

1 Determining the Safety of Office Based Surgery:

2 What Ten Years of Florida Data and Six Years of Alabama Data Reveal

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9 **Background:** This report is a continued examination of ten years of prospectively collected
10 Florida in-office adverse event data and new comparable data from mandatory Alabama in-office
11 adverse event data reporting.

12 **Objective:** To determine which office surgical procedures have resulted in reported
13 complications.

14 **Methods:** This study is a compilation of mandatory reporting of office surgical complications by
15 Florida and Alabama physicians to a central agency. Reports resulting in death or a hospital
16 transfer were further investigated via telephone or internet follow-up to determine the reporting
17 physician's board certification status, hospital privilege status, and office accreditation status.

18 **Results:** In ten years in Florida there were 46 deaths and 263 procedure-related complications
19 and hospital transfers. A total of 57% (26/46) of the deaths and 49.8% (131/263) of hospital
20 transfers were associated with non-medically necessary (cosmetic) procedures. The majority of
21 non-medically necessary (cosmetic) procedure related deaths (67%) and hospital transfers (74%)
22 were from procedures performed on patients under general anesthesia. Liposuction and
23 liposuction with abdominoplasty or other cosmetic procedure resulted in 10 deaths and 34

24 hospital transfers. Of the offices reporting adverse events, 38% of offices were accredited by an
25 independent accrediting agency, 93% of physicians were board-certified, and 98% of physicians
26 had hospital privileges. The most common specialty of physicians reporting adverse events was
27 plastic surgery (45% of all reported complications). Dermatologists reported 4 total
28 complications (no deaths), and accounted for 1.3% of all complications over this 10 year period.

29 In six years in Alabama there were 3 deaths and 49 procedure related complications and
30 hospital transfers. A total of 42% (22/52) of hospital transfers and zero deaths were associated
31 with non-medically necessary (cosmetic) procedures. The majority of cosmetic procedure related
32 hospital transfers (86%) were from procedures performed on patients under general anesthesia.
33 Liposuction accounted for no deaths and 2 hospital transfers. Of the offices reporting adverse
34 events, 71% of offices were accredited by an independent accrediting agency, and 100% of
35 physicians were board-certified. Plastic surgery was the most common specialty represented in
36 adverse event reporting (42.3% of all reported complications). Dermatologists reported 1
37 complication (no deaths), and accounted for 1.9% of all complications over this 6 year period.

38 **Conclusion:** Continued analysis reveals that medically necessary office surgery does not
39 represent an emergent hazard to patients. The data obtained from 10 years of Florida and 6
40 years of Alabama adverse event reporting are both comparable and consistent. Medically
41 necessary surgical procedures performed in the office setting by dermatologists have an
42 exceedingly low complication rate, and complications that did arise were largely unexpected,
43 isolated, and possibly unpreventable. Cosmetic procedures performed in offices by
44 dermatologists under local and dilute local anesthesia yielded no reported complications.

45 Complications from cosmetic procedures accounted for nearly half of all reported
46 incidents in both Florida and Alabama, and in both states plastic surgeons were most represented

47 in adverse event reports. Liposuction performed under general anesthesia requires further
48 investigation as deaths from this procedure continue to occur despite the possibility of using
49 dilute local anesthesia for this procedure. Requiring physician board certification and physician
50 hospital privileges does not seem to increase safety of patients undergoing surgical procedures in
51 the office setting. Mandatory reporting of adverse events in the office setting should continue to
52 be championed. Reporting of delayed deaths after hospital outpatient and ambulatory surgery
53 center (ASC) procedures should be implemented. All data should be made available for scientific
54 analysis after protecting patient confidentiality.

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57 Increased media attention on human error in medicine has continued to bring patient
58 safety issues to the forefront of a national debate, and in response numerous state medical boards
59 have drafted, and will continue to draft, regulations designed to protect patients undergoing
60 procedures in the office setting. As legislative bodies move to protect patient safety, regulations
61 should be drafted based on sound data and the best available evidence. We have previously
62 reported examinations of the data collected by the state of Florida from 1 year, 19 months, 3
63 years, 4 years, 5 years, and 7 years.^{1,2,3,4,5,6,7} Since the last report Florida data collection has
64 continued, but 6 years of office surgery incident reports from the Alabama State Board of
65 Medical Examiners have also been obtained (via special request).

66 **Materials and Methods**

67 The state of Florida instituted mandatory physician office adverse event reporting in
68 February of 2000. These reports are public domain, and are reported to the Agency for Health
69 Care Administration (AHCA, Tallahassee, FL). Reportable events include: the death or hospital

70 transfer of a patient, brain or spinal damage, procedure performed on the wrong patient or
71 surgical site, other damages not included in the informed consent, and the removal of unplanned
72 foreign objects remaining from a surgical procedure. As underreporting is a recognized potential
73 problem, the AHCA crosschecks these reports with malpractice claims and spontaneous
74 complaints. Any physician with a discrepancy in adverse event reporting is required to submit a
75 report and is investigated and sanctioned. The Florida reports are the only source to list the
76 reporting physician's identity which allows for investigation of credentials, office accreditation,
77 and hospital privileges.

78 The state of Alabama instituted mandatory physician office adverse event reporting in
79 December of 2003. Any procedure in an office that results in death, patient transfer to hospital,
80 anesthetic or surgical events requiring CPR, unscheduled hospitalization related to the surgery,
81 and surgical site deep wound infection must be reported.

82 While these reports are currently not public domain, we petitioned the Alabama Board of
83 Medical Examiners to obtain these data. The reports were obtained from the Board with
84 supplemental information on physician board certification and office accreditation to match the
85 comparative data set from Florida.

86 As these adverse events are required to be reported by state law and there was no
87 intervention on human subjects, approval by an Institutional Review Board (IRB) was not sought
88 for this study.

89 All incidents in Florida from 3/2000-1/2010 and Alabama from 12/03-12/09 filed with
90 the Florida AHCA and Alabama Board of Medical Examiners, respectively have been collected
91 and analyzed. These reports and summary spreadsheets are available and can be downloaded at
92 <http://www.theskincancercenter.net/reports>. Physician hospital privileges were determined via

93 internet at the Florida Department of Health Healthcare Practitioner License Search at
94 <https://ww2.doh.state.fl.us/IRM00PRAES/PRASLIST.ASP>. This information was then verified
95 with the respective hospitals. Physician board certification was determined by internet
96 verification at <https://www.abms.org/WC/login.aspx>. Office accreditation was determined via
97 internet at Accreditation Association for Ambulatory Health Care (AAAHC) at
98 http://www.aaahc.org/eweb/dynamicpage.aspx?site=aaahc_site&webcode=find_orgs, the
99 American Association of Accreditation of Ambulatory Surgery Facilities (AAASF) at
100 <http://www.aaaasf.org>, and The Joint Commission at
101 <http://www.qualitycheck.org/consumer/searchQCR.aspx>.

102 **Results:**

103 Data collected from each state are presented in Table 1, 2, and 3.

104 Florida:

105 In 10 years of Florida data there were a total of 309 reported adverse incidents arising
106 from an office based surgical procedure. Of these, 46 resulted in death, and 263 in reportable
107 complications or hospital transfers. Cosmetic procedures accounted for 57% (26/46) of deaths
108 and 49.8% (131/263) of hospital transfers. The overwhelming majority of cosmetic cases
109 resulting in hospital transfer or death (79% and 67%, respectively) were performed under general
110 anesthesia. The most common cosmetic procedures resulting in hospital transfer and/or death
111 were liposuction and abdominoplasty. Liposuction resulted in 28% of all cosmetic
112 complications (14% of total complications), and resulted in 32% of the cosmetic deaths (22% of
113 total deaths). All but 5 cases of liposuction were performed under general anesthesia. Many of
114 the deaths reported after liposuction were delayed by several hours to days and were most
115 frequently due to pulmonary emboli, fat emboli, respiratory failure, and cardiorespiratory arrest.

116 There were 4 adverse event reports from dermatologists in 10 years in Florida, and none
117 resulted in death. One report involved a vasovagal episode which occurred after liposuction
118 performed under general anesthesia. Next, there was a brief episode of atrial fibrillation which
119 occurred 2 hours after an excision performed with a minimal amount of local anesthesia.
120 Another report involved a wrong surgical site during a Mohs procedure performed with local
121 anesthesia. One mentally impaired patient on home oxygen therapy suffered a 2nd degree burn to
122 the face during an excision under IV sedation when an electrocautery spark ignited the oxygen
123 supply.

124 Alabama:

125 In 6 years of Alabama data there were a total of 52 adverse surgical incident reports.
126 Three resulted in death, and 49 in reportable complications, or hospital transfers. There were no
127 deaths from cosmetic procedures. Nearly half of all reported incidents (42%) were from cosmetic
128 procedures, and 89% of these procedures were performed under general anesthesia. Liposuction
129 performed under general anesthesia was responsible for 2 hospital transfers over this 6 year
130 period, but there were no reported deaths. These 2 hospital transfers were due to pulmonary
131 edema.

132 Over the 6 years of Alabama data examined there were no deaths and only one hospital
133 transfer reported by a dermatologist. This was for a documented Methicillin-resistant
134 Staphylococcus aureus (MRSA) infection and seroma development subsequent to a melanoma
135 excision under local anesthesia.

136 Physician Specialty:

137 Data collected from each state are presented in Tables 1, 2, and 3.

138 Analysis of the adverse event reports by physician specialty revealed that plastic surgeons
139 were responsible for 44.9% of all reported complications over a 10 year period in Florida and
140 42.3% of all complications in a 6 year period in Alabama. Plastic surgeons represent 0.55% and
141 0.53% of the total number of physicians in the states of Florida and Alabama, respectively.
142 Table 2 highlights the complications by physician subspecialty in both states. According to the
143 Medicare physician registration information, the number of practicing physicians in Florida total
144 about 55,000, while those for Alabama total about 9,200. Based on the number of complications
145 reported in each state over the compiled 16 years, both reveal a minimal rate of percent
146 complication per physician less than 0.5%.

147 Office Accreditation:

148 The Alabama Board of Medical Examiners encourages all surgical offices registered with
149 the Board to maintain accreditation by an independent organization, and indeed 71% of reporting
150 offices in this analysis were accredited. Florida's Department of Health has begun an annual
151 inspection of all surgical offices not otherwise accredited by AAAHC, AAAASF, or JCAHO in
152 an effort to have 100% of offices being accredited by an independent organization. However, at
153 the time of initial data collection of each incident, only 38% of offices reported independent
154 accreditation. The data reveal no clear pattern that suggests independent accreditation is
155 particularly effective in preventing complications leading to death and hospital transfers after
156 office procedures.

157 Physician Board Certification and Hospital Privileges:

158 The overwhelming majority of physicians (93% of Florida and 100% of Alabama)
159 reporting adverse events were board certified. In Florida, 98% of reporting physicians had
160 hospital privileges. We were unable to assess hospital privileges from the data collected from

161 Alabama. Of those who were not board certified and/or had no hospital privileges, there was no
162 increase or pattern of increased adverse events noted. However, the sample sizes of both non
163 board certified physicians and physicians without hospital privileges were both extremely small
164 and thus too small to analyze. Therefore, no conclusions can be drawn regarding impact of
165 physician hospital privileges and/or board certification on overall safety of patients undergoing
166 surgical procedures in the office setting.

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168 **Discussion:**

169 Patient safety issues, especially protection of patients undergoing surgical procedures in
170 the office setting, have moved to the forefront of a national debate, and therefore have become an
171 important topic for legislative leaders and health care providers. This analysis of adverse event
172 reporting from two states continue to solidify trends which have been previously identified in
173 earlier analyses of this data.¹⁻⁶ Analysis now includes 10 years of Florida adverse event
174 reporting data, and remarkably the pattern of deaths and injuries has remained consistent with the
175 first year of reports, that just over half of complications arose from cosmetic procedures. The
176 significance of these trends are strengthened by the addition of 6 years of Alabama adverse event
177 reporting data. These support the trends seen in the data collected from Florida, with nearly half
178 (42%) of all reports arising from cosmetic procedures.

179 The pattern of deaths and injuries specifically from liposuction performed under general
180 anesthesia in Florida continues to be remarkable. Liposuction under general anesthesia
181 accounted for 22% of total procedure related deaths and 14% of total procedure related
182 complications. Liposuction under general anesthesia accounted for 32% of cosmetic procedure
183 related deaths and 22% of all cosmetic procedure related complications. Review of the Florida

184 data shows that deaths and adverse events associated with liposuction under general anesthesia
185 have trended lower. This is presumed to be secondary to the Florida Board of Medicine's
186 restriction of the number of cosmetic procedures that can occur at once when liposuction is being
187 performed.⁸ Although Florida requires physicians operating under general and intravenous
188 sedation to keep case logs, these logs are not public domain, and the total number of liposuction
189 cases performed in each state under general anesthesia could not be obtained, preventing
190 calculation of an accurate fatality rate. However, a recent report estimated that a fatality rate as
191 high as 1 in 5224 for liposuction under general anesthesia.⁹

192 Although the exact number of liposuction cases performed in each state under general
193 anesthesia are not obtainable currently, we sought context from 2010 national statistics regarding
194 liposuction procedure volume. National statistics compiled separately by The American Society
195 for Aesthetic Plastic Surgery (ASAPS)¹⁰ and The American Society for Plastic Surgeons
196 (ASPS)¹¹ demonstrated that liposuction was one of the top five invasive cosmetic surgical
197 procedures performed in 2010, with 289,016 and 203,106 cases listed respectively. The 2010
198 ASPS further stratifies procedure volume by region. Data on specific states are not available at
199 this time. "Region 4", i.e. Florida, Delaware, District of Columbia, Georgia, Maryland, North
200 Carolina, South Carolina, Virginia, West Virginia, and Puerto Rico accounted for 44,075 (22%)
201 of all liposuction cases performed. "Region 3", i.e. Alabama, Kentucky, Mississippi, Tennessee,
202 Arkansas, Louisiana, Oklahoma, and Texas, accounted for 29,101 (14%) of total liposuction
203 cases performed.

204 This analysis shows that in 16 years of adverse event reporting data combined from two
205 states there were no reports arising from liposuction performed under dilute local (tumescent)
206 anesthesia, and this is compatible with recent reports of the high safety of liposuction using

207 exclusively tumescent local anesthesia.^{12,13} Liposuction performed under general anesthesia
208 requires further investigation as deaths from this procedure continue to occur despite the
209 possibility of using dilute local anesthesia for this procedure. As liposuction remains one of the
210 most commonly performed cosmetic surgical procedure in the United States^{10,11} and a recent
211 report estimates that one-third of all liposuction in the United States is performed with
212 tumescent anesthesia,¹⁴ we contend that continued use of general anesthesia for liposuction must
213 be called into question and investigated rigorously.

214 The majority of patient deaths occurring in the context of general anesthesia (especially
215 when used for liposuction) were delayed. There were two patient deaths reported that appear to
216 be caused directly by general anesthesia-one death from malignant hyperthermia, and one death
217 due to an allergic reaction. The remaining deaths occurring in this context were associated with,
218 but not caused by, general anesthesia. Mandatory reporting of delayed deaths by Ambulatory
219 Surgery Center (ASC) and hospital outpatient facilities, which is not currently done, would be
220 beneficial.

221 The data show that the requirement for physicians to be board-certified has little to no
222 impact on patient safety as 93% of Florida and 100% of Alabama reporting physicians were
223 board-certified in their respective specialties. Similarly, office accreditation does not seem to
224 offer significant patient safety advantages as 38% of Florida and 71% of Alabama reporting
225 facilities were accredited by an independent organization. There is no clear pattern that suggests
226 that board certification or accreditation are effective in preventing deaths, complications, and
227 hospital transfers after office-based surgical procedures.

228 We again have found that most of the incidents due to medically necessary procedures
229 presented here were isolated, unexpected, and possibly unpreventable. With continued legislation

230 ongoing regarding regulation for office based surgical procedures, we again call for
231 consideration of the balance between prevention of loss of life by increased regulations vs. loss
232 of life created by decreased access to medically necessary care. Such regulations will only be
233 effective if based on objective analysis of sound, complete data.

234 The benefit of a national discussion among patients, providers, and patient safety
235 advocates regarding the prevalence of deaths and injuries due to cosmetic surgical procedures
236 cannot be underestimated. Mandatory reporting of adverse events in the office setting should
237 continue to be championed. Reporting of delayed deaths after hospital outpatient and
238 ambulatory surgery center (ASC) procedures should be implemented. All data should be made
239 available for scientific analysis after protecting patient confidentiality. As physicians strive to
240 practice "evidence-based medicine", we welcome evidence-based regulations that can continue
241 to forward patient safety measures and the reduction of medical errors while avoiding severely
242 restricted access to medically necessary care.

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Table 1: Subspecialty comparison of complication rates by state

Specialty	Florida		Alabama	
	% of complications	% of physicians in state	% of complications	% of physicians in state
Plastic surgery	44.9%	0.55%	42.3%	0.53%
Gastroenterology	11.0%	1.4%	1.9%	1.3%
Nephrology/Interventional Nephrology	1.3%	0.8%	51.9%	1.2%
Ob-Gyn	6.4%	2.6%	0	3.5%
Radiology/Interventional Radiology	10.4%	6.0%	0	5.8%
Cardiology	9.1%	2.6%	0	3.0%
ENT/Facial plastic surgery	4.2%	0.66%	0	0.91%
Vascular surgery	3.2%	0.23%	0	0.62%
Dermatology/Dermatologic surgery	1.3%	1.2%	1.9%	0.78%

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274 **Table 2: 10 years of Florida Data**

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276 Florida data breakdown: Ten years total

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- 278 ■ Total number of physicians in state = 54, 923
- 279 ■ Total number of complications = 309
- 280 ■ Total number of deaths (all cause) = 46 (14.9%)
- 281 ■ Total number of hospital transfers/complications = 263 (85.1%)
- 282 ■ Total number of anesthesia complications = 39 (12.6%)
- 283 ■ Total number deaths (due to anesthesia) = 8 (17.4%)
- 284 ■ Total number of complications due to tumescent anesthesia = 2 (0.76%)
- 285 ■ % complication per physician in Florida = 0.56%
- 286 ■ # of complications per year in Florida = 31

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289 Physician breakdown by specialty:

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Specialty	# of complications	% of complications	# of physicians in state	% of physicians in state
Plastic surgery	139	44.9%	303	0.55%
Gastroenterology	34	11%	759	1.4%
Neph/Int nephrology	4	1.3%	442	0.80%
Ob-gyn	20	6.4%	1447	2.6%
Rad/Int radiology	32	10.4%	3281	5.97%
ENT	15	4.2%	365	0.66%
Urology	11	3.6%	657	1.2%
Cardiology	28	9.1%	1443	2.6%
Orthopaedics	1	0.3%	927	1.7%
Dermatology	4	1.3%	651	1.2%
OMFS	2	0.7%	144	0.26%
Vascular surgery	10	3.2%	129	0.23%
Anesthesiology	5	1.6%	2810	5.1%
Colorectal surgery	0	0	81	0.15%

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293 **Table 3: 6 years of Alabama data**

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295 Alabama data breakdown: Six years total

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- 297 ■ Total number of physicians in state = 9210
- 298 ■ Total number of complications = 52
- 299 ■ Total number of deaths (all cause) = 3 (5.7%)
- 300 ■ Total number of hospital transfers/complications = 49 (94.2%)
- 301 ■ Total number of anesthesia complications = 2 (3.8%)
- 302 ■ Total number deaths (due to anesthesia) = 0
- 303 ■ Total number of complications due to tumescent anesthesia = 0
- 304 ■ % complication per physician in Alabama = 0.56%
- 305 ■ # of complications per year in Alabama = 8.6

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308 Physician breakdown by specialty:

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Specialty	# of complications	% of complications	# of physicians in state	% of physicians in state
Plastic surgery	22	42.3%	49	0.53%
Gastroenterology	1	1.9%	123	1.3%
Neph/Int nephrology	27	51.9%	108	1.2%
Ob-gyn	0	0	320	3.5%
Rad/Int radiology	0	0	531	5.77%
ENT	0	0	84	0.91%
Urology	0	0	88	0.96%
Cardiology	0	0	275	3.0%
Orthopaedics	0	0	346	3.8%
Dermatology	1	1.9%	72	0.78%
Oral Surgery	0	0	47	0.51%
Vascular surgery	0	0	57	0.62%
Anesthesiology	0	0	349	3.8%
Colorectal surgery	1	1.9%	10	0.11%

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