



THE INTERNATIONAL COMMITTEE FOR QUALITY ASSURANCE,
MEDICAL TECHNOLOGIES AND DEVICES IN PLASTIC SURGERY

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POSITION STATEMENT OF IQUAM
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On April 6, 2009, IQUAM issued its 8th Position Statement, which reads as follows:

IQUAM, the International Committee for Quality Assurance and Medical Devices in Plastic Surgery, is a professional medical and scientific organization committed to the surveillance of existing and new technologies and devices in Plastic Surgery. IQUAM is dedicated to the safe use of medical devices, technologies and procedures in plastic surgery, and to the guarantee of patients' safety. IQUAM reviews and evaluates updated literature and studies, scientific data, and recommends standards of treatment for new devices or technologies. IQUAM proscribes potentially deleterious use of products, devices and technologies, or their unintended application or application for unsuitable indications.

Breast Augmentation and Reconstruction

The purpose of breast augmentation and reconstruction is to improve the psychological and physical condition of the patient. The breast augmentation method should be chosen depending on the needs of the patient and the compatibility in the individual case.^{1,2,3,4,5}

1. Silicone Breast Implants.

A. Since IQUAM's former declarations, silicone implants filled with either silicone gel or saline, textured by various methods or smooth surfaced, or covered



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by polyurethane, continue to be widely used internationally for breast implantation, with the types varying by geographic region.

B. Additional medical studies have not demonstrated any association between silicone-gel filled breast implants and carcinoma or any metabolic, immune or allergic disorder.. These studies re-confirm prior data.^{6,7,8,9,10,11}

C. Silicone-gel filled breast implants do not adversely affect pregnancy, fetal development, breast-feeding or the health of breast-fed children.^{12,13, 14,15}

D. Further changes in implants structure and composition need to be evaluated.

2. Autologous breast reconstruction and augmentation techniques

Surgical methods for breast reconstruction and –augmentation with autologous tissue such as microsurgical tissue transfer from various donor areas and extent, pedicled flaps and local flap techniques undergo constant re-evaluation and are well established according to individual indications and conditions. They have been employed in combination with silicone breast implants without specific inherent complications reported.^{16 17 18 19 20}

3. Autologous fat grafting

Fat grafting for soft tissue defects has been performed since about 40 years with a low complication rate. Ongoing studies show promising results of fat grafting procedures for breast reconstruction and augmentation. There is clear evidence that the volume of the fat grafts and its take can be increased by the preoperative and postoperative use of a vacuum device. More studies are required to evaluate the efficacy and optimal duration of vacuum application.^{21, 22, 23 24}

4. Other Injectables for Breast Augmentation

New alternative materials and methods, such as exogenous injectables, recently also stabilized hyaluronic acid and therefore potentially fully resorbable products are under review.²⁵

General Recommendations for Breast Augmentation and Reconstruction



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- A. IQUAM believes it is important to advise patients of potential hazards and risks, the possible need for re-operations, as well as the benefits of breast augmentation or reconstructive surgery. A detailed and updated Patients Information and Consent Form must be provided and discussed with the patient prior to surgery.
- B. A reasonable period of time should be allotted following consultation, for the comprehension and evaluation of data before decision to and performance of surgery.
- C. It is recommended to postpone breast augmentation surgery until after the age of eighteen, Such procedure in teenagers requires in depth evaluation of motivation and emotional and physical maturity before considering surgery even in medically indicated cases.
- D. Patients with breast implants should be encouraged to have regular and long term follow-up, preferably by the operating surgeon^{26 27}
- E. No definite period of time has yet been defined for the longevity of breast implants. Routine replacement of implants is not recommended. The indications for replacement should be based on specific patient indications.
- F. IQUAM calls for continuous clinical and scientific research, for documentation and monitoring of breast implants and patients by means of a national and/or international registry.
- G. Advertising of breast implant procedures should be restricted to the medical aspects of the surgery, and presented in a professional dignified way and without exaggerated claims..
- H. IQUAM calls for the approval of silicone-gel filled breast implants for global clinical use and unrestricted availability to all patients.

Stem Cell Therapy

One of the most exciting frontiers in medicine today is the use of stem cells. Unlike the controversial evaluation of embryonic stem cells, adult stem cells deriving from adipose tissue are easily available without ethical controversy.

Respecting the guidelines that

- the injections are performed in the same operative session as the liposuction procedure to remove the fat
- the stem cells have been only minimally manipulated and
- the stem cell enhanced fat transfer does not alter the original relevant biologic function of the stem cell –



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the therapeutic use of autologous stem cells is not submitted to drug therapy regulations. Reinjection of autologous stem cells in a separate session therefore is not recommended.

For over a decade now it has been shown that successful autologous fat grafting is highly dependent on the techniques used for extracting (liposuction at low negative pressure), processing (centrifugation and decanting of the extracted fat) and reinjection to result in a high concentration of adult stem cells, producing long lasting results and even therapeutic effects in injured tissues.

Indications of stem cell enhanced adipose tissue transfer under the above conditions include augmentation or of the subcutaneous layer, e.g. for defects after liposuction complications and other acquired tissue defects e.g. in the face, breast, gluteal area, hips, thighs or in the dorsum of the hands.

Under investigation to date are e.g. treatment of radiotherapy injuries and breast reconstruction after cancer . Stimulated by our experience with fat grafting, numerous basic laboratory and animal model studies are underway in many parts of the world.^{27 28 29 30 31 32 33}

Tissue Engineering

Tissue engineering holds the promise of generating tissues de novo and Adipose tissue is the ideal soft tissue surrogate to redefine body contour defects Due to its intrinsic plastic characteristics.

Regenerative medicine is a promising road for future advancements in plastic surgery. Laboratory engineered constructs must consist of safe components before implantation in patients. Institutions, such as C.E.N., are setting strict measures³⁴
^{35 36 37}

Wound Healing

Growth Factors



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An increasing number of growth factors is becoming commercially available for an ever wider range of indications, either as a therapeutic agent or as an adjunct per se or as an element of tissue engineered constructs. IQUAM is warning for the indiscriminate application of growth factors before undesired side effects (uncontrolled cell divisions, malignancies) having been diligently studied on the short and long term of their application. Notified bodies issuing CE-marks should be aware of this and stress that only temporary CE-marks are being granted, while awaiting longer term studies.^{38 39}

Shock Wave Therapy

Recent studies suggest that Extra Corporal Shock Wave Therapy originally developed for resolution of kidney stones, is useful in the treatment of chronic wounds, burns and tendinopathies. More studies are needed to evaluate the frequency and duration of application. It is likely that more indications will be suggested in the future^{40 41 42}

Injectables

Lipolysis or Lipodissolve Injections by Phosphatidylcholine derivatives.

Phosphatidylcholine has been used for various clinical indications for many years. Phosphatidylcholine is currently being used 'off label' for dissolving fat in clinical aesthetic applications. Data concerning the efficacy, outcome and the safety of its use have not yet been established. Further basic science and clinical trials should precede the use of this drug for aesthetic application. PMA trials are underway.^{43 44}
^{45 46}

Botulinum Toxin A

- A. Botulinum Toxin A (BTxA) has been extensively used for aesthetic purposes.
- B. BTxA in high dosages has been used in various clinical applications with minimal reported significant adverse effects.



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- C. Current clinical data confirm the safety of BTxA's for aesthetic indications when used by experienced doctors under medically acceptable conditions.
- D. Patients should be provided with detailed information, and a signed informed consent should be obtained prior to performing the procedure [Addendum III].

Injectable fillers

Today more than 35% of the procedures performed by plastic surgeons are no longer purely surgical. The use of resorbable substances is preferable to the use of non-resorbable fillers, as recommended by many national health authorities or academic societies. Furthermore, IQUAM stresses that degradability should be discerned from resorbability.

Permanent fillers (excluding autogenous tissue) can give a definitive correction but have been reported to be associated with long-term irreversible complications and should be used with extreme caution.

Risks depend on the nature of the implant, volume, depth and site of the injection especially in permanent substances, but also resorbable products.

The patient's history and the long-term follow up are important for documenting allergic or late reactions.

Most important is the benefit/risk ratio for each product as the perfect material doesn't yet exist.

IQUAM recommends reporting complications of fillers to regulatory bodies and mandatory registration of adverse effects associated with injection of fillers to better estimate the extent of complications.^{48 49 50}

- Collagen Fillers

Collagen derived soft tissue fillers from bovine origin have lost their importance and have not been subjected to any chemical or manufacturing changes over the last years due to the prevalence of other substances. Most of the available products are obligatorily subjected to be employed only after a negative allergy skin testing



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at least 6 weeks before injection. This is not the case for a porcine derived product which has not shown different efficacy or local complication rate like infection, granuloma, nodule formation or visibility through the skin. Allergies have not been reported so far.^{51 52 53 54 55}

- **Hyaluronic Acid Fillers**

Commercially available HA's have a wide variety of properties which have an extensive impact on their use and clinical outcomes. Combining objective factors that influence filler chemistry with clinical experience will improve patient care, make optimal results more likely and should decrease complications.

Not all HA fillers have stood the test of time and some have decreased in popularity. Regulation of these injectables varies widely from country to country and approval is often gained after short term studies of one year or less. To avoid confusion in the use of materials, IQUAM recommends that users verify the validation of the CE-mark or FDA approval prior to clinical use.^{56 57}
^{58 59 60 61 62}

Continued long-term post-marketing surveillance by both industry and Notified Bodies is essential. Physicians should stay alert to detect late adverse events and report these to the competent authorities. Patients and users need to be given updated information on the risks of these materials. Supply of injectables should be limited to trained physicians.^{63 64}
^{65 66}

However, appropriate guidelines are often lacking, and as their clinical use expands rapidly, there is considerable overlap in application. More choices demand greater clinical judgment and continuing clinical trials to highlight the differences, the safety, the efficacy and the evolution of the use of these materials.

- **Cross Linked Polyacrylamide Hydrogel**

Permanent fillers based on acrylamides have been in clinical use for more than 15 years. The current European manufacturer has attained CE certification with the remaining monomer content as below 2 ppm, which is considered a non



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carcinogenic level and claims completely renewed production standards in comparison with earlier acrylamide products. especially from non E.U. countries. Used strictly subcutaneously and in small volumes by experienced surgeons in a selected group of patients polyacrylamide hydrogel has shown efficacy and no higher complication rate as in resorbable fillers in a European multicenter 8 year follow up study. Removal of the gel is possible, but will require surgical setting and an experienced surgeon.^{67 68 69 70 71 72 73 74 75}

- **PolyMethylMethAcrylate /Collagen Injectable Filler**

Since 10/2008 the FDA has issued the first approval for a permanent dermal filler for nasolabial folds after the product has undergone multiple additional cleaning processes (Suneva Medical).

IQUAM emphasizes that this approval does not include substances with alike or “comparable” components from other than the mentioned company. Indications, contraindications and experienced injection technique are to be respected accurately.⁷⁶

- **Gold Threads**

The implantation of thin gold threads in flaccid facial cutaneous areas has been developed by Caux 50 years ago. Histologically the absence of foreign body reaction with no macrophage cells or allergic reactions following implantation of pure gold (as in eyelid correction for facial palsy, odontologic treatments) is proven. Only limited creation of reticulin fibers can be observed.

However plication, rupture, palpability and migration of the threads due to the mobility of the face are frequent.

Efficacy has not been proven and cannot be a gold standard for facial rejuvenation.⁷⁷

IQUAM urges governments to pass legislation to protect patients from unduly trained physicians and non-medical personnel injecting or implanting materials for various indications.

Based on past experience IQUAM states that CE-marks and FDA approvals are required steps in establishing the safety of medical devices, but are not necessarily sufficient. Post market surveillance revealing new adverse



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information should lead to reconsideration of the approval status. Therefore, it is the IQUAM's members' imperative duty to continuously monitor the short and long term outcomes to protect the safety of patients.

Objective medical and media reports contribute to the reassurance of patients. IQUAM will continue to provide updated information about medical devices in general, implants in particular, injectables and new technologies.

Addendum

BOTULINUM TOXIN TYPE A INFORMED CONSENT *
(Botox Cosmetic)



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Botox is made from Botulinum Toxin Type A, a protein produced by the bacterium *Clostridium botulinum*. For the purpose of improving the appearance of wrinkles, small doses of the toxin are injected into the affected muscles blocking the release of a chemical that would otherwise signal the muscle to contract. The toxin thus paralyzes or weakens the injected muscle. The treatment usually begins to work within 24 to 48 hours and can last up to four months. The Food and Drug Administration (FDA) approved the cosmetic use of Botulinum Toxin Type A for the temporary relief of moderate to severe frown lines between the brow and recommends that the procedure be performed no more frequently than once every three months.

It is not known whether Botulinum A Toxin can cause fetal harm when administered to pregnant women or can affect reproductive capabilities. It is also not known if Botulinum A Toxin is excreted in human milk. For these reasons, Botulinum A Toxin should not be used on pregnant or lactating women.

I authorize and direct _____, M.D., with associates or assistants of his or her choice, to perform the following procedure of Botulinum A Toxin injection(s) on _____ for the treatment of _____ (Patient Name).
(e.g. brow, forehead, crow's feet, etc.)

_____ The details of the procedure have been explained to me in terms I understand.

_____ Alternative methods and their benefits and disadvantages have been explained to me.

_____ I understand that the FDA has only approved the cosmetic use of Botulinum A Toxin for frown lines between the brow. Any other cosmetic use is considered off label.

_____ I understand and accept the most likely risks and complications of Botulinum A Toxin injection(s) include but are not limited to:

- *paralysis of a nearby muscle that could interfere with opening the eye(s)*
- *local numbness*
- *headache, nausea, or flu-like symptoms*
- *swallowing, speech, or respiratory disorders*
- *swelling, bruising, or redness at injection site*
- *disorientation, double vision, or past pointing*
- *temporary asymmetrical appearance*
- *abnormal or lack of facial expression*
- *inability to smile when injected in the lower face*
- *facial pain*
- *product ineffectiveness*

_____ I understand and accept that the long-term effects of repeated use of Botox Cosmetic are as yet unknown. Possible risks and complications that have been identified include but are not limited to:

- *muscle atrophy*
- *nerve irritability*
- *production of antibodies with unknown effect to general health*

- _____ I understand and accept the less common complications, including the remote risk of death or serious disability, that exist with this procedure.
- _____ I am aware that smoking during the pre- and postoperative periods could increase chances of complications.
- _____ I have informed the doctor of all my known allergies.
- _____ I have informed the doctor of all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies, and any others.
- _____ I have been advised whether I should take any or all of these medications on the days surrounding the procedure.
- _____ I am aware and accept that no guarantees about the results of the procedure have been made or implied.
- _____ I have been informed of what to expect post-treatment, including but not limited to: estimated recovery time, anticipated activity level, and the necessity of additional procedures if I wish to maintain the appearance this procedure provides me.
- _____ I am not currently pregnant or nursing, and I understand that should I become pregnant while using this drug there are potential risks, including fetal malformation.
- _____ If pre- and postoperative photos and/or videos are taken of the treatment for record purposes, I understand that these photos will be the property of the attending physician.
- _____ I understand that these photos may only be used for scientific or reco *(Over, please)*
- _____ The doctor has answered all of my questions regarding this procedure.
- _____ I have been advised to seek immediate medical attention if swallowing, speech, or respiratory disorders arise.

Patient Consent

I certify that I have read and understand this treatment agreement and that all blanks were filled in prior to my signature.

Patient Signature/Date

Witness Signature/Date

Print Patient Name

Print Witness Name



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Physician Certification

I certify that I have explained the nature, purpose, benefits, risks, complications, and alternatives to the proposed procedure to the patient. I have answered all questions fully, and I believe that the patient fully understands what I have explained.

Physician Signature

Date

Copy was given to patient: _____
Date Initials

Original was placed in chart: _____
Date Initials

* Provided by The Doctors Company, USA.



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References

- ¹ Postoperative complications after breast implantation. Chekaroua K, Trevidic P, Foyatier JL, Comparin JP, Delay E. *Ann Chir Plast Esthet*, 50(5):544- 53, Oct.2005
- ² The non-perfect results of breast implants. Dionyssopoulos A. *Ann Chir Plast Esthet*, , 50(5):534-43, Oct .2005
- ³ The fate of breast implants: a critical analysis of complications and outcomes. Handel N, Jensen JA, Black Q, Waisman JR, Silverstein MJ: *Plast Reconstr Surg*, (7):1521-33, 1995
- ⁴ Complications leading to surgery after breast implantation. Gabriel SE, Woods JE, O'Fallon WM, Beard CM, Kurland LT, Melton LJ 3rd: *N. Engl Med*, 336(10):677-8, 1997
- ⁵ An analysis of complications after implantation of saline-filled silicone prosthesis for augmentation mammoplasty in 294 cases. Zhu H, Lin W, Quan G. *Zhonghua Zheng Xing Shao Shang Wai Ke Za Zhi*, (4):248- 50, Jul. 1995
- ⁶ Safety of Silicone Breast Implants, Report of the Committee on the Safety of Silicone Breast Implants, Bondurant S, Ernster V, Herdman R (eds). Division of Health Promotion and Disease Prevention, Institute of Medicine (hereinafter IOM). National Academy Press, Washington, D.C., June 22, p187. , 1999: www.4.nationalacademies.org/news.nsf
- ⁷ United Kingdom Report of the Independent Review Group (hereinafter IRG) "Silicone Gel Breast Implants," p25. www.silicone-review.gov.uk
- ⁸ European Parliament Directorate General for Research, Scientific and Technological Options Assessment (hereinafter STOA) "Health Risks Posed by Silicone Implants in General with Special Attention to Breast Implants – Final Study," p22-23. European Parliament Resolution on the petitions declared admissible concerning silicone implants (Petitions Nos 470/1998 and 771/1998) (2001/2068[INI]) www.europarl.eu.int
- ⁹ Health Council of the Netherlands (hereinafter Netherlands) "Gezondheidsrisico's van siliconenborstimplantaten – Health Risks of Silicone Breast Implants" English Executive Summary, p11. www.gezondheidsraad.nl
- ¹⁰ The Mentor Study on Contour Profile Gel Silicone MemoryGel Breast Implants. Cunningham B. *Plast Reconstr Surg*.;120(7 Suppl 1):33S-39S., 2007
- ¹¹ Inamed silicone breast implant core study results at 6 years. Spear SL, Murphy DK, Slicton A, Walker PS; Inamed Silicone Breast Implant U.S. Study Group. *Plast Reconstr Surg*.;120(7 Suppl 1):8S-16S; discussion 17S-18S., 2007



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¹² IOM p204

¹³ IRG p24

¹⁴ STOA p25-26

¹⁵ Netherlands p34

¹⁶ Comparison of superior gluteal artery musculocutaneous and superior gluteal artery perforator flaps for microvascular breast reconstruction. Boyd JB, Gelfand M, Da Lio A, Shaw W, Watson JP. *Plast Reconstr Surg.* ;123(6):1641-7, Jun. 2009

¹⁷ Superficial inferior epigastric vessels in the massive weight loss population: implications for breast reconstruction. Gusenoff JA, Coon D, De La Cruz C, Rubin JP. *Plast Reconstr. Surg.*;122(6):1621-6. PMID: 19050514, Dec. 2008

¹⁸ Alternative autologous breast reconstruction using the free microvascular gracilis muscle flap with horizontal skin island. Schirmer S, Warnecke IC, Frerichs O, Cervelli A, Fansa H. *Handchir Mikrochir Plast Chir.*;40(4):262-6, Aug. 2008

¹⁹ Breast reconstruction with the TRAM flap: pedicled and free Serletti JM. *J Surg Oncol.* 1;94(6):532-7, Nov 2006

²⁰ One hundred free DIEP flap breast reconstructions: a personal experience. Blondeel PN. *Br J Plast Surg.*;52(2):104-11, 1999

²¹ Fat grafting to the breast revisited: safety and efficacy., Coleman SR, Saboeiro AP., *Plast Reconstr Surg.* 2007 Mar;119(3):775-85; discussion 786-7 *last Reconstr Surg.*;110(6):1593-5; author reply 1595-8, Nov 2002

²² Initial experience with the Brava nonsurgical system of breast enhancement. Smith CJ, Khouri RK, Baker TJ. *Plast Reconstr Surg.*;105(7):2500-12; discussion 2513-4., Jun 2000



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MEDICAL TECHNOLOGIES AND DEVICES IN PLASTIC SURGERY

-
- ²³ The Brava external tissue expander: is breast enlargement without surgery a reality? Schlenz I, Kaider A. *Plast Reconstr Surg*. 2007 Nov;120(6):1680-9; discussion 1690-1. Comment in: *Plast Reconstr Surg*. 2008 Sep;122(3):989-90.
- ²⁴ Bicompartamental breast lipostructuring Zocchi, M. L.; Zuliani, F.. *Aesthetic Plast Surg* 32:313-328; 2008.
- ²⁵ Body shaping and volume restoration: the role of hyaluronic acid. Hedén P, Sellman G, von Wachenfeldt M, Olenius M, Fagrell D. *Aesthetic Plast Surg*;33(3):274-82, 2009
- ²⁶ European Parliament resolution on the communication from the Commission on community and national measures in relation to breast implants (COM(2001) 666 - C5-0327/2002 - 2002/2171(COS))
- ²⁷ European Parliament Texts Adopted by Parliament Provisional Edition : 13/02/2003
Breast implantsP5_TA (2003)0063 A5-0008/2003
- ²⁸ Adipose-Derived Mesenchymal Stem Cells: Past, Present, and Future. Gino Rigotti Æ Alessandra Marchi Æ Andrea Sbarbati, *Aesth Plast Surg* ;33:271–273. DOI 10.1007/s00266-009-9339-7, 2009
- ²⁹ Adipose-derived stem cells for soft tissue reconstruction Cherubino, M.; Marra, K. G.. *Regen Med* 4:109-117; 2009
- ³⁰ Adult stem cell plasticity: fact or artifact? Raff, M. *Annu Rev Cell Dev Biol* 19:1-22; 2003
- ³¹ Origin and potential of embryo stem cells, *Stem cells today*: A. Edwards, R. G.. *Reprod Biomed Online* 8:275-306; 2004.
- ³² Historical review of the use of adipose tissue transfer in plastic and reconstructive surgery. Mojallal, A.; Foyatier, J. *L'Ann Chir Plast Esthet* 49:419-425, 2004.
- ³³ Collagen matrices from sponge to nano: new perspectives for tissue engineering of skeletal muscle. Beier JP, Klumpp D, Rudisile M, Dersch R, Wendorff JH, Bleiziffer O, Arkudas A, Polykandriotis E, Horch RE, Kneser U., *BMC Biotechnol*. 15;9:34, Apr. 2009
- ³⁴ Adult bone marrow stem/progenitor cells (MSCs) are preconditioned by microenvironmental "niches" in culture: a two-stage hypothesis for regulation of MSC fate. Gregory, C. A.; Ylostalo, J.; Prockop, D. J. *Sci STKE* 2005:pe37; 2005



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MEDICAL TECHNOLOGIES AND DEVICES IN PLASTIC SURGERY

-
- ³⁵ Human clinical experience with adipose precursor cells seeded on hyaluronic acid-based spongy scaffolds.. Stillaert FB, Di Bartolo C, Hunt, Rhodes NP, Tognana E, Monstrey S, Blondeel PN. *Biomaterials.*;29(29):3953-9, Oct. 2008
- ³⁶ Adipose tissue induction in vivo..Stillaert FB, Blondeel P, Hamdi M, Abberton K, Thompson E, Morrison WA. *Adv Exp Med Biol.*;585:403-12JA, 2006
- ³⁷ An arteriovenous loop in a protected space generates a permanent, highly vascular, tissue-engineered construct.. Lokmic Z, Stillaert F, Morrison WA, Thompson EW, Mitchell GM. *FASEB J.*; 21(2):511-22, Feb. 2007;
- ³⁸ New therapeutics for the prevention and reduction of scarring. Occleston NL, O'Kane S, Goldspink N, Ferguson MW. *Drug Discov Today.*;13(21-22):973-81, Nov. 2008
- ³⁹ Prevention and reduction of scarring in the skin by Transforming Growth Factor beta 3 (TGFbeta3): from laboratory discovery to clinical pharmaceutical. Occleston NL, Lavery HG, O'Kane S, Ferguson MW. *J Biomater Sci Polym Ed.*;19(8):1047-63, 2008
- ⁴⁰ Soft Tissue Treatment. Giménez Garcia MC, Lliorente de la Fuente A In Coombs R, Schaden W, Zhou S (edg), *Musculoskeletal Shockwave Therapy*, Greenwich Medical Media Ltd, London: 25-32, 2000
- ⁴¹ Clinical outcome of ESWT for selected chronic tendinopathies in physically active subjects. Goh P., 3rd Congress of the ISMT - Naples. Abstract: 82, 2000
- ⁴² Shock wave therapy for acute and chronic soft tissue wounds: a feasibility study. Schaden W, Thiele R, Köpl C, Pusch M, Nissan A, Attinger CE, Maniscalco-Theberge ME, Peoples GE, Elster EA, Stojadinovic A., *J Surg Res.*;143(1):1-12., 2007
- ⁴³ Treatment of lower eyelid fat pads using phosphatidylcholine: clinic trial and review. Ablon G, *Rotunda Am. Dermatol Surg.*;30:422-7., 2004
- ⁴⁴ 'Fat dissolving' substance injects CCs of controversy. Bates B. *Skin Allergy News* 34:1.,2003
- ⁴⁵ Lipostabil: the effect of phosphatidylcholine on subcutaneous fat. Young VL.. *Aesth Surg J.*; 23:413-7, 2003
- ⁴⁶ A new methode to quantify the effect after subcutaneous injection of lipolytic substances. Klein SM, Prantl, Berner A, et al., *Aesthetic Plastic Surgery*; 32 (4): 667-672, Jul 2008



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- ⁴⁷ Normal and pathologic tissue reactions to soft tissue gel fillers. Christensen, L., *Dermatol Surg*, 33 Suppl 2: p. S168-75, 2007
- ⁴⁸ Facial dermal fillers: selection of appropriate products and techniques. Dayan SH, Bassichis BA *Aesthet Surg J* ; 28(3):335-47, May-Jun.2008
- ⁴⁹ Reversible vs. nonreversible fillers in facial aesthetics: concerns and considerations. Smith KC., *Dermatol Online J*. 15;14(8):3, Aug. 2008
- ⁵⁰ Understanding, avoiding, and managing dermal filler complications., Cohen JL., *Dermatol Surg*.;34 Suppl 1:S92-9, Jun.2008
- ⁵¹ Porcine filler for facial lipoatrophy associated with human immunodeficiency virus treatment. Reytan N, Rzany B., *J Drugs Dermatol*.;7(9):884-6, Sep.2008
- ⁵² The use of injectable collagens for aesthetic rejuvenation., Matarasso SL., *Semin Cutan Med Surg*.;25(3):151-7, Sep. 2006
- ⁵³ The use of injectable collagens for aesthetic rejuvenation., Matarasso SL., *Semin Cutan Med Surg*.;25(3):151-7, Sep. 2006
- ⁵⁴ A two-stage phase I trial of Evolence30 collagen for soft-tissue contour correction. Monstrey SJ, Pitaru S, Hamdi M, Van Landuyt K, Blondeel P, Shiri J, Goldlust A, Shoshani D., *Plast Reconstr Surg*.; 120(1):303-11, Jul.2007
- ⁵⁵ Comparison of smooth-gel hyaluronic acid dermal fillers with cross-linked bovine collagen: a multicenter, double-masked, randomized, within-subject study., Baumann LS, Shamban AT, Lupo MP, Monheit GD, Thomas JA, Murphy DK, Walker PS; JUVEDERM vs. ZYPLAST Nasolabial Fold Study Group., *Dermatol Surg*.;33 Suppl 2:S128-35, Dec. 2007
- ⁵⁶ Facial dermal fillers: selection of appropriate products and techniques. Dayan SH, Bassichis BA *Aesthet Surg J*.;28(3):335-47, May-Jun. 2008
- ⁵⁷ Effectiveness of Juvéderm Ultra Plus dermal filler in the treatment of severe nasolabial folds. Lupo MP, Smith SR, Thomas JA, Murphy DK, Beddingfield FC 3rd., *Plast Reconstr Surg*. Jan;121(1):289-97, 2008
- ⁵⁸ The science of hyaluronic acid dermal fillers Tezel A, Fredrickson GH.: *J Cosmet Laser Ther*. (1):35-42, 2008



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MEDICAL TECHNOLOGIES AND DEVICES IN PLASTIC SURGERY

-
- ⁵⁹ Synthesis and Characterization of a Novel Double Crosslinked Hyaluronan Hydrogel, Zhao, XB, Fraser, JE, Alexander, C Lockett C, White BJ, J. of Materials Science: Materials in Medicine 13: (2002) 11-16.
- ⁶⁰ The Polysaccharide of the Vitreous Humor Meyer, K and Palmer, JW J. Biol. Chem. 107 (3): 629-634., 1934
- ⁶¹ Campoccia, AD, Doherty, P, Radice, M, Brun, P, Abatangelo, G, Williams, DF, Semisynthetic Resorbable Materials From Hyaluronan Esterification Biomaterials 19(23) : 2101-2127, 1998
- ⁶² DeBelder, AN , Malson, T US Patent 4,886, 787, 1989.
- ⁶³ Zhao, XB, Alexander, C Fraser, J, US Patent 7, 226, 972, 2007.
- ⁶² Kablik, J, Monheit, G, Liping, Y, Chang, G, Gershkovich, J. Comparative Physical Properties of Hyaluronic Acid Dermal Fillers, Dermatol. Surg. 35: Suppl 1: 302-12, 2009
- ⁶⁵ U.S. Food and Drug Administration, Restylane Injectable Gel – P020023, Labeling Information and Approval Letter December 12, 2003.
- ⁶⁶ U.S. Food and Drug Administration, Juvéderm 30, Juvéderm 24HV and Juvéderm 30HV Injectable Dermal Filler – P050047, Labeling Information and Approval Letter, June 2, 2006.
- ⁶⁷ Complications of breast augmentation with injected hydrophilic polyacrylamide gel Cheng, N.X., Y.L. Wang, J.H. Wang, X.M. Zhang, and H. Zhong,. Aesthetic Plast Surg, 26 (5): p. 375-82, 2002.
- ⁶⁸ Normal and pathologic tissue reactions to soft tissue gel fillers. Christensen, L., Dermatol Surg, 33 Suppl 2: p. S168-75, 2007.
- ⁶⁹ Biocompatibility and tissue interactions of a new filler material for medical use. Zarini, E., R. Supino, G. Pratesi, D. Laccabue, M. Tortoreto, E. Scanziani, G. Ghisleni, S. Paltrinieri, G. Tunesi, and M. Nava, Plast Reconstr Surg, 114 (4): p. 934-42, 2004.
- ⁷⁰ Biocompatibility of two novel dermal fillers: histological evaluation of implants of a hyaluronic acid filler and a polyacrylamide filler. Fernandez-Cossio, S. and M.T. Castano-Oreja, Plast Reconstr Surg, 117 (6): p. 1789-96, 2006.



THE INTERNATIONAL COMMITTEE FOR QUALITY ASSURANCE,
MEDICAL TECHNOLOGIES AND DEVICES IN PLASTIC SURGERY

- ⁷¹ Polyacrylamide hydrogel injection in the management of human immunodeficiency virus-related facial lipoatrophy: a 2-year clinical experience. De Santis, G., V. Jacob, A. Baccarani, A. Pedone, M. Pinelli, A. Spaggiari, and G. Guaraldi, *Plast Reconstr Surg*, 121 (2): p. 644-53. 2008.
- ⁷² Efficacy and safety of polyacrylamide hydrogel for facial soft-tissue augmentation in a 2-year follow-up: a prospective multicenter study for evaluation of safety and aesthetic results in 101 patients. von Buelow, S. and N. Pallua, *Plast Reconstr Surg*, 118 (3 Suppl): p. 85S-91S, 2006
- ⁷³ Unacceptable Results with an Accepted Soft Tissue Filler: Polyacrylamide Hydrogel Manafi, A., A.H. Emami, A.H. Pooli, M. Habibi, and L. Saidian, *Aesthetic Plast Surg*, May.2009
- ⁷⁴ Augmentation of the malar area with polyacrylamide hydrogel: experience with more than 1300 patients. Reda-Lari, A., *Aesthet Surg J*, 28 (2): p. 131-8, 2008
- ⁷⁵ Complications from repeated injection or puncture of old polyacrylamide gel implant sites: case reports. El-Shafey el, S.I., *Aesthetic Plast Surg*, 32(1): p.162-5, 2008.
- ⁷⁶ ArteFill: a long-lasting injectable wrinkle filler material--summary of the U.S. Food and Drug Administration trials and a progress report on 4- to 5-year outcomes. Cohen SR, Berner CF, Busso M, Gleason MC, Hamilton D, Holmes RE, Romano JJ, Rullan PP, Thaler MP, Ubogy Z, Vecchione TR. Division of Plastic Surgery, Department of Dermatology, University of California: *Plast Reconstr Surg*. 118(3 Suppl):64S-76S, 2006
- ⁷⁷ The "golden thread lift": radiologic findings. Stark GB, Bannasch H. *Aesthetic Plast Surg*. Mar-Apr;31(2):206-8., 2007