeper injections can be eliminated or whether they will always occur with some finite frequency.

Although we have identified factors that the questionnaire and a review of anatomy suggests will reduce risk, it must be emphasized that it is not statistically valid to use those numbers to calculate the rate of PFEs if the recommendations were to be followed. This leads to an important question: how will surgeons know whether these recommendations reduce the risk, and if so, what the rate of PFEs will be? Without a registry surgeons will have to wait until another paper such as this is published, with its inevitable deficiencies. And if there is not some postmortem determination of the location of the fat and of the venous injury it will not be known whether the procedure is dangerous in all planes or whether there is a risk-free technique.

Surgeons and patients will ask if the procedure is "safe." The Task Force has focused on data and believes that defining safety is a philosophical question that should be answered by the community of plastic surgeons and patients.

CONCLUSION

Gluteal fat grafting is a popular aesthetic surgical procedure with a previously unknown incidence of pulmonary fat embolism and mortality. The three methodologies used to calculate the risk of death yielded estimates from a low of 1:6214 to a high of 1:2351. Surgeons answering the survey who reported injection of fat into the subcutaneous plane and into the superficial to midmuscular plane experienced 63% and 82% risk reductions respectively of pooled fatal and nonfatal PFEs. In contrast, those reporting injections into the deep muscular plane experienced a 403% increase in the risk of pooled fatal and nonfatal PFEs. It has been suggested that gluteal vein injury allows an ingress of the injected fat across a pressure gradient. It is strongly recommended that practitioners performing this procedure avoid deep muscle injections. Though mid to superficial muscle

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and subcutaneous injections are safer, it is likely that some risk remains with them. It is further recommended that large bore single-hole cannulae larger than 4.1 mm be used for grafting and that the cannula not be directed downward. It is possible that there may be protective value in keeping the injection cannula in motion while injecting to avoid a single large bolus injection into a vessel. PFE should be considered in a patient experiencing significant hemodynamic or pulmonary instability during the intra- and postoperative period, and such patents should be immediately transferred to a hospital with critical care services. The recommendations of the Task Force are summarized in Table 5. More research is needed to identify techniques that avoid these catastrophic complications and may include perioperative imaging to identify gluteal vessels in advance of fat injections, ideal incisional access locations, refined instrumentation, investigation into fat preparation, and pharmacologic venoconstriction. Patients interested in gluteal augmentation through fat grafting should be made aware of the risk of pulmonary fat embolism, techniques that can be employed to decrease known risks of mortality and complications with this procedure, and alternatives that include silicone implant-based gluteal augmentation. Further anatomical, clinical, and postmortem studies are needed to confirm findings of this limited study and to identify techniques that may improve the safety of gluteal fat grafting.

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