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## Stellungnahme des NETZWERK-Lipolyse zur Übernahme in die Arzt Haftpflichtversicherung

Die meisten deutschen und österreichischen Haftpflichtversicherungen für Mediziner schließen die Injektions-Lipolyse ein, wenn die behandelnden Ärzte Mitglieder des NETZWERK-Lipolyse sind und unsere juristisch geprüften Aufklärungsformulare verwenden.

Einige wenige Arzthaftpflichtversicherer jedoch lehnen eine Übernahme zunächst ab. Begründung ist meistens, dass es sich bei der Injektions-Lipolyse um einen Off-Label-Use handelt.

Wir möchten im Namen des Medical Advisory Boards des NETZWERK-Lipolyse dazu wie folgt Stellung nehmen:

### 1. Off-Label-Use

Nicht nur in der ästhetischen Medizin, sondern in vielen medizinischen Fachbereichen ist der Off-Label-Use ein gängiges Therapieschema. Aber auch ästhetische Therapien werden häufig Off-Label durchgeführt. Das wohl breiteste Spektrum bieten die Behandlungen mit Botulinum Toxin A (Botox). Bislang sind für ästhetische BTX Behandlungen lediglich Glabella Falte und Krähenfüße zugelassen. Betrachtet man jedoch die gesamte Bandbreite ästhetischer BTX Behandlungen, kann konstatiert werden, dass alle Ärzte BTX im Off-Label-Use verwenden, denn es gibt eine große Anzahl weiterer Injektionspunkte, die nicht zugelassen sind.

### 2. Risiko

Für einen Versicherer steht naturgemäß die Risikoeinschätzung – hier einer Therapie – im Vordergrund. Wenn dem tatsächlich so ist, sollte dies auch für die Injektions-Lipolyse gelten.

Ganz dezidiert kann hier festgestellt werden, dass es mittlerweile drei Publikationen gibt, die statistische Erhebungen zu Komplikationen bei Injektions-Lipolyse dokumentieren. Duncan et al. haben mehr als 56.000 Behandlungen statistisch erfasst, Palmer et al. haben 10.500 Behandlungen dokumentiert und auch das NETZWERK-Lipolyse hat unter seinen Mitgliedern Befragungen durchgeführt. In 2012 sind 43.000 Behandlungen dokumentiert worden. Eine neue, noch nicht publizierte Statistik vom September 2015 weist sogar 74.000 dokumentierte Behandlungen aus. Innerhalb des Netzwerks haben wir ein Risikoprofil von 0,07 %, wenn alle Komplikationen eingerechnet werden. Schwerere Komplikationen sind Nekrosen und Abszesse, die nicht mehr prozentual, sondern absolut erfasst werden. In den letzten 14 Jahren wurden dem Medical Advisory Board des Netzwerks insgesamt 9 Fälle von Nekrose und 2 Abszesse gemeldet.

Wir haben alle diese Fälle untersucht und festgestellt, dass individuelle Behandlungsfehler seitens der Ärzte oder Nichtbeachtung von



Hinweisen durch die behandelten Patienten als Ursache angesehen werden konnten.

### 3. Allgemeine Sicherheitsarchitektur im NETZWERK-Lipolyse

Neben diesen ganz konkreten Hinweisen zum Risiko können wir hier weitere allgemeine Hinweise geben:

Alle Mitglieder des NETZWERK-Lipolyse arbeiten nach einem standardisierten Behandlungsprotokoll, das Höchstdosierung je Sitzung, Injektionsabstände und -tiefen sowie die Dosierung je Injektion festlegt.

Die von Dr. Hasenschwandtner entwickelte Injektionsformulierung besteht aus einem Nachbau des ursprünglich verwendeten Lipostabil N (wegen formaler Fehler im Nachzulassungsprozess vom Markt genommen) und einer Verdünnung mit einem VitaminB Zusatz. Durch die Verdünnung werden die Nebenwirkungen (Schmerz, Schwellung) stark reduziert.

Das Netzwerk lässt alle am Markt angebotenen Produkte oder von Apotheken hergestellten Magistraliterrezepturen auf ihre Korrektheit der Zusammensetzung hin von einem unabhängigen Labor überprüfen und gibt diese Informationen unmittelbar an seine Mitglieder weiter, so dass auch für eine korrekte Injektionslösung Verantwortung übernommen wird.

Es besteht eine Hotline und ein Komplikationsmanagement. In kürzeren Abständen werden die Mitglieder über neue Entwicklungen durch elektronische Rundschreiben sowie in schriftlicher Form über unser Organ, die „Kosmetische Medizin“, informiert.

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#### Anlagen

Literaturliste Injektions-Lipolyse und ausgewählte Publikationen Risikoprofil  
Aufklärungs- und Dokumentationsbögen

## List of publications

1. Ablon G, Rotunda AM: Treatment of lower eyelid fat pads using phosphatidylcholine: clinical trial and review. *Dermatol. Surg.* 2004; 30: 422-7
2. Adelson H: Management of side effects and adverse reactions from injection of phosphatidylcholine. *Am. J. Mesotherapy* 2006; 5: 16-7
3. Atiyeh BS, Ibrahim AE, Dibo SA: Cosmetic mesotherapy between scientific evidence, science fiction, and lucrative business. *Aesthet. Plast. Surg.* 2008; 32: 842-9
4. Avelar JM: Comment on "refinement of technique in injection lipolysis based on scientific studies and clinical evaluations". *Clin. Plast. Surg.* 2009; 36: 211-3
5. Bates B: 'Fat dissolving' substance injects CCs of controversy: despite growing U.S. interest, Lipostabil's safety remains uncertain, experts warn. *Skin & Allergy News* 2003; 34: 1
6. Baumann L: Cosmeceutical critique: phosphatidylcholine. *Skin & Allergy News* 2003; 34: 24-5
7. Bechara FG, Mannherz HG, Jacob M, Mazur AJ, et al: Induction of fat cell necrosis in human fat tissue after treatment with phosphatidylcholine and deoxycholate. *JEADV* 2012; 26: 180-5
8. Bechara FG, Georgas D, Sand M, Tomi N, et al: Incapsulated fat necrosis after lipolysis of the calf with phosphatidylcholine. *Dermatology* 2008; 216: 180-1
9. Bechara FG, Skrygan M, Kreuter A, Altmeyer P, et al: Cytokine mRNA levels in human fat tissue after injection lipolysis with phosphatidylcholine and deoxycholate. *Arch. Dermatol.* 2008; 300: 455-9
10. Bechara FG, Sand M, Hoffmann K, Sand D, et al: Fat tissue after lipolysis of lipomas: a histopathological and immunohistochemical study. *J. Cutan. Pathol.* 2007; 34: 552-7
11. Bechara FG, Sand M, Sand D, Rooterdam S, et al: Lipolysis of lipomas in patients with familial multiple lipomatosis: an ultrasonography-controlled trial. *J. Cutan. Med. Surg.* 2006; 10: 155-9
12. Bechara FG, Sand M, Altmeyer P, Hoffmann K: Intralesional lipolysis with phosphatidylcholine for the treatment of lipomas: pilot study. *Arch. Dermatol.* 2006; 142: 1069-70
13. Bellman B: Phosphatidylcholine reaction. *Skin & Allergy News* 2003; 34: 12
14. Brown SA: Commentary on: Metabolic and structural effects of phosphatidylcholine and deoxycholate injections on subcutaneous fat: a randomized, controlled trial. *Aesthet. Surg. J.* 2013; 33: 409-10
15. Brown SA: The science of mesotherapy: chemical anarchy. *Aesthet. Surg. J.* 2006; 26: 95-8
16. Bryant R: Controversial mesotherapy: could it be the next botox? *Dermatol. Times* 2004; 25: 1
17. Chase CC: Common complications and adverse reactions in a mesotherapy practice. *Am. J. Mesotherapy* 2006; 1: 14-5
18. Chung SJ, Chung HL, Ho SL, Sung TK, et al: The role of phosphatidylcholine and deoxycholic acid in inflammation. *Life Sci.* 2014, <http://dx.doi.org/10.1016/j.lfs.2014.05.013>
19. Co AC, Abad-Casintahan MF, Espinoza-Thaebtharm A: Submental fat reduction by mesotherapy using phosphatidylcholine alone vs. phosphatidylcholine and organic silicium: a pilot study. *J. Cosm. Dermatol.* 2007; 6: 250-7
20. De Paula Mesquita T, de Almeida HL, de Paula Mesquita MC: Histological resolution of naevus lipomatosus superficialis with intralesional phosphatidylcholine. *JEADV* 2009; 23: 714-5
21. Dobrodin A: The treatment for eye pads revealed. *Am. J. Mesotherapy* 2006; 1: 16-7
22. Doerr TD: Lipoplasty of the face and neck. *Curr. Opin. Otolaryngol. Head Neck Surg.* 2007; 15: 228-32

23. Duncan DI: Commentary on: Metabolic and structural effects of phosphatidylcholine and deoxycholate injections on subcutaneous fat: a randomized, controlled trial. *Aesthet. Surg. J.* 2013 33: 411-3
24. Duncan DI: Letter to the editor – Response to “injection lipolysis with phosphatidylcholine and deoxycholate”. *Aesthet. Surg. J.* 2013; 33: 1073-5
25. Duncan D, Rotunda AM: Injectable therapies for localized fat loss: state of the art. *Clin. Plast. Surg.* 2011; 38: 489-501, vii
26. Duncan D, Rubin JP, Golitz L, Badylak S, et al: Refinement of technique in injection lipolysis based on scientific studies and clinical evaluation. *Clin. Plast. Surg.* 2009; 36: 195-209,v-vi; discussion 211-3
27. Duncan DI, Palmer M: Fat reduction using phosphatidylcholine/sodium deoxycholate injections: standard of practice. *Aesthetic Plast. Surg.* 2008; 32: 858-72
28. Duncan DI: The role of phosphatidylcholine in non-surgical body contouring. In: *Aesthetic Mesotherapy and Injection Lipolysis in Clinical Practice*, ed. by Sh.Madhère. Replika press Pvt, Ltd./India 2007: chapter 8: 61-75
29. Duncan DI, Chubaty R: Clinical safety data and standards of practice for injection lipolysis: a retrospective study. *Aesthet. Surg. J.* 2006; 26: 575-85
30. Duncan DI, Hasenschwandtner F: Lipodissolve for subcutaneous fat reduction and skin retraction. *Aesthet. Surg. J.* 2005; 25: 530-43
31. Friedland JA: Comment on “mesotherapy and injection lipolysis”. *Clin. Plast. Surg.* 2009; 36: 193
32. Frisari P, Pinto R: Mesosculpt with phosphatidylcholine. *Am. J. Mesotherapy* 2006; 6: 9
33. Fritz K, Tiplica G-S: *Kosmet. Med.* 2011; 32: 280-6
34. Göller A: Lipolyse in der plastischen Chirurgie. *Dissertation*, Ulm 2011
35. Gupta A, Loboeki C, Singh S, Robertson M, et al: Actions and comparative efficacy of phosphatidylcholine formulation and isolated sodium deoxycholate for different cell types. *Aesthet. Plast. Surg.* 2009; 33: 346-52
36. Hasegawa T, Matsukura T, Ikeda S: Mesotherapy for benign symmetric lipomatosis. *Aesthet. Plast. Surg.* 2010; 34: 153-6
37. Hasenschwandtner F, Gundermann K: Injection lipolysis with phosphatidylcholine and deoxycholate. *Aesthet. Surg. J.* 2013; 33: 1071-2
38. Hasenschwandtner F: Statistische Auswertung einer Befragung der Ärzte des NETZWERK-Lipolyse. *Kosmet. Med.* 2013; 34: 29-30
39. Hasenschwandtner F, List P, Spannauer M: Objektive Messung der Körperzusammensetzung nach Injektionslipolyse mit Polyenylphosphatidylcholin mittels DEXA-Methode (Dual-Energy X-Ray-Absorptiometrie). *Kosmet. Med.* 2010; #5: 246-52
40. Hasenschwandtner F: Fat melting injections – The latest scientific findings, terms and methods. *Kosmet. Med.* 2009; #2: 10-5
41. Hasenschwandtner F, Brandl D: Phosphatidylcholine. NETWORK-Lipolysis, 2009, <http://www.network-lipolysis.com/index.php?id=1513>
42. Hasenschwandtner F: Injection lipolysis: a new method of body contouring. In: *Handbook of Cosmetic Skin Care – 2<sup>nd</sup> Edition*, e3dt. By A.Shai, H.I.Maibach, R.Baran, Repikla press Pvt Ltd./India, 2009; chapter 13: pp. 102-5
43. Hasenschwandtner F: Altersbedingte Fettgewebsveränderungen: Lipolyse, Cellulitebehandlung. In: *Hautalterung – Grundlagen, Prävention, Therapie*, ed. By J.Krutmann, T.Diepgen and C.Billmann-Krutmann, Springer press, Heidelberg 2008, chapter 10: pp. 151-165
44. Hasenschwandtner F, Furtmueller F, Spannauer M, Silye R: Detailed documentation of one lipolysis treatment: blood values, histology, and ultrasound findings. *Aesthet. Surg. J.* 2007; 27: 204-11
45. Hasenschwandtner F: Injection lipolysis for effective reduction of localized fat in place of minor surgical lipoplasty. *Aesthet. Surg. J.* 2006; 26: 125-30
46. Hasenschwandtner F: Fat melting injections. *Am. J. Mesotherapy* 2006; 6: 24-25

47. Hasengschwandtner F: The subcutaneous injection of phosphatidylcholine for means of lipolysis. Lipodissolve – The non surgical liposculpture. *Akt. Dermatol.* 2005; 31: 549-52
48. Hasengschwandtner F: Phosphatidylcholine treatment to induce lipolysis. *J. Cosmet. Dermatol.* 2005; 4: 308-13
49. Heinrich K-G: Efficacy of injection of phosphatidylcholine into fat deposits – a non-surgical alternative to liposuction in body-contouring. *Indian J. Plast. Surg.* 2005; 38: 119-22
50. Heinrich KG: Injection lipolysis with phosphatidylcholine. *Cosmet. Med.* 2004; #5-6: 238-40
51. Hexsel DM, Serra M, de Oliveira Dal’Forno T, Zechmeister do Prado D: Cosmetic uses of injectable phosphatidylcholine on the face. *Otolaryng. Clin. N. Am.* 2005; 38: 1119-29
52. Hexsel D, Serra M, Mazzuco R, de Oliveira Dal’Forno T, et al: Phosphatidylcholine in the treatment of localized fat. *J. Drugs Dermatol.* 2003; 2: 511-8
53. Hoffmann K: Injection lipolysis. *Hautarzt* 2010; 61: 847-55
54. Hoffmann K, Altmeyer P: Verfahren zur Körperformung. In: *Ästhetische und plastische Operationen in der Dermatologie*, W3L-press/Herdecke/Witten, 2007; chapter 6.1-6.3
55. Hui KC: Body contouring by liposculpture. *The Hong Kong Medical Diary* 2008; 13: 20-3
56. Hübner N-F, Horch RE, Polykandriotis E, Rau TT, Dragu A: A histopathologic and immunohistochemical study on liquification of human adipose tissue ex vivo. *Aesth. Plast. Surg.* 2014; 38: 976-84
57. Hübner NF: Adipocytolyse durch Lipostabil®: Ex vivo Untersuchungen an humane Gewebe (Adipocytolysis by Lipostabil® ex vivo investigations with human tissue). *Dissertation* July 11, 2012
58. Hunstad JP, De Souza M: Review of “the lipodissolve technique: clinical experience” and author’s comment. *Clin. Plast. Surg.* 2009; 36: 223-6
59. Hunter NS, El Tawdy AM, Hegazy RA, El Samanoudy SI, et al: Letter: A 15-patient pilot trial of lipolysis of the hips and thighs using a phosphatidylcholine and deoxycholate formulation. *Dermatol. Surg.* 2013; 39: 791-4
60. Janke J, Engeli S, Gorzelniak K, Luft FC: Compounds used for ‘injection’ lipolysis destroy adipocytes and other cells found in adipose tissue. *Obes. Facts* 2009; 2: 36-9
61. Kardorff B, Gansel RW, Tats R, Balzer L, et al: 2004 Lipodissolve Clinical Report [http://www.asal-meso.com/html/news/june\\_1B\\_2005\\_news.htm](http://www.asal-meso.com/html/news/june_1B_2005_news.htm)
62. Karolchyk S, Seibert L: Detergent effects of sodium deoxycholate are a major feature of an injectable phosphatidylcholine formulation used for localized fat dissolution: a review. *Am. J. Mesotherapy* 2006; 1: 18-9
63. Kato M, Watanabe T, Yamada N, Yoshida Y, et al: Mixed cell granulomatous panniculitis on the cheek due to injection of a solution containing phosphatidylcholine and deoxycholate. *Dermatol. Surg.* 2010; 36: 1779-81
64. Khan MH, Victor F, Rao B, Sadick NS: Treatment of cellulite – Part II. Advances and controversies. *J. Am. Acad. Dermatol.* 2010; 62: 373-384
65. Kim HS, Park YM, Kim HO, Lee JY: Intralesional phosphatidylcholine and sodium deoxycholate: a possible treatment option for nevus lipomatosus superficialis. *Ped. Dermatol.* 2012; 29: 119-21
66. Kirn TF: Injection lipolysis is both defended, criticized: ‘we’ve been using injection lipolysis in my clinic for 2 years now and getting excellent results’. *Skin & Allergy News* 03/01/08
67. Klein SM, Schreml S, Nerlich M, Prantl L: In vitro studies investigating the effect of subcutaneous phosphatidylcholine injections in the 3T3-L1 adipocyte model: lipolysis or lipid dissolution? *Plast. Reconstr. Surg.* 2009; 124: 419-27
68. Klein SM, Prantl L, Berner A, Schreml S, et al: A new method to quantify the effect after subcutaneous injection of lipolytic substances. *Aesthet. Plast. Surg.* 2008; 32: 667-72; discussion 673-4

69. Kopera D, Horejsi R, Werner S, Moeller R: Injektionslipolyse zur Reduktion von seitlich im Bereich des Trochanters gelegenen Fettdepots („Reithosen“) – kontrollierte Halbseiten-Pilotstudie. *JDDG* 2008; 6: 287-291
70. Kopera D, Binder B, Toplak H, Kerl H, et al: Histopathologic changes after intralesional application of phosphatidylcholine for lipoma reduction – report of a case. *Am. J. Dermatopathol.* 2006; 28: 331-3
71. Kopera D, Binder B, Toplak H: Intralesional lipolysis with phosphatidylcholine for the treatment of lipomas: pilot study. *Arch. Dermatol.* 2006; 142: 395-6
72. Kutlubay Z: Evaluation of mesotherapeutic injections of three different combinations of lipolytic agents for body contouring. *J. Cosmet. Laser Ther.* 2011; 13: 142-53
73. Kyong YY, Choi KH: Woman with hemorrhagic spots on her abdomen. *Clin. Toxicol.* 2013; 51: 804-5
74. Le Coz J, Rittes PG: Guidelines and limitations on the use of phosphatidylcholine (Lipostabil) in mesotherapy. *Am. J. Mesotherapy* 2006; 2: 6-7
75. Levy SLJ: Tratamiento de la adiposidad localizada con fosfatidilcolina subcutánea a diferentes concentraciones. Una evaluación histological de su efecto. *Dissertation, Mexico* October 2013
76. Li H, Lee J-H, Kim SY, Yun H-Y: Phosphatidylcholine induces apoptosis of 3T3-L1 adipocytes. *J. Biomed. Sci.* 2011; 18: 91
77. Madhère S: Mesotherapy in the management of cellulite. In: *Aesthetic Mesotherapy and Injection Lipolysis in Clinical Practice*, ed. by S.Madhère, Informa Healthcare Replika press Pvt Ltd./India 2007; chapter 10: 85-98
78. Mahmud K, Crutchfield CE: Lipodissolve for body sculpting - safety, effectiveness, and patient satisfaction. *J. Clin. Aesthet. Dermatol.* 2012; 5: 16-9
79. Maggiori S: Traitement mésothérapique des xanthelasmas à la phosphatidilcoline polyinsaturée. 5<sup>th</sup> Cong. Int. Mésothérapie, Paris/France 1988, Oct.07-09, p.364
80. Mann MW, Palm MD, Sengelmann RD: New advances in liposuction technology. *Semin. Cutan. Med. Surg.* 2008; 27: 72-82
81. Matarasso A, Pfeifer TM: Mesotherapy and injection lipolysis. *Clin. Plast. Surg.* 2009; 36: 181-92
82. Matarasso A, Pfeifer TM, and the Plastic Surgery Educational Foundation DATA Committee: Mesotherapy for body contouring. *Plast. Reconstr. Surg.* 2005; 115: 1420-4
83. McNamara D: Lipolysis melts away appearance of double chin. *Skin & Allergy News* 04/01/09
84. McNamara D: Data validate some lipolysis, but not mesotherapy. *Skin & Allergy News* 2006; 37: 20
85. McNamara D: Mesotherapy gaining ground as surgery-free fat reducer. *Skin & Allergy News* 2005; 36: 17
86. Meißner T: Spritze rückt Fettpolstern und Lipomen zu Leibe. *Ärzte Zeitung* 04.03.2011
87. Mocosch A, Mota R, Gerber PA, Homey B: Severe toxic dermatitis after injection lipolysis. *Der Hautarzt* 2012; 63: 282-5
88. Môle B: A five years experience of subcutaneous chemical lipolysis with phosphatidylcholine injections. *Ann. Chir. PLast. Esthét.* 2011; 56: 112-9
89. Motolese P: Phospholipids do not have lipolytic activity. A critical review. *J. Cosmet. Laser Ther.* 2008; 10: 114-8
90. Myers P: The cosmetic use of phosphatidylcholine in the treatment of localized fat deposits. *Cosmet. Dermatol.* 2006; 19: 416-20
91. Nanda S: Treatment of lipomas by injection lipolysis. *J. Cutan. Aesthet. Surg.* 2011; 4: 135-7
92. Noh Y, Heo C-Y: The effect of phosphatidylcholine and deoxycholate compound injections to the localized adipose tissue: an experimental study with a murine model. *Arch. Plast. Surg.* 2012; 39: 452-6
93. Noreldin AA, Abd Elhamid AM, Hashem AM, Afifi AM: A pilot study on the use of injection lipolysis in visceral adipose tissues. *Aesthet. Surg. J.* 2013 33: 431-5

94. Olbertz F-W: Injektionslipolyse – ein Erfahrungsbericht nach einjähriger Anwendung. *Frauenarzt* 2007; 48: 576-7
95. Ono S, Hyakusoka H: Complications after self-injection of hyaluronic acid and phosphatidylcholine for aesthetic purposes. *Aesthet. Surg. J.* 2010; 30: 442-7
96. Palmer M, Curran J, Bowler P: Clinical experience and safety using phosphatidylcholine injections for the localized reduction of subcutaneous fat: a multicentre, retrospective UK study. *J. Cosmet. Dermatol.* 2006; 5: 218-26
97. Palumbo P, Melchiorre E, La Torre C, Miconi G, et al: Effects of phosphatidylcholine and sodium deoxycholate on human primary adipocytes and fresh human adipose tissue. *Int. J. Immunopath. Pharmacol.* 2010; 23: 481-9. Erratum 2010; 23: 970
98. Park E-J, Kim H-S, Kim M, Oh H-J: Histological changes after treatment for localized fat deposits with phosphatidylcholine and sodium deoxycholate. *J. Cosmet. Dermatol.* 2013; 12: 240-3
99. Peckitt N: Evidenced Based Practice: Phosphatidylcholine – A Review of Evidence for the Mode of Action in Injection Lipolysis. Jeremy Mills Publishing Ltd., Huddersfield, UK, 2005, ISBN: 9781905217137
100. Pindur L, Sand M, Altmeyer P, Bechara FG: Recurrent growth of lipomas after previous treatment with phosphatidylcholine and deoxycholate. *J. Cosmet. Laser Ther.* 2011; 13: 95-6
101. Rallis E, Kintzoglou S, Moussatoo V, Riga P: Mesotherapy-induced urticaria – Letter to the Editor. *Dermatol. Surg.* 2010; 36: 1355-7
102. Reeds DN, Mohammed S, Klein S, Boswell CB, et al: Metabolic and structural effects of phosphatidylcholine and deoxycholate injections on subcutaneous fat: a randomized, controlled trial. *Aesthet. Surg. J.* 2013; 33: 400-8. Comments by Brown SA: *Aesthet. Surg. J.* 2013; 33: 409-10 & Duncan D: *Aesthet. Surg. J.* 2013; 33: 411-3
103. Rein P: Injektionslipolyse mit Phosphatidylcholin – Erfahrungen mit der „Fett-Weg-Spritze“. *Der Deutsche Dermatologe* 2006; #9: 619-20
104. Rey JW, Schreiner O, Barreiros AP, Heise M, et al: *Z. Gastroenterol.* 2011; 49: 340-3
105. Rha EY, Kang JA, Lee JH, Oh DY, et al: Comparative analysis about the effect of isolated phosphatidylcholine and sodium deoxycholate for the viability of adipocyte. *J. Korean Soc. Plast. Reconstr. Surg.* 2010; 37: 531-4
106. Rittes PG, Rittes C: Treatment of aging neck with „Lipostabil“ endovena. *J. Drugs Dermatol.* 2009; 8: 937-9
107. Rittes PG: The lipodissolve technique: clinical experience. *Clin. Plast. Surg.* 2009; 36: 215-21
108. Rittes PG: Non-surgical body contouring: the Brazilian experience. In: *Aesthetic Mesotherapy and Injection Lipolysis in Clinical Practice*, ed. by Sh.Madhère, Replika press, Pvt. Ltd./India 2007; chapter 9, pp. 77-83
109. Rittes PG: Complications of Lipostabil endovena for treating localized fat deposits. *Aesthet. Surg. J.* 2007; 27: 146-9
110. Rittes PG, Rittes J, Amary MFC: Injection of phosphatidylcholine in fat tissue: experimental study of local action in rabbits. *Aesthetic Plast. Surg.* 2006; 30: 474-8
111. Rittes PG: The use of phosphatidylcholine for correction of localized fat deposits. *Am. J. Mesotherapy* 2006; 2: 8-11
112. Rittes PG: The use of phosphatidylcholine for correction of localized fat deposits. *Aesthetic Plast. Surg.* 2003; 27: 315-8
113. Rittes PG: The use of phosphatidylcholine for correction of lower lid bulging due to prominent fat pads. *Dermatol. Surg.* 2001; 27: 391-2
114. Rose PT, Morgan M: Histological changes associated with mesotherapy for fat dissolution. *J. Cosmet. Laser Ther.* 2005; 7: 17-9
115. Rotunda AM: Injectable treatments for adipose tissue: terminology, mechanism, and tissue injection. *Lasers Surg. Med.* 2009; 41: 714-20
116. Rotunda AM: Injectable treatments for adipose tissue: terminology, mechanism, and tissue interaction. *Lasers Surg. Med.* 2009; 41: 714-20

117. Rotunda AM, Weiss SR, Rivkin LS: Randomized double-blind clinical trial of subcutaneously injected deoxycholate versus a phosphatidylcholine-deoxycholate combination for the reduction of submental fat. *Dermatol. Surg.* 2009; 35: 792-803
118. Rotunda A: Scientific studies aim to dispel controversy surrounding injection lipolysis. *The European Aesthetic Guide Autumn 2008*, 74 – 84
119. Rotunda AM: Scientific studies aim to dispel controversy surrounding injection lipolysis. *The European Aesthetic Guide, Autumn 2008*; 76-84; [www.euroabg.com](http://www.euroabg.com)
120. Rotunda AM: Mesotherapy and injection lipolysis. In: *Facial Rejuvenation – A Total Approach*, ed. by D.J.Goldberg, Springer press Berlin Heidelberg 2007; chapter 7: 147-65
121. Rotunda AM, Kolodney MS: Mesotherapy and phosphatidylcholine injections: historical classification and review. *Dermatol. Surg.* 2006; 32: 465-80
122. Rotunda AM, Ablon G, Kolodney MS: Lipomas treated with subcutaneous deoxycholate injections. *J. Am. Acad. Dermatol.* 2005; 53: 973-8
123. Rotunda AM, Avram MM, Avram AS: Cellulite: Is there a role for injectables? *J. Cosmet. Laser Ther.* 2005; 7: 147-54
124. Rotunda AM, Suzuki H, Moy RL, Kolodney MS: Detergent effects of sodium deoxycholate are a major feature of an injectable phosphatidylcholine formulation used for localized fat dissolution. *Dermatol. Surg.* 2004; 30: 1001-8
125. Salles AG, Valler CS, Ferreira MC: Histologic response to injected phosphatidylcholine in fat tissue: experimental study in a new rabbit model. *Aesthet. Plast. Surg.* 2006; 30: 479-84
126. Salti G, Ghersetich I, Tantussi F, Bovani B et al: Phosphatidylcholine and sodium deoxycholate in the treatment of localized fat: a double-blind, randomized study. *Dermatol. Surg.* 2008; 34: 60-6
127. Salti G, Rauso R: Comments on “Injection Lipolysis with phosphatidylcholine and deoxycholate”. *Aesthet. Surg. J.* 2014; 34: 639-40
128. Schuller-Petrovic S, Wölkart G, Höfler G, Neuhold N, et al: Tissue-toxic effects of phosphatidylcholine/deoxycholate after subcutaneous injection for fat dissolution in rats and a human volunteer. *Dermatol. Surg.* 2008; 34: 529-43
129. Sobel HD: Editorial – Off-label usage of medical devices. *Int. J. Cosm. Surg. Aesthet. Dermatol.* 2002; 4: 259
130. Steinert M: Injektionslipolyse. *DERMAforum* 2009; #1: 4
131. Strahan JE, Cohen JL, Chorny JA: Granuloma annulare as a complication of mesotherapy: a case report. *Dermatol. Surg.* 2008; 34: 836-8
132. Tanner B, Barabas T, Crook D, Link C: A future for injection lipolysis. *Aesthet. Surg. J.* 2013; 33: 456-7
133. Tawfik HA, Zuel-Fakkar NMA, Wlmarasy R, Talib N, et al: Phosphatidylcholine for the treatment of prominent lower eyelid fat pads: a pilot study. *Ophthalm. Plast. Reconstr. Surg.* 2011; 27: 147-51
134. Toledo LS: a) Preface b) Emerging techniques in aesthetic plastic surgery. *Clin. Plast. Surg.* 2009; 36: a) xi-xiii b) 177-80
135. Treacy PJ, Goldberg DJ: Use of phosphatidylcholine for the correction of lower lid bulging due to prominent fat pads. *J. Cosmet. Laser Ther.* 2006; 8: 129-32
136. Uygur F, Evinç R, Duman H: Is phosphatidylcholine harmful to the peripheral neural tissue? An experimental study in rats. *Aesthet. J. Surg.* 2008; 28: 663-7
137. Walsh N: Some would halt lipolysis Tx pending safety data. *Skin & Allergy News* 2004; 35: 26
138. Weiss DD, Carraway JH: Eyelid rejuvenation: a marriage of old and new. *Curr. Opin. Otolaryngol. Head Neck Surg.* 2005; 13: 248-54
139. Witort EJ, Pattarino J, Romano FM, Dini M, et al: Lipolytic effectiveness of phosphatidylcholine in the treatment of ‘buffalo hump’ of HIV patients. *J. Plast. Reconstr. Aesthet. Surg.* 2011; 64: e26-8

140. Won TJ, Nam Y, Lee HS, Chung S, et al: Injection of phosphatidylcholine and deoxycholic acid regulates gene expression of lipolysis-related factors, pro-inflammatory cytokines, and hormones on mouse fat tissue. *Food Chem. Toxicol.* 2013; 60: 263-8
141. Wong GR, Chen W-P: Phosphatidylcholine/deoxycholate lipolysis and hyaluronic acid augmentation to enhance nonsurgical lower facial contouring using botulinum toxin type A. *J. Cosmet. Dermatol.* 2011; 10: 159-62
142. Worcester S: Lipodissolve mesotherapy is gaining popularity. *Skin & Allergy News* 2007; 38: 25
143. Young VL: Letter to the editor – Response to “injection lipolysis with phosphatidylcholine and deoxycholate”. *Aesthet. Surg. J.* 2013; 33: 1076
144. Young VL: Lipostabil: the effect of phosphatidylcholine on subcutaneous fat. *Aesthet. Surg. J.* 2003; 23: 413-7
145. Zhang Y, Gao J-h, Jiang P, Wang L-y, et al: *Chin. J. Aesthet. Med.* 2006; 15: 1346-8

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# Clinical Safety Data and Standards of Practice for Injection Lipolysis: A Retrospective Study

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**AQ1**

*There is increasing interest in injection lipolysis as a technique for reducing small, localized fat deposits. While many articles have been published about injection lipolysis, none specifically address safety issues. A clinical safety data survey was sent to physicians practicing injection lipolysis. Seventy-five physicians from 17 countries responded. Data from the treatment of 17,376 patients who underwent a total of 56,320 injection sessions were analyzed. Among the topics reviewed in the survey were indications and contraindications for treatment, best and worst areas for treatment, and additives to the formula and their efficacy. Expected sequelae were differentiated from unexpected complications.*

*The safety data collected here indicate that, when practiced by licensed and certified physicians, the safety record for injection lipolysis is excellent. There were no deaths or hospitalizations resulting from treatment. There were also no bacterial or atypical mycobacterial infections, no reports of skin loss or ulceration, and no episodes of dermatitis or chronic skin irritation. Among the 17,376 patients treated, 0.0021% experienced transient hyperpigmentation, 0.015% had persistent pain beyond 2 weeks posttreatment, 0.0003% had a late allergic reaction, and 0.00006% had a contour irregularity requiring additional injection treatment. Disappointment at a less-than-expected aesthetic result was expressed by 12.34% of patients. There was consensus among responding physicians on the need for pretreatment patient education regarding realistic expectations.*

*This survey is a representative, not definitive, survey of treatment results that is intended to serve as a starting point for further development and improvement of injection lipolysis technique. (Aesthetic Surg J 2006;26:000.)*

**T**here is a rapidly growing global interest in noninvasive aesthetic procedures. Currently, the most reliable technique for spot reduction of subcutaneous fat deposits is lipoplasty, which is effective but requires some recovery time and is not risk-free.

Statistics from the US Centers for Disease Control show that one third of Americans are obese and one third are overweight.<sup>1</sup> Many of the remaining third have localized fat deposits that are resistant to reduction through diet and exercise alone. While surgery could effectively reduce subcutaneous fat in all 3 groups, only a small percentage of people choose to undergo surgical correction. A major factor in the decision to forego surgery is fear; potential patients are afraid of surgery, a prolonged recovery phase, pain, and potential complications. A noninvasive alternative may reduce the recovery period, pain, and risks associated with fat reduction.

**AQ2** The original technique of mesotherapy developed by Pistor was not specifically for fat reduction. Indications for traditional mesotherapy vary from chronic pain to scalp rejuvenation. Most frequently, the “nappage” method was used to inject minute quantities of a variety of pharmaceuticals and homeopathic solutions into the dermis or superficial subcutaneous tissue. Because of the

extreme variation in formulas injected, and the wide variety of complaints treated, it has been difficult to establish efficacy or safety for this technique.

Since 2002, there has been a surge of interest in using an injectable lipolytic agent to reduce localized subcutaneous fat deposits.<sup>2,3</sup> While the current technique is based on mesotherapy, injection lipolysis is different from the original technique in many ways. The practice of injection lipolysis worldwide uses a fairly standard formula with few additives. The technique is consistent, and the purpose is focused: reduction of small localized areas of excess subcutaneous fat.<sup>4</sup> Current estimates from the Global Network Lipolysis and AestheticMD reveal that more than 1000 physicians are performing injection lipolysis worldwide. This survey was undertaken as a contribution to efforts by our specialty to investigate the clinical safety and efficacy of injection lipolysis.

**AQ3**

**AQ4**

The survey was written by the senior author (DID) and sent to Global Network Dissolve and AestheticMD for distribution. The Network posted the survey on its website with a request that members respond to the author; 34 responses were received. AestheticMD e-mailed the form to 600 members, of whom 41 responded to the author. This representative sample of 75 physician

injectors included respondents from 17 countries and most of the published authors on the topic. Respondents had the opportunity to comment on the various issues addressed in the survey as well as to answer specific questions.

The survey is retrospective and is intended to provide data on safety, efficacy, and the current standard of practice of injection lipolysis. It is representative, not definitive, and should be considered as only a starting point from which the injection lipolysis technique can be further understood, developed, and improved.

This summary of efficacy and safety based on current worldwide data includes:

- Investigator experience
- Preinjection evaluation and documentation
- Types of formulas and maximum doses
- Additives to the formula and their efficacy
- Indications and contraindications for treatment
- Best and worst areas to treat
- Expected sequelae and unexpected complications

This article is not intended to be a guide to injection lipolysis for the new practitioner. As with any developing technique, we recommend that each physician obtain training and certification through a reputable organization before initiating this procedure in his or her practice.

### Investigator Experience

The range of duration of experience with the injection lipolysis technique among respondents was 1 month to 11 years. The average amount of time each practitioner has been performing this procedure was 17.32 months. Altogether, 17,376 patients were treated with a phosphatidylcholine (PPC)-based compound and 56,320 injection sessions were reported. The average number of treatment sessions per patient was 3.24. The consensus among physicians was that an average of 3 injection sessions is needed in most body areas to obtain optimal improvement. Usually 2 treatments in the face and submental neck achieve good results.

### Types of Formulas Used

Many of the physicians used more than 1 type of injectable formula. Eight doctors reported Lipostabil, manufactured by Natterman, as a frequently used formula. **AQ5** **AQ6** Two preferred Lipostabil from Essentiale. A compounded formula was the standard for 68 out of 75 reporting physicians (91%), with 7 using the Global Network's preparation. Thirty-five physicians used a

PPC-based formula without additives, and 30 used a compounded formula with additives. Thirteen also reported using other formulas, some not PPC-based.

### Maximum safe dosage

Most of those surveyed reported a maximum safe limit of 2000 to 2500 mg of PPC-based solution per treatment session. At a dilution of 25 mg/mL, 100 cc per session could be safely used. At 50 mg/mL, only 50 cc could be injected per session in order to adhere to the 2500-mg limit. Four physicians reported occasionally using more formula, up to 4000 mg. An increase in postinjection nausea and diarrhea was noted with these higher doses; about 5% of the higher-dose patients experienced these symptoms.

Until further studies are done to establish the safety of higher doses, the consensus of injecting physicians was that a 2500-mg daily limit has proven to be safe.

### Additives and Their Efficacy

Forty percent (30/75) of the reporting physicians used additives to their PPC-based formula. Seventeen of those believed strongly that the additives increased the efficacy of the formula. Among the 75 reporting physicians, 26.6% (20/75) felt that additives increased the side effects, particularly light-headedness, without providing additional efficacy, whereas 13.3% (10/75) were uncertain whether the additives made any difference in outcome. Additives reported included L-carnitine, aminophylline, various vasodilators, and lidocaine. Some physicians used a formula that included vitamin E, which is included in Lipostabil. Other multivitamins, hyaluronidase, and collagenase were sometimes used as well. Only one physician reported using multiple additives with a traditional mesotherapy format. **AQ7**

### Indications

All respondents agreed that the primary indication for the use of injection lipolysis is the reduction in size of small localized fat pads. Large areas of lipodystrophy are better treated with lipoplasty. Soft fat was thought to respond better than firm, fibrous fat. Although documented skin retraction has occurred, especially with superficial injections, none of the physicians indicated that this was a primary focus of treatment, nor did they promise this to their patients. Only 4% of respondents (3/75) reported using this technique to increase smoothness in an area with an irregular surface, including postlipoplasty deformities. Sixteen percent (9/75) reported successful use of the technique to improve cellulite,

while 4% (3/75) reported regular injections of lipomas with a phosphatidylcholine-based formula.

### Contraindications

The most frequently listed contraindication was pregnancy. No children under age 18 were treated. Breastfeeding patients were instructed to wait until 6 weeks after they ceased lactating before beginning treatment. Most respondents did not perform injection lipolysis on obese patients. This procedure is not meant to be used as a rapid weight loss program. No treatments were performed for the purpose of breast reduction.

An allergy to soy products, or other formula components such as benzyl alcohol, was clearly noted as a contraindication to treatment with these injections. If in doubt, a small “patch test” could be performed 1 week prior to the anticipated treatment.

Most respondents did not treat diabetics, especially in the distal extremities. Microangiopathy and vascular insufficiency were considered contraindications as well. While Lipostabil is licensed in Germany for intravenous use in cases of coronary artery compromise, many physicians avoided treating hypertensive and cardiac patients. Respondents noted that a patient with severe chronic illness should not be injected, especially those who are immunocompromised. The Global Network Lipolysis recommends not treating any patient with autoimmune disease, with the exception of patients with Hashimoto’s thyroiditis and rheumatoid arthritis. While some physicians avoided treating patients with human immunodeficiency virus (HIV), many others achieved good results injecting the “buffalo hump” that frequently occurs with HIV medication.

**AQS** Most physicians avoided treatment of patients who were taking anticoagulant agents, such as Coumadin or Plavix. While some avoided treating patients taking non-steroidal anti-inflammatory drugs, most did not see their use as an absolute contraindication.

Patients on chemotherapy were also contraindicated until their immune system had recovered, as were those receiving prednisone or another steroid regimen. Patients who were acutely ill, or who had a serious ongoing illness, such as liver or renal failure, were also not considered candidates for treatment with injection lipolysis.

Local skin conditions are often considered a contraindication for treatments with injection lipolysis. An open, nonhealing sore, or infection near the treatment region was a contraindication to treatment. Many respondents did not treat patients with active eczema or psoriasis.

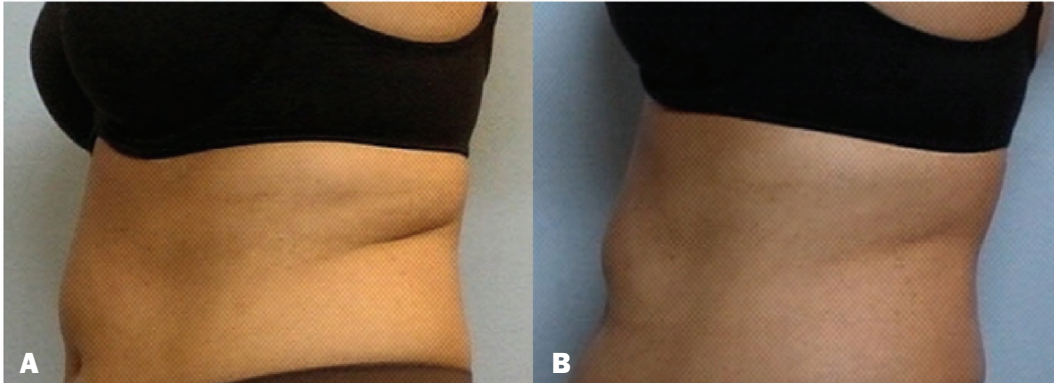
Respondents also considered unrealistic expectations a contraindication to treatment. Many survey physicians reported a less-than-expected outcome as their only complication. Treatment resulted in improvement, not total correction, of the localized lipodystrophy. The reported non-response rate varied from less than 1% to 25%. Patient selection was very important. If patients were noncompliant and underwent only 1 treatment, they were not satisfied with the outcome. Also, those patients who would not adhere to a diet and exercise plan, and saw the injections as a “quick fix,” were judged poor candidates for this treatment.

### Best Areas for Treatment

The respondents listed 11 areas that generally responded well to injection lipolysis. Opinions varied with respect to 3 regions—the flank, thighs, and knee region—with many listing good results and others indicating that one or another of these regions was the “worst area” to treat.

The best areas to treat are ranked in order of the perceived response to treatment by patients and physicians.

1. Abdomen: Good results were reported by 78.7% of respondents (59/75).
2. Flanks: Good results were reported by 42.7% of physicians (32/75). Several noted that soft fat responds best, and that better results were obtained in female patients than in male patients.
3. Submental chin: Good results were reported by 37.3% (28/75) of respondents when treating this region.
4. Back and “bra rolls”: One third of respondents (25/75) felt that this was an optimal treatment area. It is usually small and well localized, and often has soft fat that appears to melt away significantly with 2 to 3 treatments (Figure 1).
5. Outer thigh: Surprisingly, 37% of those surveyed (23/75) reported good results when treating the outer thigh. The area has been considered less than optimal for treatment because fat deposits in this area are frequently fibrous in nature.
6. Inner thigh: This was considered a good region to treat by 21.3% (16/75) of physicians. Many respondents treated the inner thigh area with lipolysis in order to avoid skin laxity or contour irregularity that might result from lipoplasty. Although the treatment areas in this region were small, they generally required 3 treatments for optimal results.
7. Jowls: Good fat reduction and skin retraction were obtained by 21.3% (16/75) respondents when injecting the jowl region (Figure 2).



**Figure 1.** **A,** Pretreatment view of a 52-year-old woman. **B,** Posttreatment view 6 weeks after a single injection session to the back roll area.



**Figure 2.** **A, C,** Pretreatment views of a 38-year-old Asian woman. **B, D,** Posttreatment view 6 weeks after 2 injection sessions to the jowls, submental chin, and submandibular jawline.

8. Upper arms. Twelve percent (9/75) of physicians reported a good response when treating this area. The results were variable in the upper arm region, due to the frequent finding of associated skin laxity. The best candidates were younger patients without a large amount of excess skin.
9. Neck; submandibular jawline: Good results were reported by 12% (9/75) of respondents. This is an

often overlooked area that responded well to treatment. Superficial injections just under the mandible enhanced the jaw contour by creating a shadow under the mandible and the mandibular angle. **AQ9**

10. Knees: In this difficult area, 10.7% (8/75) respondents reported excellent treatment results. The results are strongly technique dependent.

11. Gluteal fold: Significant improvement in the “banana roll” region at or immediately below the gluteal fold was reported by 9.3% (7/75) of respondents.

### Worst areas to treat

The thigh region (both outer thighs and inner thighs) was considered the most difficult area to treat by 30.7% of physicians (23/75). Four factors contributed to the problems in treating this area: skin laxity, textural lumpiness or cellulite, firm fibrotic fat, and the location of the fat deposit over a broad area rather than a thick, localized site. It was harder to define and document improvement on such a broad, slightly rounded surface than in a thick protuberant bulge.

One third of respondents (25/75) disliked using the injection treatment on the knees, for the reasons listed previously. More experienced practitioners found that skillful technique could provide some improvement in skin quality and in fat thickness in this area, where surgery is usually avoided.

Treatment of the lower abdomen was avoided by 14.7% (11/75) of respondents. While most physicians regarded the abdomen as a good treatment region, those who avoided it did so because of the presence of large deposits of pendulous fat, obesity, unrealistic expectations and, in some cases, firm fibrous fat in the epigastrium that was minimally responsive to injection lipolysis.

Twelve percent of respondents (9/75) have tried injecting the upper arm/triceps subcutaneous region, with minimal results. Skin laxity is the main problem in many patients. The subcutaneous fat in this area is not well localized but tends to be broad and flat in distribution. While a definite reduction in circumference was achieved, patient satisfaction with the outcome was less than optimal.

Treatment below the knee is never attempted by 9.3% of respondents (7/75). Their main concern is tissue loss due to microangiopathy and vascular insufficiency.

**AQ10**

The infraorbital fat pad region was listed by 6.7% (5/75) of physicians as an area in which achievement of dramatic results is difficult. Although Dr. Rittes has demonstrated great skill in treating this area, less experienced physicians reported that the risk is high and the results, marginal.

**AQ11**

The chin region and hips were suboptimal targets for injection, according to 4% of respondents (3/75). Patient selection was considered an important factor in determining results, in that stiff, fibrous fat was relatively nonresponsive to treatment. For the same reason, one

respondent felt that gynecomastia was not a good indication for injection lipolysis.

Although many reports of successful injection of lower eyelid fat pads have been published in the medical literature, most survey physicians believed that this area was best reserved for those physicians with experience in the injection technique. Additionally, the standard of practice among respondents was to avoid injecting the breasts because of the potential for formation of calcifications and other structural abnormalities that might make the diagnosis of breast cancer more difficult.

Firm flank fat deposits, especially in men, were also noted to be marginally responsive to treatment.

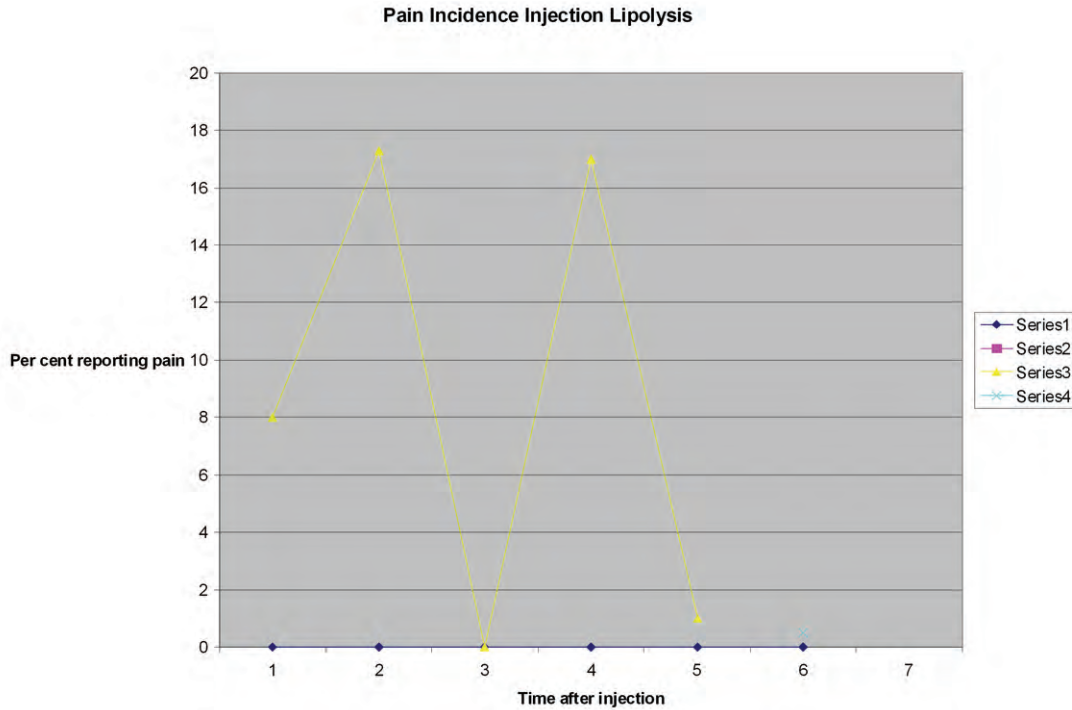
Generally speaking, the consensus on areas to avoid was as follows:

1. Stay away from areas below the knee as there is a high risk of skin loss and /or ulceration.
2. Avoid broad, flat fat deposits.
3. Avoid firm, fibrous fat.
4. Avoid regions with a large amount of skin laxity.
5. Do not treat areas of obesity.

### Preinjection Documentation

There was strong agreement among all physicians with respect to the importance of preinjection documentation. Because alterations in body contour resulting from injection lipolysis are very gradual, it was noted that many patients perceived little to no change in a treated region upon completion of the injections. Pretreatment photographs were considered essential for confirming the contour changes. It was recommended that all pretreatment and posttreatment photos should be taken with the patient wearing the same clothing and with the same camera and lighting techniques.

Other measurements that reinforced the treatment value included measuring skinfold thickness in the same area before and after treatment, as well as measuring a circumference in applicable areas. Unfortunately, these measurements are difficult to standardize. Respondents indicated that body mass index (BMI), patient height, and weight should be measured by the physician, not simply reported by the patient. This helped to prevent patients from either claiming that any success was due to weight loss when there was none, or that lack of improvement was treatment-related when noncompliance and weight gain were the reasons. Most practitioners avoided treatment of patients with a BMI of 30 or higher, as the diffuse and large amount of subcutaneous fat in these patients does not respond well to phosphatidylcholine-based injections.



**Figure 3.** Pain incidence following injection lipolysis.

**AQ12**

**AQ13**

Occasionally, body fat percentages, pants or dress sizes, and/or a verbal description by the patient of the deformity's size and effect on daily life were recorded. Norek reported success with an ultrasonic measurement of fat thickness before and after treatment. The Vectra system by Canfield also holds promise for measuring accurate volumetric change. Neither of these measuring devices is inexpensive, nor are they in standard use in most doctors' offices.

### Expected Sequelae

The respondents reviewed the following list of reported sequelae following injection lipolysis and documented their experience (Figure 3). The first area of concern was pain and its management during and after treatment, assessed as follows:

1. Significant pain on injection: immediate
2. Significant pain on injection at 30 minutes postinjection
3. Significant pain on injection at 1 hour postinjection
4. Significant pain on injection at 1 day postinjection
5. Significant pain on injection at 1 week postinjection
6. Significant pain on injection at 2 weeks postinjection
7. Significant pain on injection at 1 month postinjection
8. Significant pain on injection at 3 months postinjection

Twenty percent (15/75) investigators noted that their patients seemed to feel significant pain during the injection process. This number includes any physician who noted that at least one third of the patients complained of discomfort at some point during the injection process. These ratings are very subjective. Minimal pain and discomfort during the injection process, defined as less than 5% of patients complaining of significant discomfort at any time during the process, was noted by 53.3% of respondents (40/75). Only 8% of respondents (6/75) felt that the initial injection process was significantly painful to the patients. While a small group reported using a topical anesthetic such as Betacaine or lidocaine on the areas to be treated, most used the pinch technique or a mesogun to reduce perceived pain.

**AQ14**

**AQ15**

At 30 minutes postinjection, 17.3% of investigators (13/75) reported a sensation of noticeable discomfort was experienced by their patients. This seemed to be the peak of the uncomfortable period; burning and stinging sensations, accompanied by a sensation of swelling, was reported by <5%-100% of patients. At 1 hour posttreatment, most patients felt that the pain became a "background" sensation; a little soreness and swelling was noted but pain requiring icing or medication was rare. Only 1 investigator felt that significant discomfort was still present in his patients at 1 hour.

**AQ16**



**Figure 4.** Posttreatment view one week after a single injection session to the epigastric abdomen. Note localized bruising and swelling.

On the following day, many patients noted a “gelatinous” feeling in the treated area. The swelling tended to peak between the first and third postinjection day, and many patients reported an improvement in their discomfort after they began using some type of compression garment. Seventeen percent of physicians (13/75) reported complaints about pain among 5% or more of their patients at this point. Most noted that swelling and soreness were also most profound at this time.

At 1 week posttreatment, the swelling and bruising had begun to recede; 0% to 1% of patients noted significant pain at this point. At 2 weeks posttreatment and continuing until 13 months posttreatment, 0% to 0.5% of the 17,376 patients noted pain as an issue.

#### **Immediate erythema**

Erythema was a frequent finding in most patients; 72% of the physicians (54/75) noted episodes of transient erythema occurring from the time of injection to 24 hours postinjection. It was more common at 30 minutes posttreatment than immediately after injection. Few respondents noted redness extending beyond the 1-day mark.

#### **Stinging and burning**

Over 90% of respondent physicians (68/75) said that most of their patients experienced some stinging and burning sensations. Onset of the sensation most com-

monly occurred from immediately to 1 hour after treatment, with the usual peak at 30 minutes postinjection. Twenty percent reported that the sensation sometimes persisted for more than 1 hour postinjection. Ninety-nine percent of patients had no stinging or burning beyond 24 hours postinjection.

#### **Swelling**

Postinjection swelling was noted in most patients by 88% of respondents (66/75) (Figure 4). This appears to be a dose-related side effect. The swelling began to appear as early as 30 minutes after the injections, and peaked at 1 to 3 days. At 1 week, less than 10% of patients reported significant swelling.

#### **Bruising**

Only 16% of physicians (12/75) saw no bruising with this treatment; 84% (63/75) reported bruising and noted a peak at 1 week postinjection. Bruising persisted into the second postinjection week in 0% to 7% of cases. Most reporting physicians felt that bruising related to injection lipolysis was less severe and resolved more quickly than bruising associated with lipoplasty.

#### **Nausea**

Twenty-four percent of respondents (18/75) noted a less than 10% incidence of postinjection nausea in their

patients, usually peaking within the first 24 hours. No patients had nausea lasting longer than 48 hours postinjection. Seventy-six percent of physicians (57/75) reported no patients with postinjection nausea. Those who had patients with this symptom felt that it tended to occur in those patients receiving higher doses of the compound.

#### **Diarrhea**

Fourteen respondents (18.6%) noted that transient diarrhea developed in less than 2% of patients and resolved after 24 hours. Patients reporting diarrhea tended to have larger areas of injection and receive larger doses.

#### **Small hematomas at the injection site**

Small hematomas at the injection sites were noted by 56% of respondents (42/75). They were most marked between 1 hour postinjection and 1 week. All resolved with no further treatment. The incidence ranged from 0% to 25%.

#### **Hives at the injection site**

Injectors avoided treating patients with a known allergy to soy-based products and an allergy to the preservative benzyl alcohol. Development of transient hives was reported by 18.7% of respondents (14/75). Most occurred within the first 24 hours posttreatment and resolved with time and/or administration of Benadryl. Three patients had a late episode thought to be due to an allergy to benzyl alcohol.

**AQ17**

#### **Dizziness/light-headedness**

Respondents suggested that 3 factors may cause a feeling of dizziness in the first several hours to 1 day postinjection. Use of a vasodilator as an additive to the injected formula may cause transient orthostatic hypotension. Third spacing of fluid due to swelling may cause relative dehydration. Some patients also noted a vasovagal response to the injections and may have needed extra recovery time after the treatment. Twenty-five physicians (34.6%) noted this symptom in about 5% of their patients.

**AQ18**

#### **Dose-related side effects**

Dose-related side effects of transient diarrhea and nausea were noted when the injection session maximum was more than 3000 mg of phosphatidylcholine. Light-headedness and dizziness tended to occur when a vasodilator was added in less than 5% of the patient population.

#### **Educating the patient**

It was suggested that patients be told in detail what to expect during and after the injection process. Most will experience minimal discomfort during the injection process if the injector is skilled. They will also note some redness, stinging, and burning within 15 minutes to 2 hours postinjection. Swelling occurs rapidly, and tends to peak at 1 to 3 days postinjection. A small to moderate amount of bruising is common and tends to resolve, in most cases, by about 7 to 10 days postinjection. By the end of the first week, small subcutaneous nodules may appear; these indicate ongoing fat necrosis. Evidence of mild skin retraction may begin to appear at 10 to 14 days postinjection. By the 4th to 6th postinjection week, most patients will be able to see an improvement in the volume of the localized fat deposit. This improvement may be more evident in a photograph than in the patient's own estimation. Frequently, the patient perceives little to no change, when in fact, a noticeable change is apparent in serial photographs.

Measurement of circumference, skinfold thickness changes, and final photographs are usually performed about 6 to 8 weeks following the final injection session. Because the inflammatory process is not complete at that time, patients should be advised that they may not see the final result for up to a year.

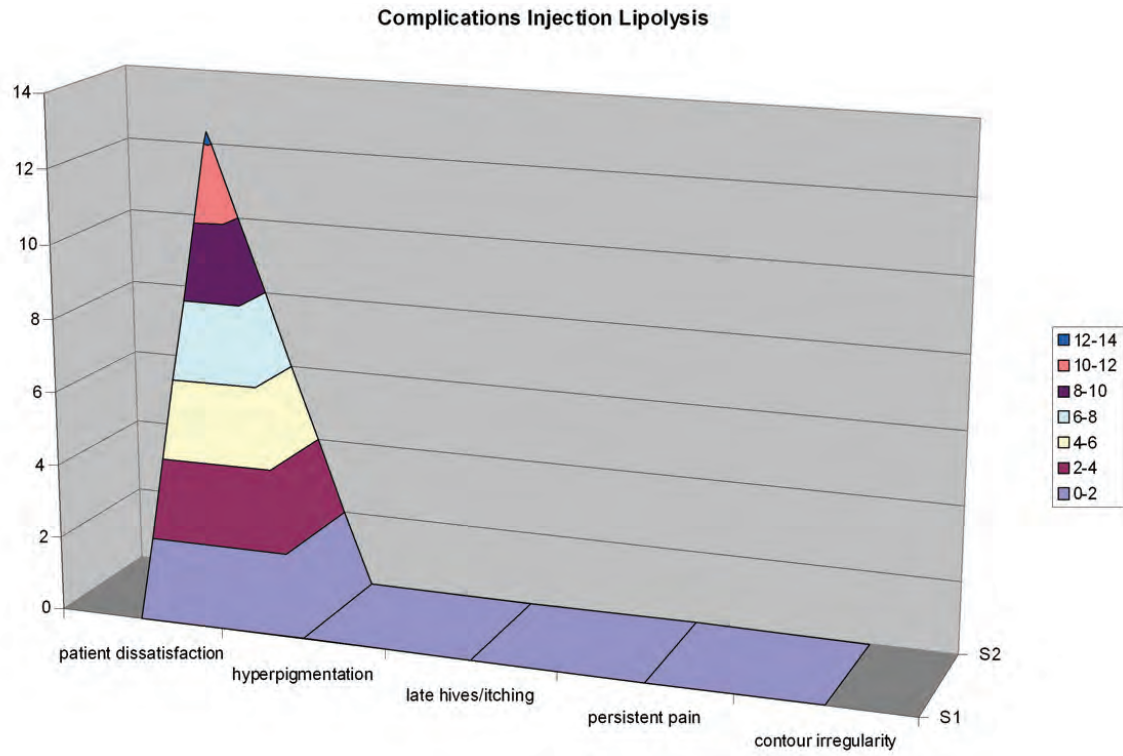
Maintenance of a good diet and exercise program should always be stressed, and patients should be reminded that injection lipolysis is not a substitute for a healthy lifestyle.

#### **Complications**

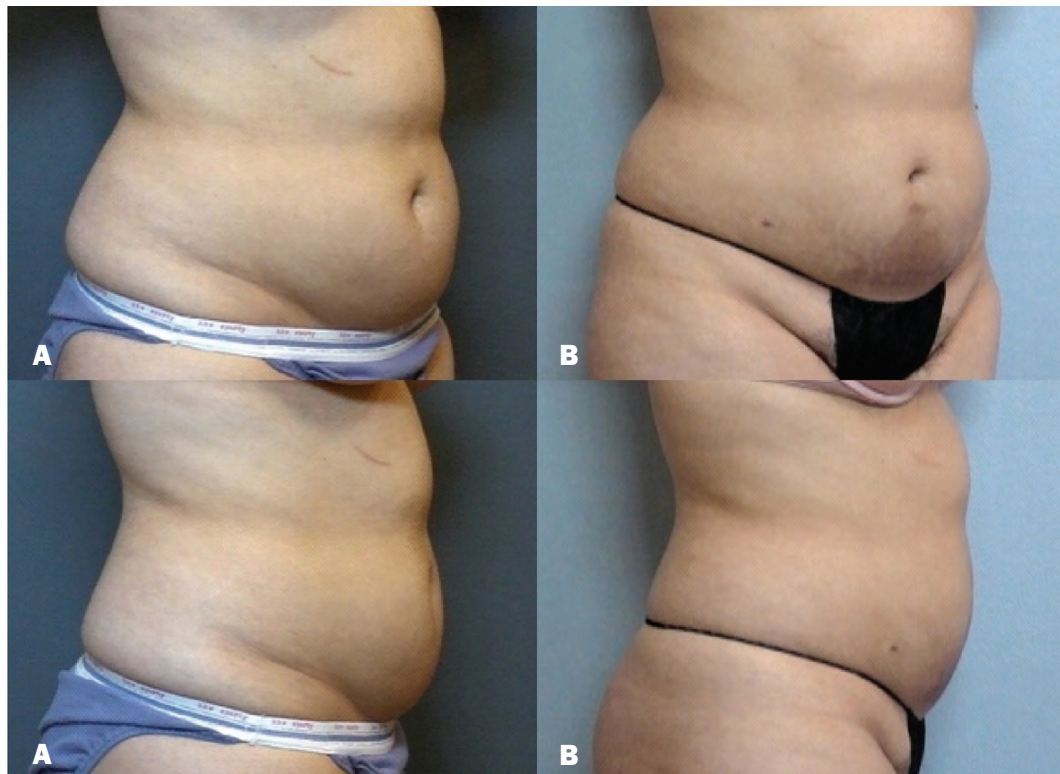
Complications following this treatment were surprisingly rare. Among of the 17,376 patients treated, there were no deaths. No patients were reported to need hospitalization for any sequelae. The most frequently reported complication was less-than-expected aesthetic improvement. Parameters examined included: hyperpigmentation, late itching, and hives, persistent pain beyond 2 weeks, little to no response to treatment, bacterial infection, atypical mycobacterial infection, chronic skin irritation or dermatitis, skin necrosis in the treated areas, an open or nonhealing wound, and a permanent skin contour deformity requiring treatment (Figure 5).

#### **Hyperpigmentation**

A low incidence of transient hyperpigmentation was reported by 18.7% of physicians (14/75). Only 37 of 17,376 patients (incidence, 0.0021%) were reported to have this problem (Figure 6). The discoloration resolved



**Figure 5.** Complications following injection lipolysis.



**Figure 6. A,** Pretreatment view of a 38-year-old woman. **B,** Posttreatment view 6 weeks after 3 abdominal injection sessions. Note the triangular distribution of hyperpigmentation. Clinical correction of abdominal protuberance and skin overhang is excellent.

within 3 months in most cases. Hyperpigmentation secondary to injection lipolysis is thought to be caused by hemosiderin deposition under the skin, and is not a melanocytic event. Those noting this problem felt that it occurred most often in dark-skinned patients.

#### **Late hives/itching**

Among all patients treated, only 6 reported the development of late hives or itching. The incidence of an apparent delayed hypersensitivity reaction was 0.0003%. An allergic reaction to the benzyl alcohol preservative was thought to be the primary cause. All cases resolved with antihistamine treatment and time.

#### **Persistent pain beyond 2 weeks**

Occasional cases of persistent pain beyond 2 weeks posttreatment were reported by 4% of respondents (5/75). The incidence reported was 0.015%. Seventy physicians (96%) reported no persistent pain in any of their patients after the initial 2 week posttreatment phase.

Those reporting noted that an increase in the percentage of sodium deoxycholate, or use of deoxycholate without PPC, tended to be associated with these reports. Treatment of large areas also increased the incidence of persistent pain.

#### **Little to no response**

A less-than-expected response to treatment among some patients was noted by 77.2% of respondents (58/75). Only 22.8% of physicians (17/75) felt that all of their patients were satisfied. The incidence of dissatisfaction with outcome varied widely. Of the 33 practitioners reporting a percentage, 9 reported that their low-response rate was less than 5%, 10 felt that 10% to 20% of patients were dissatisfied, and 6 stated that more than 20% of their patients were unhappy with their results. Most of these physicians felt that unrealistic expectations on the part of the patient were the major factor in these responses. Poor patient selection and a low dose injected in a large area were also noted as factors. Several respondents recommended using a larger dose in a smaller area as a possible remedy, as results are noted to be dose-related.

Several doctors described an incidence of true nonresponders as less than 1%. These were patients who clearly did not seem to have any improvement in either the patient's or physician's view, despite what both felt was adequate treatment. Factors associated with no response include obesity, severe hypothyroidism, and areas of firm, fibrous fat.

Data collated from those physicians reporting both patient numbers and the incidence of less than expected aesthetic results showed that the average incidence of patient dissatisfaction with treatment was 12.34%.

#### **Infection**

No patients were reported to have developed a bacterial infection in the treated area following injection. All certified practitioners followed a preinjection preparation protocol, using an antibacterial solution such as Hibiclens or Betadine prior to treatment.

**AQ19**

#### **Atypical mycobacteria**

Despite isolated reports of atypical mycobacterial infection occurring in South America and Washington, DC, following mesotherapy injections, no patients in this survey population developed an atypical mycobacterial infection.

#### **Chronic skin irritation, dermatitis**

No patients developed a chronic skin irritation in the area of treatment.

#### **Skin necrosis in the treated area**

No patients developed skin necrosis in the treated areas.

#### **Open nonhealing wound in treated area**

No patients developed an ulcerated or nonhealing wound in a treated area. Most respondents did not treat areas distal to the knee in an effort to avoid this problem.

#### **Permanent skin contour irregularity requiring treatment**

One patient developed a skin contour deformity that required further treatment following injection lipolysis. The irregularity was successfully treated with another injection series.

#### **Conclusion**

Seventy-five physicians with varying ranges of experience responded to the Clinical Safety Data Survey. They performed injection lipolysis for 17,376 patients that included 56,320 injection sessions.

The single best indication for the procedure is a request for treating a small area of localized fat. Contraindications include pregnancy, lactation, age less than 18, severe acute or chronic illness, immunocompromised status, anticoagulant therapy or chemotherapy,

obesity, and unrealistic expectations. The area distal to the knee is not recommended for treatment. An allergy to soy products and/or the benzyl alcohol preservative is a contraindication to injection lipolysis with the phosphatidylcholine-based solution. These injections should not be performed for breast reduction in women. Noncompliant patients are not treated. Those patients with vascular insufficiency are best treated with other modalities. The 3 best areas to treat, in the opinion of those surveyed, are the abdomen, flanks and submental chin. The least responsive areas are felt to be the inner and outer thighs and knees.

Expected sequelae are those events that occur commonly during and after the injection process. These are transient and do not affect the final outcome. Patients undergoing injection lipolysis may experience sequelae that include pain during or shortly after the injections, immediate erythema, some stinging and burning, swelling, and bruising. Most of these symptoms improve or resolve after 1 week. A small number of patients may experience transient nausea or diarrhea, especially with larger treatment areas and higher doses of the solution. Few report small hematomas at the injection site, dizziness or light-headedness, or hives at the injection site.

Complications resulting from this treatment are rare. No patients died or were hospitalized following injection lipolysis. No patients developed skin irritation or necrosis at the injection site. There were no bacterial or atypical mycobacterial infections. No open, ulcerated sores developed in the areas of treatment.

Complications that did occur included hyperpigmentation (incidence, 0.0021%); late development of hives 2 weeks or later after injection (incidence, 0.0003%); persistent pain beyond 2 weeks postinjection (incidence, 0.015%); and less than expected aesthetic result (incidence, 12.34%).

All but one survey physician reported that they would continue to use the treatment on a regular basis for treatment of small, localized adipose deposits.

The degree of improvement was reported to be dose-related. The maximum degree of improvement in an area using a full dose (2000-2500 mg) of PPC-based solution was reported to be a 1-cm thickness reduction. In small areas and thinner patients, this would be a significant change. However, in an obese patient, there may be no perceived difference. Practitioners are cautioned to educate the prospective patient about their expectations and the possibility that they may not be achieved in all cases. ■

## References

1. Prevalence of Overweight and Obesity Among Adults: United States, 2003-2004. Centers for Disease Control. National Center for Health Statistics. Available at: [www.cdc.gov/nchs/products/pubs/pubd/hestats/obese03\\_04/overwght\\_adult\\_03.htm](http://www.cdc.gov/nchs/products/pubs/pubd/hestats/obese03_04/overwght_adult_03.htm). Last accessed August 18, 2006.
2. Rittes PG. The use of phosphatidylcholine for correction of localized fat deposits. *Aesthetic Plast Surg* 2003;27:315-318.
3. Rotunda AM, Suzuki H, Moy RL, Kolodney MS. Detergent effects of sodium deoxycholate are a major feature of an injectable phosphatidylcholine formula used for localized fat dissolution. *Dermatol Surg* 2004;30:1001-1008.
4. Hexsel D, Seera M, Mazzuco R, Dal'Forno T, Zechmeister D. Phosphatidylcholine in the treatment of localized fat. *J Drugs Dermatol* 2003;2:511-518.
5. Duncan DI, Hasengschwandtner F. Lipodissolve for subcutaneous fat reduction and skin retraction. *Aesthetic Surg J* 2005;25:530-543.
6. Young VL. Lipostabil: the effect of phosphatidylcholine on subcutaneous fat. *Aesthetic Surg J* 2003;23:413-417.
7. Rotunda AM, Kolodney MS. Mesotherapy and phosphatidylcholine injections: historical clarification and review. *Dermatol Surg* 2006;32:465-480.
8. Salles AG, Valler CS, Ferreira MC. Histologic response to injected phosphatidylcholine in fat tissue: experimental study in a new rabbit model. *Aesthetic Plast Surg* 2006;30:479-84.
9. Ablon G, Rotunda AM. Treatment of lower eyelid fat pads using phosphatidylcholine: clinical trial and review. *Dermatol Surg* 2004;30:422-427.

AQ20

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## SCIENTIFIC FORUM

AQ1: Please provide Dr. Chubaty's affiliation.

AQ2: Can you supply a reference?

AQ3: Please check name(s) I have found AestheticMD on Web but not Global Network Lipolysis.[A reference should be given for these websites. -CE]

AQ4 Correct as edited? Can you supply references for each of these estimates?

AQ5: Please indicate location (city/state) of manufacturer.

AQ6: Please provide manufacturing information.

AQ7: Please clarify the meaning of "traditional mesotherapy format."

AQ8: Coumadin and Plavix are trade names. Please provide manufacturing information.

AQ9: How accurate is it to say this area responds well to treatment when only 12% of respondents reported good results?

AQ10: This sentence is unclear; is your meaning that tissue loss caused by microangiopathy and vascular insufficiency is the main concern of those practitioners who never treat below the knee?

AQ11: Reference?

AQ12: We need a reference for this report.

AQ13: Please provide location (city/state) of manufacturer.

AQ14: Earlier statement, first sentence in paragraph, said 20%; it is not clear what constitutes the injection process versus the initial injection process.

AQ15: Betacaine is a trade name. Please provide manufacturing information.

AQ16: 5%-100% correct range?

AQ17: Benadryl is a trade name. Please provide manufacturing information.

AQ18: Correct as written?

AQ19: Hibiclens and Betadine are trade names. Please provide manufacturing information.

AQ20: Please indicate date received.

# Clinical experience and safety using phosphatidylcholine injections for the localized reduction of subcutaneous fat: a multicentre, retrospective UK study

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## Summary

**Background** Phosphatidylcholine has been in safe use for over 30 years. Subcutaneous injections of phosphatidylcholine have now become used internationally for localized subcutaneous fat reduction on the face and body, but concerns about the safety of this treatment have arisen.

**Aims** To assess retrospectively treatment outcomes and adverse effects associated with subcutaneous phosphatidylcholine use.

**Patients and methods** Thirty-nine UK doctors specifically trained and experienced in this treatment completed questionnaires, focusing on outcome and adverse effects experienced by patients.

**Results** Ten thousand five hundred and eighty-one treatments had been administered over a mean duration of 13.1 months. Localized adverse effects (swelling, erythema, burning/stinging, pain, tenderness and bruising) were described by most patients as "very mild" (18.4%) or "mild" (39.2%). The total incidence of systemic side-effects was 3%: diarrhoea, nausea, dizziness/light-headedness and intermenstrual bleeding were described by most patients as "very mild" (36%) or "mild" (55%). Only 15 (0.14%) "unexpected, unusually severe or prolonged" adverse reactions (commonly pain and/or swelling) were reported. These were all self-limiting and none were judged as serious. 73.8% of patients were either "very satisfied" or "satisfied" with treatment.

**Conclusions** This treatment appears to be associated with minimal risks when used by specifically trained and experienced doctors. The possible risks associated with this treatment should be balanced against the risks of other treatment options.

**Keywords:** adverse effects, phosphatidylcholine, subcutaneous fat

## Introduction

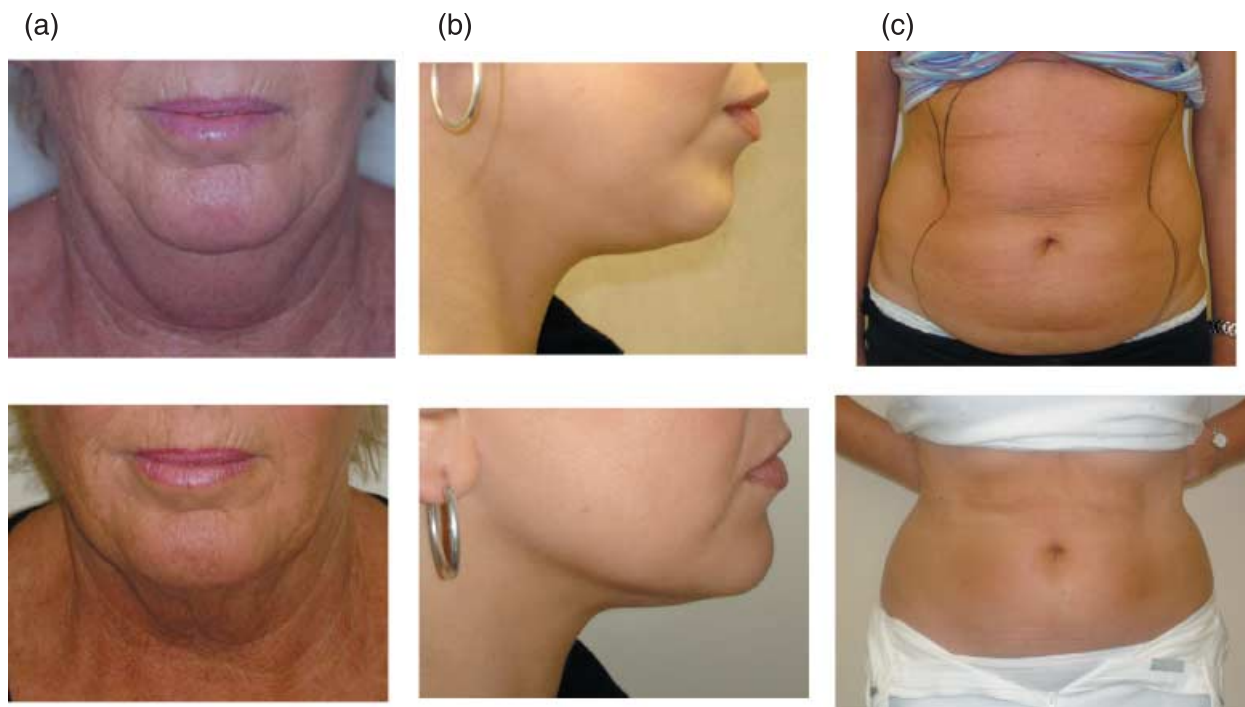
Phosphatidylcholine has been in use safely for over 30 years for prevention and treatment of fat embolism.

There is no evidence of toxicity or teratogenicity and it is well-tolerated at high daily doses. It has been safely and effectively used at high doses intravenously for the treatment of severe liver failure and surfactant preparations containing 70–80% phosphatidylcholine are administered endotracheally to treat premature neonates suffering from respiratory distress syndrome.<sup>1–9</sup>

Phosphatidylcholine preparations have become used internationally for localized reduction of subcutaneous

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**Figure 1** (Photos by Dr M A Palmer) (a) One treatment session, results after 8 weeks, no weight loss. (b) One treatment session, results after 8 weeks, no weight loss. (c) Three treatment sessions at 8 weekly intervals, no significant weight loss, results after 24 weeks.

fat by subcutaneous injection.<sup>10–22</sup> Promising results have been demonstrated, in some cases avoiding the patient undergoing cosmetic surgery (Fig. 1).

Recent studies and publications have investigated the histological effects of this method of treatment and have discussed in detail the likely physiological and biochemical cellular mechanisms and processes involved.<sup>11,14,23</sup>

However, this method of treatment has been criticised in the UK, partly due to a lack of any published collective UK data regarding safety, partly due to widespread lack of awareness of the collective published research and data to date, and partly due to the manufacturer of the major brand of phosphatidylcholine injection, Lipostabil (Nattermann, Germany), including a warning on the data sheet stating that this product should not be injected subcutaneously. Furthermore, criticism has arisen because of unfounded lay press speculation of the drug's adverse effects on lipid profiles (phosphatidylcholine improves lipid profiles<sup>24,25</sup>), as well as an ill-informed tendency towards generalized discrimination against cosmetic treatments in the UK which are sometimes viewed as unnecessary.

Thousands of treatments have been administered in the UK by specifically trained and experienced doctors<sup>10</sup> in the use of phosphatidylcholine for subcutaneous fat

reduction (maximum dose: 2.5 g every 8 weeks,<sup>10</sup>). In most cases, the treating doctor individually assessed and examined each patient several weeks post-treatment, resulting in the doctor being fully informed of treatment outcomes and of the incidence and nature of any emergent adverse effects. The preparations used contain 250 mg phosphatidylcholine per 5 mL and comprise 70% phosphatidylcholine, 4.2% deoxycholate as a solubilising agent and 3% benzyl alcohol as a preservative.<sup>14</sup>

In this study, we aimed to collect and collate the outcome data from UK doctors known to us to be using this form of treatment. In particular, we collected information on any adverse effects experienced by patients, especially focusing on any reported unexpected, severe, prolonged or serious adverse reactions.

### Scientific rationale and mechanism of action

Although phosphatidylcholine is the main ingredient in most injectable preparations, in common with other injectable pharmaceuticals, it must be mixed with sodium deoxycholate (a bile salt) to make it soluble enough for injection. Most injectable formulations contain between 4.2% and 4.7% sodium deoxycholate. A small amount of benzyl alcohol is also added as a preservative.<sup>11</sup>

Recent studies have demonstrated that deoxycholate alone causes significant cell lysis on cultured human keratinocytes as well as in porcine fat *in vitro*. Furthermore, necrosis of fat and muscle has been histologically observed after tissue incubation with a phosphatidylcholine/deoxycholate formulation and with deoxycholate alone. It has been concluded that the detergent effects of the bile salt alone cause nonspecific cell lysis.<sup>26</sup> Similar to injecting botulinum toxin, fillers, and sclerosing agents, careful and correct placement of these substances is therefore very important.

Although some have recently argued that the bile salt alone is primarily responsible for fat cell destruction<sup>27</sup> others argue that deoxycholate is responsible for localized inflammatory effects and nonspecific cell lysis, hence the concentration of deoxycholate used must not be too high, nor should it be used alone. Their hypothesis is that phosphatidylcholine is essential for efficacy and that a synergistic sequence of bioactive events occurs following treatment.<sup>11,12 23,28</sup> They hypothesize this sequence of events may be as follows:

The solution containing the phosphatidylcholine, sodium deoxycholate and benzyl alcohol initially causes some cell membrane disruption. However, once injected into the subcutaneous layer the phosphatidylcholine is then responsible for a chain of reactions over an 8–10-week period. Mathur *et al.*<sup>29</sup> describes a critical concentration of 250 mmol phosphatidylcholine that is necessary to destabilize the adipocyte cell membrane. Peckitt<sup>28</sup> also demonstrates the destabilization of the adipocyte cell membrane following injection of a critical concentration of phosphatidylcholine. This change in the physical properties of the cell membrane then appears to cause a complex enzymatic cascade involving the release of lipases and other enzymes as well as a rapid apoptotic cascade that causes adipocyte cell death. If the critical concentration is not reached, the unstable cell membrane forms gaps or pores, allowing efflux of some of the cytoplasmic contents. This mechanism may account for the reduction in viable fat cell diameter present in human histological sections post-treatment.<sup>11</sup>

## Materials and methods

A total of 172 UK doctors thought to be using phosphatidylcholine injections for the reduction of subcutaneous fat were identified from a database held by the British Association of Cosmetic Doctors. All doctors were contacted by e-mail and provided with a questionnaire (Table 1) asking if they had used this method of treatment. Those doctors who replied and confirmed that they had used phosphatidylcholine injections for subcutaneous

fat reduction were then asked to complete the full questionnaire, which included detailing any adverse reactions experienced by patients.

In order to try to avoid under-reporting bias, it was made clear that all the results of the survey would be pooled and collated, with the doctors' details kept completely confidential, other than for administrative purposes.

## Results

Of 172 UK doctors contacted, 50 responded, with 39 confirming they had used phosphatidylcholine injections in their practice for subcutaneous fat reduction. These 39 doctors then went on to complete the full survey questionnaire.

Results showed that this treatment had been used for between 3 and 34 months, with a mean duration of 13.1 months (Fig. 2). Of the total 10 581 treatments performed, 96.2% of patients had been routinely assessed and examined by the treating doctor at a mean interval of 6.7 weeks post-treatment (see Fig. 3).

Overall, the doctors reported that 17.9% of their patients would have been prepared to undergo surgery for their condition if phosphatidylcholine injections had been unavailable.

Patient satisfaction with treatment was found to be high, with 41.6% of patients reporting to their doctors that they were "very satisfied" with the results of treatment. 31.5% of patients were reported to be "satisfied", 16.1% "fairly satisfied" and only 10.5% "dissatisfied" with the treatment.

Localized adverse effects of treatment comprised swelling (mean duration: 4.1 days), erythema (mean duration: 1.4 days), burning/stinging (mean duration: 0.9 days), pain (mean duration 1.8 days), tenderness (mean duration: 6.7 days) and bruising (mean duration: 6.3 days). Most patients reported these reactions as either "very mild" (18.4%) or "mild" (39.2%) in intensity, while 37.6% reported their reactions as "moderate", with only 5.0% of patients reporting intensity as "severe".

Infrequent systemic adverse effects included diarrhoea (1.5%), nausea (0.7%), dizziness/light-headedness (0.7%) and intermenstrual bleeding (0.1%). The majority of patients experiencing these adverse reactions reported them to be either "very mild" (36%) or "mild" (55%) to their doctors. Eight percent of patients affected reported severity to be "moderate" and 1% affected reported severity to be "severe".

Doctors were asked to provide details of any adverse reaction which they considered to be "unexpected, unusually severe or prolonged" affecting any treated patient.

**Table 1** Copy of questionnaire sent to doctors.

1. Have you used phosphatidylcholine injections for the reduction of subcutaneous fat?

YES

NO

If NO do not answer the remaining questions but please *return* the form by Fax: to enable us to complete our records.

2. When did you start using this treatment?

3. How many treatments have you performed in total?

4. What percentage of your patients do you routinely review? After how many weeks do you review them?

5. What percentage of your patients are fully informed and consented with regard to the known and potential for unknown risks of this procedure, the alternative options to this treatment and the fact that phosphatidylcholine is not licensed in the UK, nor by its manufacturer for subcutaneous use?

6. What percentage of your patients would have otherwise undergone surgery to treat their problem, had the option of phosphatidylcholine injections not been available?

7. What percentage of your patients has been satisfied with the results of treatment?

|                  |  |              |  |
|------------------|--|--------------|--|
| Very satisfied   |  | Satisfied    |  |
| Fairly satisfied |  | Dissatisfied |  |

8. The expected localized side-effects from treatment are listed below, please indicate the average number of days your patients have experienced these:

|            |  |                      |  |
|------------|--|----------------------|--|
| Swelling   |  | Bruising             |  |
| Redness    |  | Burning and stinging |  |
| Tenderness |  | Pain                 |  |

What percentage of your patients have described these localized side-effects as:

|           |  |        |  |
|-----------|--|--------|--|
| Very mild |  | Mild   |  |
| Moderate  |  | Severe |  |

9. Infrequent systemic adverse effects can include those listed below. Please indicate what percentage of your patients has experienced any of these and their average duration.

|                            | Percentage | Duration |
|----------------------------|------------|----------|
| Diarrhoea                  |            |          |
| Nausea                     |            |          |
| Dizziness/Light-headedness |            |          |
| Menstrual bleeding         |            |          |

What percentage of your patients have described these as:

|           |  |        |  |
|-----------|--|--------|--|
| Very mild |  | Mild   |  |
| Moderate  |  | Severe |  |

10. We are particularly interested in reports of any serious or unexpected adverse effects from this treatment. How many of your patients have experienced any unexpected or unusually severe or prolonged adverse effects?

Please detail below for each patient affected: (Please use additional sheet if necessary)

| Sex/age | Site treated | Total dose phosphatidylcholine injected (250 mg/5 mLs) | Adverse effect including severity | Duration (Days) | Action taken (If any) | Outcome |
|---------|--------------|--|-----------------------------------|-----------------|-----------------------|---------|
|         |              |  |                                   |                 |                       |         |
|         |              |  |                                   |                 |                       |         |
|         |              |  |                                   |                 |                       |         |
|         |              |  |                                   |                 |                       |         |

Thank you; please complete your details below. All data will be pooled and kept anonymous.

**Doctor's details**

Name: Dr. \_\_\_\_\_

Clinic Address: \_\_\_\_\_

Tel./Fax:/E-mail: \_\_\_\_\_

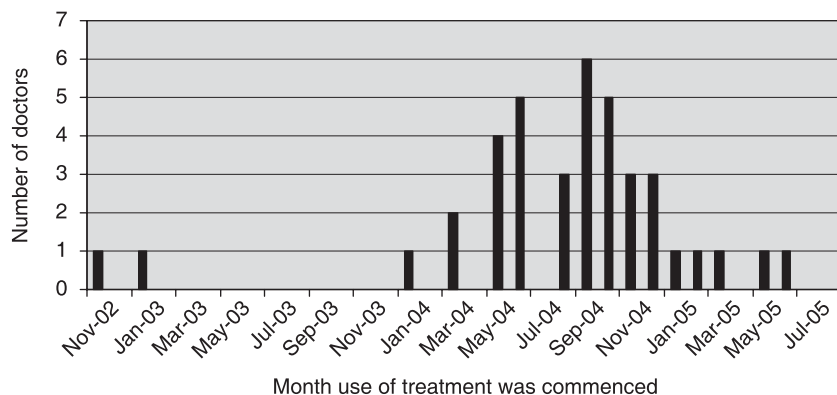


Figure 2 Duration of use of treatment.

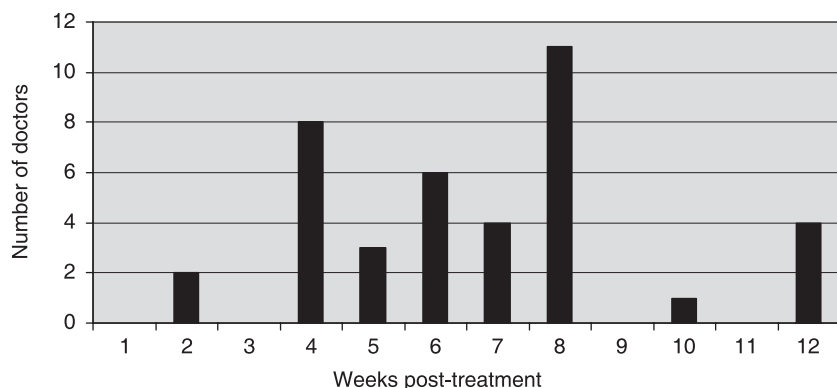


Figure 3 Timing of patient post-treatment review (weeks post-treatment).

Fifteen events were reported in total, the most common being pain and/or swelling (8 patients) and patchy hyperpigmentation/rash (4 patients). In the majority of cases, no action was taken and all events were self-limiting (Table 2).

Information relating to the total of number of treatments administered by the doctors, rather than total number of individual patients treated was collected. However as doctors were trained to follow a protocol involving 1–4 treatment sessions per patient<sup>10</sup> it can be inferred that the data presented relates to treatments carried out on between 3000 and 6000 different individual patients.

### Discussion

Phosphatidylcholine is safe and nontoxic with no significant acute or chronic toxicity, mutagenicity or teratogenicity. It is well-tolerated at daily doses of up to 18 g when taken orally and symptoms of intolerance are almost exclusively restricted to gastro-intestinal discomfort (e.g. diarrhoea and nausea).<sup>1</sup>

Phosphatidylcholine has been licensed in Europe for over 30 years for intravenous administration for the prophylaxis and treatment of fat embolism at high doses

of up to 90 mL or 4.5 g/day.<sup>2–5</sup> Consistent with its lack of toxicity, the manufacturer’s data sheet states that no intervention or action is required in the event of overdose.

Phosphatidylcholine is safe for ill and vulnerable patients, being used orally and intravenously at high doses of 6 g daily or higher for liver salvage in acute and end-stage liver failure. Since phosphatidylcholine is the primary cell membrane building block, recovery following liver damage requires substantial replacement of cell membrane mass. Results from eight double-blind trials and other clinical reports indicate consistently that significant clinical benefit, including improvement of enzymatic and other biochemical indicators, faster functional and structural rebuilding of liver tissue, accelerated restoration of subjects’ overall well-being and improved survival occur following phosphatidylcholine treatment.<sup>6–9</sup>

Preparations of exogenous surfactant (phosphatidylcholine 70–80%) are used for administration into the tracheae of premature neonates suffering from respiratory distress syndrome where it can effectively help with alveolar inflation.<sup>30,31</sup>

Criticism of the subcutaneous use of phosphatidylcholine for localized reduction of fat may have arisen due to the manufacturer of the major brand of phosphatidylcholine

**Table 2** Details of all “Unexpected, unusually severe or prolonged adverse effects” reported.

| Patient's Sex/Age | Site Treated                 | Total dose (mL) (250 mg/5 mL) | Adverse effect including severity  | Duration (days) | Action taken (if any)         | Outcome                                    |
|-------------------|------------------------------|-------------------------------|--|-----------------|-------------------------------|--|
| F/52              | Abdomen                      | 40                            | Widespread Rash, fairly mild   | 21              | None – resolved spontaneously | Patient decided to avoid further treatment |
| F/40              | Jowls/Chin                   | 7                             | Oedema   | 10              | None                          | Good result                                |
| F/64              | Lower Abdomen                | 20                            | Facial Swelling and Erythema   | 5               | Antihistamines                | Good result                                |
| F/42              | Lower Eyelids                | 0.8                           | Pain and Swelling  | 7               | Nil                           | Good result                                |
| F/44              | Lower Eyelids                | 0.8                           | Pain and Swelling  | 7               | Nil                           | No results                                 |
| F/46              | Lower Eyelids                | 0.8                           | Pain and Swelling  | 5               | Nil                           | Self-limiting                              |
| M/37              | Lower Eyelids                | 0.8                           | Pain and Swelling  | 7               | Nil                           | No results                                 |
| F/36              | Lower Eyelids                | 0.8                           | Pain and Swelling  | 7               | Nil                           | Self-limiting                              |
| F/64              | Lateral Thighs               | 40                            | Mild Diarrhoea   | 2               | None                          | Self-limiting                              |
| F/60              | Lower Abdomen                | 25                            | Post-treatment hyperpigmentation at site of bruising   | 150             | Massage, otherwise nil        | Almost fully resolved after 5 months       |
| F/50              | Posterior Arms               | 20                            | Patchy Hyperpigmentation at treatment site   | 120             | Observation only              | Slowly resolving                           |
| F/48              | Lower Abdomen                | 50                            | Patchy Hyperpigmentation at treatment site   | 150             | Observation only              | Resolved                                   |
| F/43              | Legs                         | 20                            | Painful muscle   | 14              | NSAID                         | Resolved                                   |
| M/55              | Lipoma                       | 5                             | Swelling, tenderness, neck pain  | 42              | None but considered surgery   | Resolved                                   |
| F/40              | Triceps, Knees, Love handles | 40                            | Oestrogen-like effect of fluid retention. Increased appetite and for 1 week low mood and tearfulness | 60              | Nil                           | Resolved                                   |

injection, Lipostabil (Nattermann), including a warning on the data sheet stating that it should not be injected subcutaneously. However, it has emerged that this is due to the product being freely available “over-the-counter” in Germany, and elsewhere over the internet and increasing numbers of the public are self-administering the drug subcutaneously.

There are known cases of localized tissue necrosis and other serious consequences arising entirely from such self-treatments.<sup>32</sup> The proper formula, injected in the correct location using the proper technique and dosage, is therefore critical to the safe use of injection lipolysis and there is an urgent need to take action to stop the supply of these products to the public or other nonmedical personnel.

When used by experienced medical practitioners (Hasengschwandtner/Network-Lipolysis<sup>10</sup>) this data supports the view that phosphatidylcholine can be very safely used for localized reduction of subcutaneous fat on the face and body. Common localized adverse effects are generally “mild” to “moderate” in intensity, of short duration and are well-tolerated by most patients. Systemic adverse

effects are rare and are usually “very mild” or “mild”. Patient satisfaction is high (although an improvement in the study design would have included more than one dissatisfaction response option) and, of the total of 10 581 treatments, only 15 unexpected, unusually severe or prolonged adverse events were reported. None could be considered very serious and all were self-limiting.

As 96.2% of all patients were assessed and examined by their treating doctors several weeks post treatment, we are confident that the doctors surveyed were extremely well-informed regarding treatment outcomes and occurrence and nature of any emergent adverse effects.

A negative response option could have been included on the survey form for doctors to indicate if there were any of those questioned who had tried phosphatidylcholine injections, found them unsatisfactory, and had abandoned their use.

Serious allergic reactions, such as anaphylaxis, have not been reported despite many thousands of treatments. However, the theoretical possibility of such a reaction always remains, and there may be potential for sensitization

with repeated subcutaneous administration. Therefore, as with all injectable procedures, physicians should always remain alert to this possibility and be prepared for such emergencies.

Criticism of this treatment may have further arisen, partly due to the national UK lay-press which has indicated erroneously that phosphatidylcholine treatment may have an adverse effect on plasma lipid profiles and blood coagulability. However, Hexsel *et al.*<sup>33</sup> assessed the use of phosphatidylcholine in 205 patients with different patterns of localized fat deposits. Venous blood samples were taken in 13 of the patients treated with subcutaneous injections and all results showed no significant alterations in either hepatic function or lipid profile.

Hasengschwandtner<sup>34</sup> also compiled an Austrian study of serological measurements of liver function tests in 46 patients given injections into the subcutaneous fat of the with the maximum recommended dose of 2500 mg phosphatidylcholine (Lipostabil N®). The Gamma-Glutamyl Transferase and Bilirubin values from venous blood was examined on the 5th day after first treatment, 8 weeks after first treatment and, if there was more than one treatment sessions (maximum four), 8 weeks after the last series of injections. All evaluated samples were within the normal range. The conclusion made was that phosphatidylcholine did not cause any increase of the evaluated blood values after subcutaneous application, such as is already proven after intravenous administration.

Furthermore, other reports demonstrate that phosphatidylcholine is of benefit in cardiac disease<sup>35</sup> hypertriglyceridemia<sup>36</sup> and elevated serum cholesterol.<sup>37</sup> Bobkova *et al.*<sup>25</sup> reported on the metabolic effect of Lipostabil in improving coronary atherosclerosis, hypothyroidism, and insulin resistance. They also reported an average decrease of 32% in serum triglyceride levels in cardiac patients treated with phosphatidylcholine.<sup>25</sup> Documented cardiac benefits include dissolution of atherosclerotic coronary artery plaques, decrease in LDL, triglycerides and VLDL, and an increase in serum HDL values. Phosphatidylcholine has also been shown to inhibit platelet aggregation.<sup>24</sup>

Criticism may have also arisen as a consequence of discrimination against cosmetic treatments in the UK where there is a tendency to regard cosmetic treatments as unnecessary for patient health. However, it is our experience that many patients are sufficiently psychologically distressed by a cosmetic problem that their quality of life is impaired, with some patients exhibiting signs of clinical depression severe enough to warrant antidepressant medication. Successful cosmetic treatment can often dramatically improve patient confidence and self-esteem, relieve symptoms of depression and improve patient happiness and quality of life.

Strict dieting and exercise should always be discussed with patients but may not always be appropriate since some patients have a disproportionate body shape with an excess of subcutaneous fat deposited in a very localized area. These patients may be of average or below average overall bodyweight and any further weight and fat loss from other body areas may be undesirable.

Doctors surveyed estimated that 17.9% of their patients treated by phosphatidylcholine injections would have otherwise undergone surgery, the most common surgical option being liposuction. Although generally considered a benign procedure, two independent surveys assessed the late 1990s mortality from liposuction as 1 in every 5000 procedures.<sup>38</sup> Furthermore, a critical review of the lipoplasty literature concluded that

“the mortality from lipoplasty procedures is higher than the 0.003–0.02% reported in the literature and may be as high as 0.1%”.<sup>39</sup>

More recent publications have also highlighted safety concerns regarding current techniques of tumescent liposuction.<sup>40,41</sup>

In conclusion, it is acknowledged that, at present, the use of phosphatidylcholine for subcutaneous fat reduction is an unlicensed indication. It is also acknowledged that in some countries (e.g. UK, USA) no commercially available injectable preparations of phosphatidylcholine have marketing authorization (product licences). In the UK, such products can only be prescribed strictly for a named patient and imported individually after having been dispensed to that patient for their own personal use.

It is further acknowledged that, in common with all new treatments (e.g. Intense Pulsed Light), any very long-term effects are currently unknown. Physicians should therefore exercise caution and ensure to undertake rigorous and fully informed consent with any patients treated.

However, although surgical outcomes have improved with advancing techniques, when considered against the possible risks of surgical treatment options, the data from this study suggests that disproportionate criticism of phosphatidylcholine injections is unjustified.

When used by doctors specifically trained in correct treatment protocols, this is a treatment modality which appears, from this data, to be associated with low risks for patients seeking medical intervention to reduce localized subcutaneous fat deposits.

This medication must be prevented from being available to the general public or nonmedical personnel as some serious adverse reactions have been reported as a result of attempted self-treatments by lay-persons.

## Acknowledgements

Thanks to the participating members of the BACD.

## References

- Kidd PM. Phosphatidylcholine, a superior protectant against liver damage. *Altern Med Rev* 1996; **1**: 258–74.
- Guranda AI, Vladyka AS, Golynskii GIU *et al.* Experience of anesthesiology and intensive care services in mass admission of victims with fight injuries. *Anesteziol Reanimatol* 1994; **1**: 44–7.
- Kroupa J. The role of pharmacology in the comprehensive prophylaxis of post-traumatic fat embolism. *Acta Chir Orthop Traumatol Cech* 1993; **60**: 114–22.
- Kroupa J, Uher J, Utrata F. Lipostabil in the prevention of fat embolism. *Z Exp Chir* 1972; **5**: 379–92.
- Kroupa J. Lipostabil in the prevention of fat embolism. *Rozhl Chir* 1966 July; **45**: 444–52.
- Bruha R, Marecek Z. Essential phospholipids in the treatment of hepatic encephalopathy. *Vnitřní Lekarství* 2000; **46**: 199–204.
- Niederau C, Strohmeier G, Heintges T *et al.* Polyunsaturated phosphatidylcholine and interferon alpha for treatment of chronic hepatitis H and C: a multicenter, double-blind, placebo-controlled trial. *Hepatology* 1998; **45**: 797–804.
- Kidd PM. Dietary phospholipids as anti-aging nutraceuticals. In: RA Klatz, R Goldman, eds. *Anti-Aging Medical Therapeutics*. Chicago: Health Quest Publications; 2000: pp. 283–301.
- Kidd PM. Cell membranes, endothelia, and atherosclerosis—the importance of dietary fatty acid balance. *Altern Med Rev* 1996; **1**: 148–67.
- www.network-lipolysis.com
- Duncan DI, Hasengschwandtner F. Lipodissolve for subcutaneous fat reduction and skin retraction. *Aesthetic Surg J* 2005; **25**: 530–43.
- Hasengschwandtner F. Die subcutane Injektion von Phosphatidylcholin (Lipostabil N®) zum Zwecke der Lipolyse (The subcutaneous injection of phosphatidylcholine for means of lipolysis). *Aktuelle Dermatologie* 2005; **31**: 549.
- Hexsel D, Serra M, Mazzuco R *et al.* Cosmetic Uses of Injectable Phosphatidylcholine on the Face. *Otolaryngologic Clinics of North America* 2005; **38**: 1119–29.
- Hasengschwandtner F. Phosphatidylcholine treatment to induce lipolysis. *J Cosmet Dermatol* 2005; **4**: 308.
- Rose PT, Morgan M. Histological changes associated with mesotherapy for fat dissolution. *J Cosmet Laser Ther* 2005; **7**: 17–9.
- Ablon G, Rotunda AM. Treatment of lower eyelid fat pads using phosphatidylcholine: clinical trial and review. *Dermatol Surg* 2004; **30**: 422–8.
- Worcester S. Phosphatidylcholine Improved Fat Pad Herniation. *Skin Allergy News* 2003; **34**: 34.
- Young VL. Lipostabil: The effect of phosphatidylcholine on subcutaneous fat. *Aesthetic Surg J* 2003; **23**: 413–7.
- Rittes PG. The use of phosphatidylcholine for correction of localized fat deposits. *Aesthetic Plast Surg* 2003; **27**: 315–8.
- Baumann LS. Phosphatidylcholine. *Skin Allergy News* 2003; **34**: 24.
- Donohue M. Lecithin Injection Reduces Lower Eyelid Fat Pads. *Skin Allergy News* 2001; **32**: 23.
- Rittes PG. The use of phosphatidylcholine for correction of lower lid bulging due to prominent fat pads. *Dermatol Surg* 2001; **27**: 391–2.
- Peckitt N. *Evidenced Based Practice: Phosphatidylcholine. A Review of Evidence for the Mode of Action in Injection Lipolysis*. Huddersfield, UK: Jeremy Mills Publishing; 2006.
- Parnham MJ, Wendel A. *Phospholipids and liposomes-safety for cosmetic and pharmaceutical use*. Natterman Phospholipid GMBH Scientific Publication #1995432003, 2. Cologne, West Germany: Natterman International GMBH; 1990.
- Bobkova VI, Lokshina LI, Korsunskii VN *et al.* Metabolic effect of lipostabil–forte. *Kardiologiia* 1989; **29**: 57–60.
- Rotunda AM, Suzuki H, Moy RL *et al.* Detergent effects of sodium deoxycholate are a major feature of an injectable phosphatidylcholine formulation used for localized fat dissolution. *Dermatol Surg* 2004; **30**: 1001–8.
- Rotunda AM, Ablon G, Kolodney MS. Lipomas treated with subcutaneous deoxycholate injections. *J Am Acad Dermatol* 2005; **53**: 973–8.
- Peckitt N. *The molecular biology of adipocyte differentiation and apoptosis*. Presented at the 1st International Convention for Lipodissolve, June 18–19 2005, Salzburg, Austria.
- Mathur S, Born E, Murthy S *et al.* Phosphatidylcholine increases the secretion of triacylglycerol-rich lipoproteins by CaCo-2 cells. *Biochem J* 1996; **14**: 569–75.
- Suresh GK, Soll RF. Overview of surfactant replacement trials. *J Perinatol* 2005; **25** (Suppl. 2): S40–4.
- Zimmermann LJ, Janssen DJ, Tibboel D *et al.* Surfactant metabolism in the neonate. *Biology of the Neonate* 2005; **87**: 296–307. Epub 2005 June 1.
- Meissner C. *Complications with Injection Lipolysis*. 1st International Congress Network-Lipolysis, Frankfurt, Germany, 13 November 2004; 1st International Convention for Lipodissolve, 18–19 June 2005, Salzburg, Austria; 2nd International Congress Network-Lipolysis, 26 November 2005, Paris, France.
- Hexsel D, Serra M, Mazzuco R *et al.* Phosphatidylcholine in the treatment of localized fat. *J Drugs Dermatol* 2003; **2**: 511–8.
- Hasengschwandtner F. *Lipolysis Injection with Phosphatidylcholine (Lipostabil N®). Examination of blood values after subcutaneous administration. The examination of  $\gamma$ GT (gamma glutamyl transferase) and bilirubin in 46 experimentees following lipodissolve injection*. [WWW document]. URL <http://www.doc1.at>
- Almazov VA, Freidlin IS, Krasil'nikova EI. Use of lipostabil to correct lipid metabolism disorder with ischemic heart disease. *Kardiologiia* 1986; **26**: 39–42.

- 36 Melchinskaya EN, Gromnatasky NI, Kirichenko LL. Hypolipidemic effects of Alisat and Lipostabil in patients with diabetes mellitus. *Ter Arkh* 2000; **72**: 57–8.
- 37 Lijnen P, Echevaria-Vazquez D, Petrov V. Influence of cholesterol-lowering on plasma membrane lipids and function. *Meth Find Exp Clin Pharmacol* 1996; **18**: 123–36.
- 38 Grazer FM, de Jong RH. Fatal outcomes from liposuction: census survey of cosmetic surgeons. *Plastic and Reconstructive Surgery* 2000; **105**: 436–48.
- 39 Daane SP, Rockwell WB. Analysis of methods for reporting severe and mortal lipoplasty complications. *Aesthetic Plastic Surg* 1999; **23**: 303–6.
- 40 Platt MS, Kohler LJ, Ruiz R *et al*. Deaths associated with liposuction: case reports and review of the literature. *J Forensic Sci* 2002; **47**: 205–7.
- 41 Lehnhardt M, Homann HH, Druecke D *et al*. No problem with liposuction? *Chirurg* 2003; **74**: 808–14.

LIPOLYSE-REPORT

# Statistische Auswertung einer Befragung der Ärzte des NETZWERK-Lipolyse

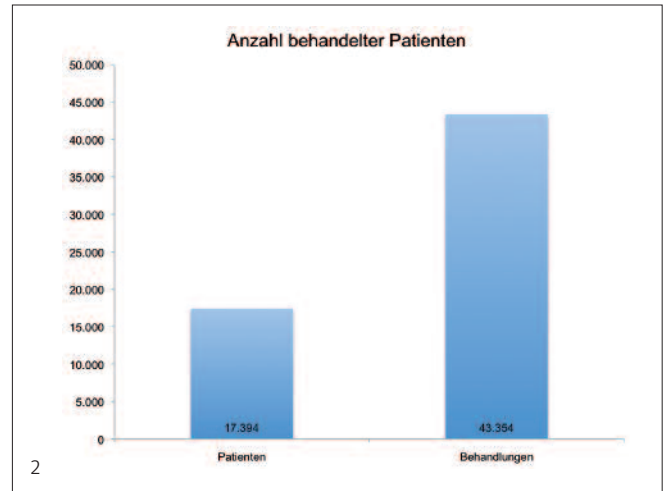
FRANZ HASENGSCHWANDTNER

Die Medizintechnik hat in den letzten Jahren zahlreiche Geräte mit immer neuen Wirkmechanismen zur Fettreduktion auf den Markt gebracht. „Dennoch haben wir mit der Injektions-Lipolyse seit etwa 10 Jahren ein wissenschaftlich gut fundiertes Instrument zur Fettreduktion in Händen, das nachweislich sehr gut geeignet ist, moderate Fettansammlungen auf Dauer nebenwirkungsarm deutlich zu verringern“, so Dr. Franz Hasengschwandtner in dem hiermit erstmals veröffentlichten Lipolyse-Report.

Das NETZWERK-Lipolyse hat derzeit etwa 3.000 weltweit ausgebildete Ärzte, die in 64 Ländern der Welt die Lipolyse bei ihren Patienten anwenden. Während der letzten Jahre konnten die Erkenntnisse über die Lipolyse ausgebaut und den praktizierenden Ärzten in Workshops auf dem neusten Stand vermittelt werden. Der hier vorgestellte Lipolyse Report erschließt einige wichtige Informationen für den behandelnden Arzt. Die einzelnen Ergebnisse der Befragung stehen für sich.

**Abb. 1:** 128 Mitglieder des NETZWERKs haben einen Fragebogen mit insgesamt 26 Fragen beantwortet. 36% der Befragten führten die Injektionslipolyse erst eine kurze Zeit seit kurzem durch und hatten dadurch wenig Erfahrung. Insofern ist diese Befragung als durchaus repräsentativ anzusehen. Mit zunehmender Erfahrung der Ärzte verringert sich die Non-responder Rate kontinuierlich.

**Abb. 2:** Insgesamt wurden innerhalb des Befragungszeitraumes (17 Monate) von den 128 Befragten 17.394 Patienten behandelt. Die Ergebnisse der Befragung zeigen also die



gestiegene Attraktivität der Behandlung für Patienten. Rechnet man die Patientenzahl auf die deutschsprachigen Mitglieder hoch (insgesamt 900), käme man auf eine jährliche Patientenzahl von 86.330. Aus Diagramm Nr. 2 kann ebenfalls die Anzahl der Behandlungen je Patient abgelesen werden. Im Durchschnitt benötigt jeder Patient 2,5 Behandlungen. Im Gesicht ist die Anzahl der Behandlungen niedriger (2,2), Körperareale benötigen mehr Behandlungen (3).

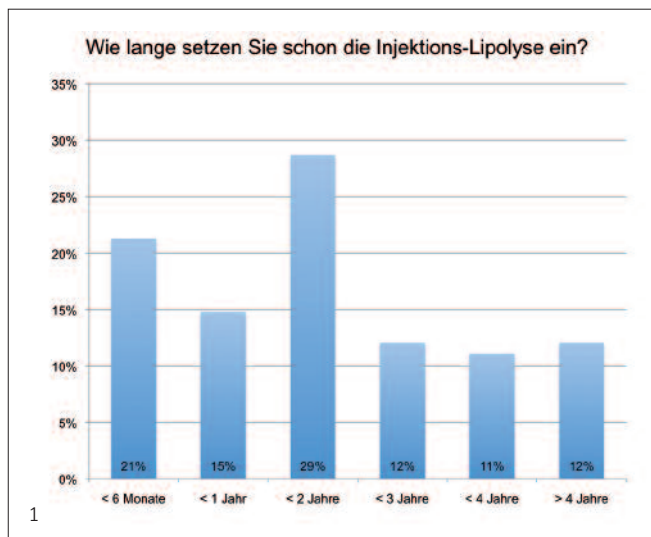
**Abb. 3:** Jedes Mitglied des NETZWERK-Lipolyse führt im Durchschnitt fast 8 Behandlungen im Monat durch.

**Abb. 4:** Doppelkinn und Hängebäckchen sind die beiden Hauptindikationen des Gesichtes. Dies entspricht auch den Empfehlungen, wir raten zu vorsichtiger Behandlung der Wangen, um den alterungsbedingten Verfall der Wangenregion zu berücksichtigen.

**Abb. 5:** Bauch und „Love Handles“ sind die von Patienten favorisierten Areale am Körper.

**Abb. 6:** 2008 hat das Medical Advisory Board die Hautstraffung als zusätzliche Indikation für IL akzeptiert. Die straffende Wirkung kann sowohl allein eingesetzt werden, als auch in Kombination mit anderen Therapien, die zwar eine Fettreduktion bewirken, jedoch keine straffenden Effekte vorweisen können.

**Abb. 7:** Neben den Lipomen und Fettverteilungsstörungen halten sich die Netzwerkmitglieder an die Empfehlungen, vorrangig keine großen Areale und übergewichtige Patienten mit einem BMI über 30 zu behandeln. Unsere Definition der Lipolyse als Therapie für kleinere, umschriebene Fettpolster ist wichtig, um keine zu großen Patientenerwartungen zu wecken.



**Abb. 8:** Die ersten drei Nebenwirkungen (Knoten, Dellen und Pigmentstörungen) treten nur temporär auf und bilden sich nach einiger Zeit zurück. Dellen oder Knoten resultieren fast immer aus zu tief gesetzten Injektionen in die Faszie. Nicht nur temporär aufgetretene Komplikationen sind demnach bei

43.354 Behandlungen 33 mal aufgetreten. Dies entspricht einer Komplikationsrate von 0,00076%, ein Wert, der im Vergleich mit anderen ästhetischen Therapien durchaus mehr als akzeptabel ist. Geschuldet ist diese niedrige Komplikationsrate unserer Ansicht nach der guten Ausbildung.

