Standard guidelines for the use of dermal fillers

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ABSTRACT

Currently used fillers vary greatly in their sources, efficacy duration and site of deposition; detailed knowledge of these properties is essential for administering them. Indications for fillers include facial lines (wrinkles, folds), lip enhancement, facial deformities, depressed scars, periocular melanoses, sunken eyes, dermatological diseases-angular cheilitis, scleroderma, AIDS lipoatrophy, earlobe plumping, earring ptosis, hand, neck, décolleté rejuvenation. **Physicians' qualifications**: Any qualified dermatologist may use fillers after receiving adequate training in the field. This may be obtained either during postgraduation or at any workshop dedicated to the subject of fillers. The physicians should have a thorough knowledge of the anatomy of the area designated to receive an injection of fillers and the aesthetic principles involved. They should also have a thorough knowledge of the chemical nature of the material of the filler, its longevity, injection techniques, and any possible side effects. **Facility:** Fillers can be administered in the dermatologist's minor procedure room. **Preoperative counseling and informed consent:** Detailed counseling with respect to the treatment, desired effects, and longevity of the filler should be discussed with the patient. Patients should be given brochures to study and adequate opportunity to seek information. Detailed consent forms need to be completed by the patients. A consent form should include the type of filler, longevity expected and possible postoperative complications. Preoperative photography should be carried out. **Choice of the filler** depends on the site, type of defect, results needed, and the physician's experience. **Injection technique and volume** depend on the filler and the physician's preference, as outlined in these guidelines.

Key Words: Wrinkles, Static wrinkles, Aging, Scars, Fillers

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Evidence - Level A- Strong research-based evidence- Multiple relevant, high-quality scientific studies with homogeneous results, Level B- Moderate research-based evidence- At least one relevant, high-quality study or multiple adequate studies, Level C- Limited research-based evidence- At least one adequate scientific study, Level D- No research-based evidence- Based on expert panel evaluation of other information

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INTRODUCTION[1,2]

Dermal fillers are substances used in soft tissue augmentation to enhance or replace volume that is lost in any part of the skin or subcutaneous fat. Fillers form an effective tool in rejuvenation, either as a stand-alone treatment or in combination with other procedures such as Laser resurfacing or botulinum toxin.[1] The use of dermal fillers in soft tissue augmentation is undergoing a renaissance period with many new filler materials appearing in the market. The

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practice of soft tissue augmentation was started by Neuber in 1893, who took fat from the arms and transplanted it into facial defects. In 1899, paraffin was used and was later given up due to foreign body granulomasor paraffinomas. In the 1940s and 1950s, silicone was used extensively until the commissioner of the US-Food and Drug Administration (US-FDA) declared the use of injectable silicone to be illegal. The field of softtissue augmentation underwent a revolutionary change in the early 1970s when researchersat Stanford University worked on the use of animal and human collagen as implant materials. The search for an ideal, permanent dermal filler is still ongoing and no single,currently available filler meets all expectations of the physician.

RATIONALE AND SCOPE

With an increasing number of filler materials flooding the marketplace, any physician practicing soft tissue augmentation should possess a thorough knowledge of the filler material, including the mode of action of every material, its technique of injection, its limitations, advantages and disadvantages. These guidelines provide a minimal framework for reference to the practicing dermatologist. The field of fillers is a rapidly evolving one, with new fillers being introduced every year but no controlled, long-term data for long-term efficacy and longevity. These guidelines are therefore based on available data and experience of the task force members.

DERMAL FILLERS-MATERIALS, CHARACTERS, TYPES AND CLASSIFICATION

Dermal filler products possess a number of attributes: substances, substance source, compounds, performance, duration and mechanism of action, consistency, approved indication(s), and substantiation. Preferences of patients and providers may differ. With temporary fillers, per injection costs are less and complications are minor and rare. However, long-term maintenance costs are higher due to the necessity of repeated injections. With longer-duration fillers, the time-and-cost horizon is shortened but any complication can potentially be more significant. A balance is achieved when all factors are taken into consideration and tempered by the provider's expertise and the patient's expectations and acceptance of potential outcomes. While the perfect filler is yet to be available, characteristics of optimal filler are listed in Table 1.

Table 1: Optimal filler characteristics

Dermal filler characteristic checklist Optimal characteristics-Temporary fillers	
• Long duration / persistence	• No migration
• Performance promise	• Non-animal origin
• Painless	• Easy to inject
• Reasonable cost	• Easy to store
• Nontoxic	• Ease of learning how to inject
• Noninflammatory	• Minimal side effects
• Noncarcinogenic	• Biodegradable (in case of temporary and semipermanent fillers)

TYPES OF FILLERS[3-5]

Fillers can be classified based on different criteria:

1) **Based on longevity:** Fillers are classified as temporary, semipermanent, and permanent depending on the longevity of action, as shown in Table 2.

2) Based on site of placement
- Dermal
- Subdermal
- Supraperiosteal

3) Based on origin of filler material
- Heterograft
- Allograft
- Autograft
- Synthetic material

Table 3 summarizes different fillers, site of placement, injection technique and their approval status from FDA.

Various brands are available in different parts of the world and it is therefore not possible to list every brand of filler available in the market. Annexure 1 shows different brands that

Table 2: Dermal fillers-classification by longevity

Temporary (biodegradable) < 1 year	**Semipermanent (biodegradable) 1-2 years**	**Permanent (nonbiodegradable) > 2 years**
Collagen	CaHA, Calcium Hydroxylapatite	PMMA, Polymethylmethacrylate
Collagen-Human	DEAE-Sephadex (Dextran)	PAAG, Polyacrylamide Gel
Collagen-Porcine	PLLA, Poly-L-lactic Acid	Polyalkylimide
Hyaluronic acid-avian	PVA, Polyvinyl alcohol	LIS-Silicon (polydimethylsiloxane oil)
Hyaluronic acid-bacterial	Chitosan HEMA, hydroxyethyl-metacrylate Cultured human fibroblasts	

Table 3: Different fillers and their features

Material	Site of placement	Longevity	Injection technique	FDA approval
Collagen-based Fillers				
Artefill®	Reticular dermis	2 years	Layered, tunneling technique	Yes
Zyderm® I x II Zyplast®	Dermis	2-4 months	Serial puncture, threading	Yes
Cosmoderm®, Cosmoplast®	Dermis	2-4 months	Serial puncture, threading	Yes
Hyaluronic Acid				
Restylane®	Mid-dermis	6-8 months	Threading	Yes
Perlane®	Deep dermis	6-8 months	Threading and serial puncture	Yes
Hylaform® / Hylaform Plus®	Mid dermis	4 months	Serial puncture and threading	Yes
Captique®	Mid dermis	4 months	Serial puncture and threading	Yes
Juvederm®	Mid dermis	4-8 months	Threading, serial puncture	No
Dermalive®	Mid dermis	4-6 months	Threading, serial puncture	No
Autografts				
Autologous fat	Subcutis	> 1 year	Serial puncture Cross-hatching	Yes
Autologous collagen	Mid-dermis Upper dermis	> 18 months	Threading	Yes
Synthetic materials				
Polytetrafluoroethylene	Subcutis	Permanent	Threading	Yes
Silicone	Deep dermis and subcutis	Permanent	Threading	Yes
Bioalcamid®	Subcutis	Permanent	Threading	No
Radiesse®	Deep dermis	9-18 months	Threading	Noncosmetic
Sculptra®	Deep dermis	1-2 years	Threading	HIV lipoatrophy
Aquamid®	Subcutaneous	> 1 year	Threading	No

are available. New fillers are introduced every year and it is therefore recommended that the physician seek full information from the manufacturer /distributor before using a filler.

TASK FORCE RECOMMENDATIONS: LEVEL D

1. As mentioned above, it is generally recognized that permanent and semipermanent fillers have potentially more adverse effects than temporary fillers. It would therefore, be more prudent on the part of the treating physician to use a temporary filler, at least initially, as a first injection. However, if a patient chooses to opt for a semipermanent or permanent filler for cost considerations or for longevity of results, these may be administered after duly explaining all aspects about their potential adverse affects, and recording the facts in the informed consent form.
2. In general, it is not advisable to inject different fillers in the same site in the same individual.
3. Controlled data for the longevity of the filler materials published by the manufacturing company may not always be available. Both this and the fact that individual results may vary should be explained to the patient.
4. Fillers from different countries are available in India and many of these may not have received approval from the drug authorities. It is therefore, not always possible to use only FDA-approved fillers in our country. In view of these facts, full information about the filler and its approval status should be sought from the distributor to learn about the filler substance. Moreover, every country has its own approval system and this should be taken into consideration.

INDICATIONS[3]: LEVEL C

1. Facial lines (wrinkles, folds)
2. Lip enhancement
3. Facial deformities
4. Depressed scars
5. Breast, buttock augmentation
6. Periocular melanoses, sunken eyes
7. Dermatological diseases-angular cheilitis, scleroderma, AIDS lipoatrophy
8. Earlobe plumping, earring ptosis
9. Hand, neck, décolleté rejuvenation

Of these, the most common indications of fillers are wrinkles, scars, lips, and lipoatrophy.

Informed consent should be taken after proper counseling of the patient. The consent form should include full details about the filler (chemical nature and source) to be

administered, indication for which the filler is being used, expected longevity of results, its approval status, possible side effects and the cost.

PREOPERATIVE PREPARATION[6]: LEVEL C

1. History taking should include history of medications used, history of allergies, *e.g.*, the chances of bruising might increase in a patient on anticoagulant therapy.
2. Clinical examination, particularly of the area being injected.
3. Counseling as mentioned above.
4. Preoperative photograpy is preferable.
5. Informed consent should be taken as mentioned above.

INTRAOPERATIVE PROCEDURE[6]: LEVEL C

1. Clean the area to be injected and the surrounding skin with antiseptic.
2. Anesthesia (Patient comfort technique) may be needed in certain situations and in sensitive patients. Dental block (infraorbital) is preferred for lips and nasolabial folds.
3. Injection: Different techniques such as layering, tunneling, serial puncture and cross-hatching have been described. The choice of the technique depends on the physician. Volumes of injection at different sites are shown in Table 4; however, this would vary depending on the depth of the fold / line / defect.

POSTPROCEDURAL PRECAUTIONS AND ADVICE

- Avoid exposure to extreme cold or heat
- Avoid massaging treated areas for six hours
- Avoid strenuous physical activity for six hours
- Sleep with the head elevated for one night
- Pain medication can be taken if needed
- Resume skin care products such as retinoids, alphahydroxy acids the day after the procedure.

COMPLICATIONS[7-10]: LEVEL C

Complications are infrequentand usually minor; usually, permanent and long-term fillers have greater risk for complications. These include:

Table 4: Mean volume per patient as per indication

Facial Region	Volume
Glabellar wrinkles	0.5 mL
Nasolabial folds	0.5-1.0 mL (each side)
Lips	0.5-1.0 mL (each lip)
Nose	0.5-1.0 mL
Infraorbital area	1.0-2.0 mL (each side)

Immediate complications

1. Pain
2. Bruising
3. Erythema
4. Asymmetry, bumpiness, lumpiness
5. Anaphylaxis
6. Edema
7. Acneiform eruptions

Late complications

1. Inflammatory nodule
2. Tyndall effect
3. Allergic reactions
4. Vascular occlusion
5. Granulomas

CONCLUSION

In a short span of time, fillers have come to play an important role in the nonsurgical management of ageing skin. The technique is a safe, simple and effective modality, when used by a properly trained physician. Proper knowledge of the anatomy of the area of injection, aesthetic sense and proper patient selection are essential. Fillers can also be combined with other aesthetictreatments such as Botox, microdermabrasion, peels, thread-lifts, and Laser resurfacing. As in all aesthetic techniques, proper patient counseling with respect to achievable results is important.

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Annexure 1

Dermal fillers segmentation chart (by brand)

Temporary biodegradable < 1 year	Semipermanent biodegradable 1-2 years	Permanent nonbiodegradable > 2 years
Zyderm® 1 and 2 / Zyplast®	Radiesse®	Artefill®
EVOLENCE®*	Isolagen®	Silikon® 1000™
Restylane®/ Touch®/ Perlane®/ Sub-Q®/ Lipp®	Reviderm®	Aquamid® / Aquamid Reconstruction®
Hylaform® / Fine Lines® / Plus® Captique®	MacDermol R® MATRIDEX®	Amazingel®
Puragen® / Puragen®	Plus Bioniblue®-Lips / DeepBlue®	BIO-ALCAMID®- Face / Lips
Juvederm®-18 / 24 / 30 / 24hv / 30hv	Outline®-Original / Fine	Evolution®
Hydrafill®-1 / 2 / 3 / Softline®	Cymetra®	Outline®-Ultra
Surgiderm® 18 / 30 / 24xp / 30xp / Lips	Fascian®	Beautical® 2 / Beautical® 5
ESTHÉLIS® - Soft / Basic / Men / Duo	HylaDex®	
Teosyal®-27G / 30G		
Rofilan®		
Belotero®-Basic / Soft		
MacDermol S®		
MATRIGEL®		
HylaNew® / HylaNew Ultra®		

Annexure 2

Patient's consent for treatment with fillers

The products ……..... given are sterile gels consisting of ……..... for injection into the skin to correct facial lines, wrinkles and folds, for lip enhancement and for shaping the facial contours.

The use and indications of this product has been explained to me by my practitioner and I have had the opportunity to have all my questions answered to my satisfaction. I have been specifically informed of the following: after the injection, some common injection-related reactions might occur such as swelling, redness, pain, itching, discoloration and tenderness at the implant site. Rare reactions such as granulomas, vascular occlusion and hypersensitivity may occur, necessitating further management or removal.

My practitioner has also informed me that depending on the area treated, skin types and the injection technique, the effect of treatment with this product can last…….(months/years), but that in some cases, the duration of the effect can be shorter or even longer. Touch-up and follow-up treatment will be necessary to sustain the desired degree of correction.

I have answered the questions regarding my medical history to the best of my knowledge. I have been advised about posttreatment care and will follow the advice given.

I consent to being treated with ……..... product.

Name of Patient : **Signature of patient :**

Signature of witness : **Date :**