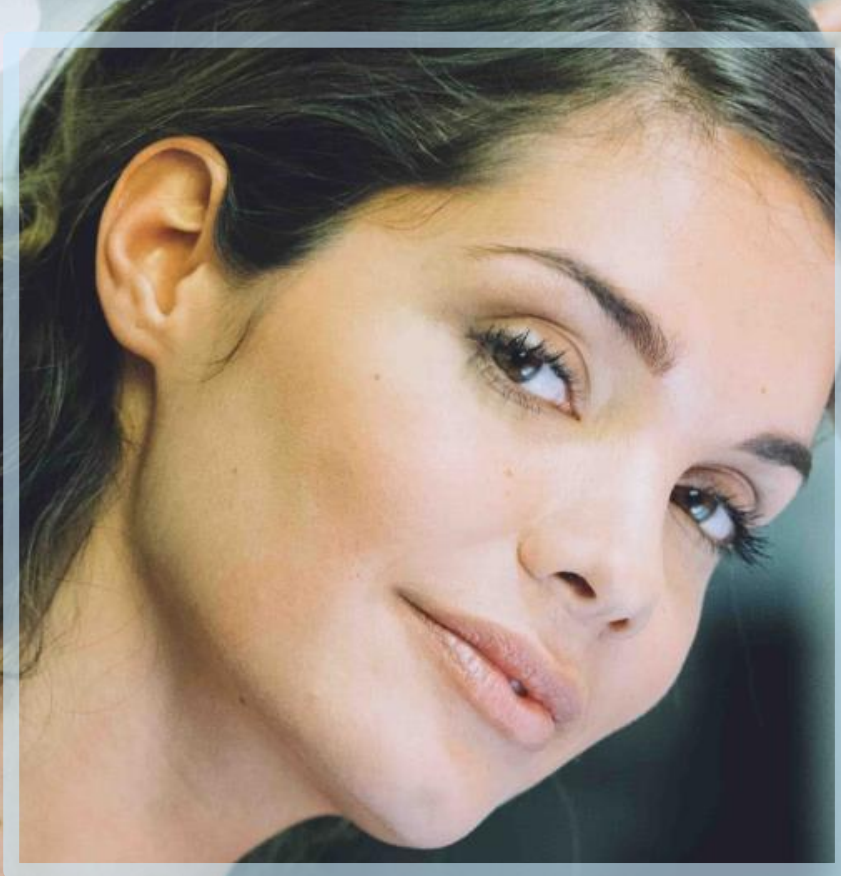


SINCLAIR



 A PERFECTHA[®]

When french touch meets beauty

PERFECTHA CLINICAL STUDIES

PERFECTHA PUBLICATIONS

Several clinical trials were performed:

- Mostly conducted locally in the countries : South America, Korea
- Often pilot studies, open-label, non-randomized.
- Some publications but several abstracts presented at symposia
- Efficacy appears similar to other HAs and no major safety issue.
- Duration of action 6-18 months
- Product use mainly based on clinical experience, case reports
- Perfectha registered and launched in many countries

PERFECTHA PUBLICATIONS

- Studies mainly performed on Perfectha Derm and Perfectha Deep the first products developed and introduced.
- CE mark 2007 (Perfectha Derm 2005 Brazil)
- Studies published mainly targeted to the treatment effect on Nasolabial fold (Perfectha Deep and Perfectha Derm) and lip contour (Perfectha Derm)
- One study in Rhinoplasty with Perfectha Deep ;not published
- One study on Perfectha SubSkin for malar and mental enhancement; not published

PERFECTHA PUBLICATIONS

Talarico S, Marques Hassun K, de Oliveira Monteiro E, Brasil Parada MO, Buratini LB, Arruda L, Bagatin E.,

Avaliação da segurança e eficácia de novo preenchedor à base de ácido hialurônico no tratamento dos sulcos nasolabiais e contorno dos lábios. Safety and efficacy evaluation of a new hyaluronic acid based filler in the treatment of nasolabial folds and lips outline. Surg Cosmet Dermatol 2010; 2:83-6.

De Arruda LH, Rocha FT, Rocha A.,

Studying the satisfaction of patients on the outcome of an aesthetic dermatological filler treatment. J Cosmet Dermatol 2008; 7:246-250

Kalil CL, Caramori AP, Mercedes Dalpiaz Balkey.,

Avaliação da permanência do ácido hialurônico injetável no sulco nasogeniano e rítes labiais.

Evaluation of the duration of injectable hyaluronic acid in nasolabial folds and perioral rhytids. Surg Cosmet Dermatol 2011; 3:112-5.

PERFECTHA PUBLICATIONS

Costa A, Della Coletta LC, Talarico AS, Fidelis MC, de Souza Weimann ET.,

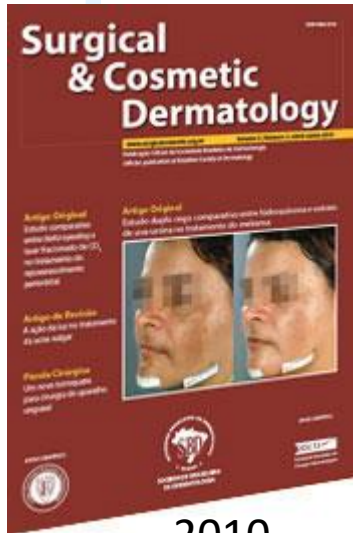
Características reológicas de preenchedores dérmicos à base de ácido hialurônico antes e após passagem através de agulhas.

Rheological characteristics of hyaluronic acid based dermal fillers before and after flowing through needles. Surg Cosmet Dermatol 2013; 5:8891.

Park KY, Kim HK, Kim BJ.,

Comparative study of hyaluronic acid fillers by in vitro and in vivo testing. J Eur Acad Dermatol Venereol 2014; 28:565-8

PERFECTHA DERM IN NLFs & LIPS



2010

Safety and efficacy evaluation of a new hyaluronic acid based filler in the treatment of nasolabial folds and lips outline

Avaliação da segurança e eficácia de novo preenchedor à base de ácido hialurônico no tratamento dos sulcos nasolabiais e contorno dos lábios

ABSTRACT

Introduction: The use of dermal filling techniques for soft tissue augmentation has greatly increased in recent years. Hyaluronic acid is one of the most used temporary dermal fillers in the treatment of facial wrinkles, furrows, and folds due to its effectiveness and safety.

Objective: To evaluate the efficacy and safety of Perfectha®, a new hyaluronic acid filler, for nasolabial folds and lip correction.

Methods: Open, multicenter study comprising 87 women. Efficacy was evaluated by the Global Aesthetic Improvement Scale and the Wrinkle Severity Rating Scale. Safety was evaluated through observation and the reporting of side effects.

Results: One week after the injection of the filler, improvement in nasolabial folds and lips was observed in 86% and 89% of the women, respectively. Mild or moderate transient inflammatory reaction and ecchymoses occurred in 15% and 9% of patients, respectively, mainly in nasolabial folds. Two patients presented labial herpes simplex after treatment of the lips. The good results were maintained in 76% and 57% of women for nasolabial folds and in 72% and 45% of women for lips after 3 and 6 months, respectively.

Conclusion: Perfectha® was effective and safe for these indications.

Keywords: hyaluronic acid; skin; inflammation.

Original article

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PERFECTHA DERM IN NLFs

Talarico S et al Brazil UNIFESP Federal University of Sao Paulo & PUCCAMP
Catholic University of Campinas Beltran R S Columbia

Design:

Multicentric, open-label, non-randomized, non controlled, therapeutic interventional study

Objective:

Evaluation of the efficacy and safety of Perfectha Derm for nasolabial folds and lip contour treatment

Patients:

N=87 females in good health, aged 39-49 years

- N=58 treated with Perfectha Derm at the Nasolabial Folds
- N= 29 treated at the level of the lip contour

PERFECTHA DERM IN NLFs

Treatment:

- Perfectha Derm
 - 1ml injected in the NLF in each side (N=58)
 - 1ml injected at the upper & lower lip contour (N=29)

Injection technique:

Linear retrograde technique

Implant deposited in the medial dermis

after anaesthesia with lidocaine and prilocaine in equal volume

PERFECTHA DERM IN NLFs

Assessment:

- Efficacy clinically evaluated on nasolabial and lip contour correction based on patient opinion, investigators and photos taken the day of the injection and one hour after and then at 7, 30, 60 , 90 and 180 days.
- Photos were examined by two independent dermatologists:
 - Evaluation made using :
 - the Global Aesthetic Improvement Scale GAIS and
 - the Wrinkle Severity Rate Scale

GAIS

Assessment:

Global Aesthetic Improvement Scale

Rating	Description
Very much improved	Optimal cosmetic result for the implant
Much improved	Marked improvement in appearance from initial condition but not completely optima. A touch up will slightly improve the result
Improved	Obvious improvement in appearance from initial condition but a touch-up or a re-treatment is indicated
No Change	Appearance essentially the same as the original condition
Worse	Appearance worst than original condition

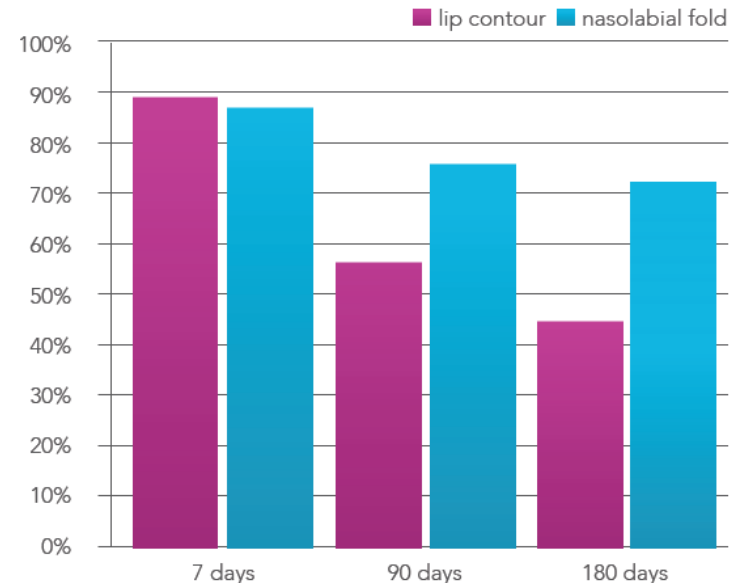
WSRS

Wrinkle Severity Rate Scale

Score	Description
5 extreme	extremely deep and long folds, detrimental to the facial appearance; 2–4 mm visible V-shaped folds when stretched.
4 severe	very long and deep folds; prominent facial features; less than 2 mm visible folds when stretched
3 moderate	moderately deep folds; clear facial features visible at normal appearance but not when stretched
2 mild	shallow but visible folds with a slight indentation; minor facial features.
1 absence	no visible folds; continuous skin line

PERFECTHA DERM IN NLFs

- One week after the injection of the filler, improvement in nasolabial folds and lips was observed in 86% and 89% of the women respectively.
- The good results were maintained in 76% and 57% of women for nasolabial folds and in 72% and 45% of women for lips after 3 and 6 months, respectively.



Results: One week after the injection of the filler, improvement in nasolabial folds and lips was observed in 86% and 89% of the women, respectively. Mild or moderate transient inflammatory reaction and ecchymoses occurred in 15% and 9% of patients, respectively, mainly in nasolabial folds. Two patients presented labial herpes simplex after treatment of the lips. The good results were maintained in 76% and 57% of women for nasolabial folds and in 72% and 45% of women for lips after 3 and 6 months, respectively.

PERFECTHA DERM IN NLFs

“ Perfectha Derm® was shown to be effective and safe for the correction of nasolabial folds and the improvement of lips outline and volume in adult women.

Immediate reactions were foreseeable and mild, and results lasted up to 180 days after application.”

Talarico S 2010

PERFECTHA IN NLFs & LIPS



2008

Studying the satisfaction of patients on the outcome of an aesthetic dermatological filler treatment

Lúcia Helena Fávaro de Arruda, MD, ¹ Fábio Theoto Rocha, BSc, ² & Armando Rocha, MD, PhD²

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1 SUMMARY

Background

Many factors contribute to extend productive life in the modern world. Competition makes people worry about physical appearance, mostly in respect to facial and skin aging. This has motivated new developments in cosmetic dermatology and the need of evaluating patient satisfaction with the new proposed treatments. Poll questionnaire has been used for such evaluation, and the analysis of the electroencephalogram (EEG) mapping obtained while the patient answers the satisfaction questionnaire may render the results less subjective.

Objectives

The purpose of this paper is to study the satisfaction of a group of 33 women (mean age, 44 years) treated with hyaluronic acid filling of nasolabial folding or lips, combining the EEG brain and questionnaire techniques.

Methods

At the third month of evaluation, two networked personal computers were used for the EEG recording and for presenting the patient with a questionnaire about her well-being feeling; self-evaluation of her face; her satisfaction with the results of the aesthetic treatment; how the family, friends, and people at work evaluated the result of the treatment; and her decision to repeat the treatment and to recommend it to friend and family.

Results

Poll results showed that patients were feeling well and were satisfied with the results of the aesthetic treatment. Furthermore, the regression EEG mappings showed patients to be satisfied with their appearance and with the treatment involving similar brain areas.

Conclusion

Patients decided to undergo the treatment because they were already considering it (54%) or because they were dissatisfied with their lips or nasolabial folding (52%). The fact that the treatment was free of charge solidified the decision. Patients consider themselves as good-looking and they wanted to preserve such a condition.

Keywords

Brain mapping, cosmetic techniques, hyaluronic acid, patient satisfaction, public opinion poll.

EFFICACY STUDY – EEG & QUESTIONNAIRE

Vanessa Contato Lopes Resende, Alessandra Haddad, Daniel Vasconcellos
Regazzini, Lydia masako Ferreira

UNFESP EPM Federal University Sao Paulo Cosmetic and laser Unit Sao Paulo

Design:

Investigational study

Objectives:

to study the satisfaction of a group of patients treated with Hyaluronic acid filling of nasolabial folding or lips combining EEG and questionnaire technique .

Subjective results evaluation of the cosmetic treatment made by using a questionnaire is evaluated by EEG as a more objective way to measure satisfaction

EFFICACY STUDY – EEG & QUESTIONNAIRE

Methods:

- Patients N= 33 women aged 30-55 years old
- HA treatment of nasolabial folds and lips

Treatment:

- Injection of 1.0 ml of HA Perfectha Deep in each nasolabial fold (2.0ml)
- Perfectha Derm 1.0ml for the upper and lower lip (2.0ml in total) under anaesthesia
- Re-evaluation 48h, 1, 2 and 3 months after initial procedure to assess treatment durability and to detect side effects.

EFFICACY STUDY – EEG & QUESTIONNAIRE

Evaluation:

- At 3 months Questionnaire and EEG recording.
- Calculation of an appearance index

Results:

- Majority of patients have a high state of well-being
- Patients were very satisfied or satisfied with the immediate results of the treatment as well at the results at 3 months Family and friends made great comments about their new appearance
- Patients firmly determined (60%) or determined (32%) to repeat the treatment
- To recommend it to family (70%), friends (60%) and others (30%)
- Factor analysis shows that well-being, treatment evaluation & recommendation were correlated

EFFICACY STUDY – EEG & QUESTIONNAIRE

- Face Component Evaluation statistically correlated with the factor of entropy calculated for the EEG activity recorded while the patients were evaluating their face components
- Results showed that patients were feeling well and were satisfied with their appearance and the results of aesthetic treatment.
- The regression EEG mapping showed them to be satisfied with their appearance and with the treatment involving similar brain areas
- The positive view of the treatment and the feelings of well-being are statistically correlated.

PERFECTHA DERM in NLF & LIPS



2011

112

Original Article

Evaluation of the duration of injectable hyaluronic acid in nasolabial folds and perioral rhytids

Avaliação da permanência do ácido hialurônico injetável no sulco nasogeniano e ríntides labiais

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ABSTRACT

Introdução: Hyaluronic acid has been increasingly used in aesthetic procedures.

Objective: To evaluate the degree of improvement and duration of results in patients who received treatment for wrinkles with hyaluronic acid.

Methods: Prospective, open, non-randomized, non-controlled study of 20 female patients who presented superficial wrinkles in the superior lips contour and a prominent nasolabial fold. The efficacy of hyaluronic acid was assessed using the Wrinkle Severity Rating Scale. The duration of results was assessed through biopsies. Safety was evaluated through clinical observation and reports of adverse events.

Results: A significant clinical improvement was observed after 15 days, which was sustained for 4 months. A minor worsening was observed after that period, although patients still presented favorable aesthetic results up to 12 months after the procedure. A majority of patients (n = 17) had a biopsy in the left retro-auricular region 180 days after the procedure. From this group, the substance was observed in 13 slides (76.4%).

Conclusion: Hyaluronic acid is an effective and safe product. This study has proven that the product remains in the dermis for up to 6 months.

Keywords: hyaluronic acid; residence time; skin.

PERFECTHA DERM in NLF & LIPS

Design:

- Prospective open non controlled study
- Patients N=20 with superficial wrinkles in the superior lips contour and a prominent nasolabial fold.
- Treated by Perfectha Derm
- Assessment by WSRS

Results:

- Significant clinical improvement was observed after 15 days, which was sustained for 4 months.
- A minor worsening was observed after that period, although patients still presented favorable aesthetic results up to 12 months after the procedure

Conclusion:

As demonstrated in other studies, HA is a safe and effective product to be used in the treatment of NLF and ULM

PERFECTHA PRODUCT CHARACTERISTICS

PERFECTHA®
When french touch meets beauty



2014

DOI: 10.1111/jdv.12135

ORIGINAL ARTICLE

Comparative study of hyaluronic acid fillers by *in vitro* and *in vivo* testing

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*Correspondence: B.J. Kim. E-mail: beomjoon@unitel.co.kr

Abstract

Background Numerous hyaluronic acid (HA) fillers seem to have similar characteristics, although manufacturers insist that monophasic and biphasic HA fillers are different in many ways. Little information regarding this is available in the literature.

Objectives To determine characteristics of monophasic fillers vs. biphasic fillers.

Material and methods We tested three different (two biphasic and one monophasic) HA fillers both *in vitro* and *in vivo*. In the *in vitro* assay, cell toxicity, resistance to enzyme degradation, syringeability and morphology of particles were tested. *In vivo*, the efficacy and safety were investigated in the dorsal skin of hairless mice.

Results There was no cell toxicity in any of the three HA fillers. Resistance to enzymatic degradation and syringeability were better in the two biphasic HA fillers than in the monophasic filler. In particle morphology test, gel type monophasic HA filler was also found as a particle type, although there was a slight difference. Volume assessment in animal skin was superior with the monophasic than with the two biphasic HA fillers.

Conclusion Biphasic HA fillers have some advantages in hyaluronidase resistance, syringeability and lower risk for overcorrection, while monophasic HA fillers may be more suitable for volume augmentation due to swelling capacity.

Received: 23 November 2012; Accepted: 14 February 2013

PERFECTHA PRODUCT CHARACTERISTICS

Park KY et al comparative study of hyaluronic acid fillers
by in vitro and in vivo testing JEADV 2013

- Effect on Cell toxicity assay
- Resistance to enzymatic degradation
- Syringeability
- Particle size morphology analysis
- Biphasic versus monophasic
Perfectha Deep versus Perlane and Juvederm Ultra-XC

PERFECTHA PRODUCT CHARACTERISTICS

Methods:

In vitro cell toxicity:

- L929 immortalized mouse fibroblast cell line with no dilution, 1/2, 1/4 dilution using 0.2 g/ml HA 37°C for 72h. Seeding of cells on 96-well plate 1x10⁴ Cells/ml at 37° overnight. WST -1 applied 30mn and measured at 450nm.

Syringeability:

- Perfectha Deep filler syringe inserted in texture analyser 27 1/2G needle at 25° and a moving speed fixed at 1mm/s.

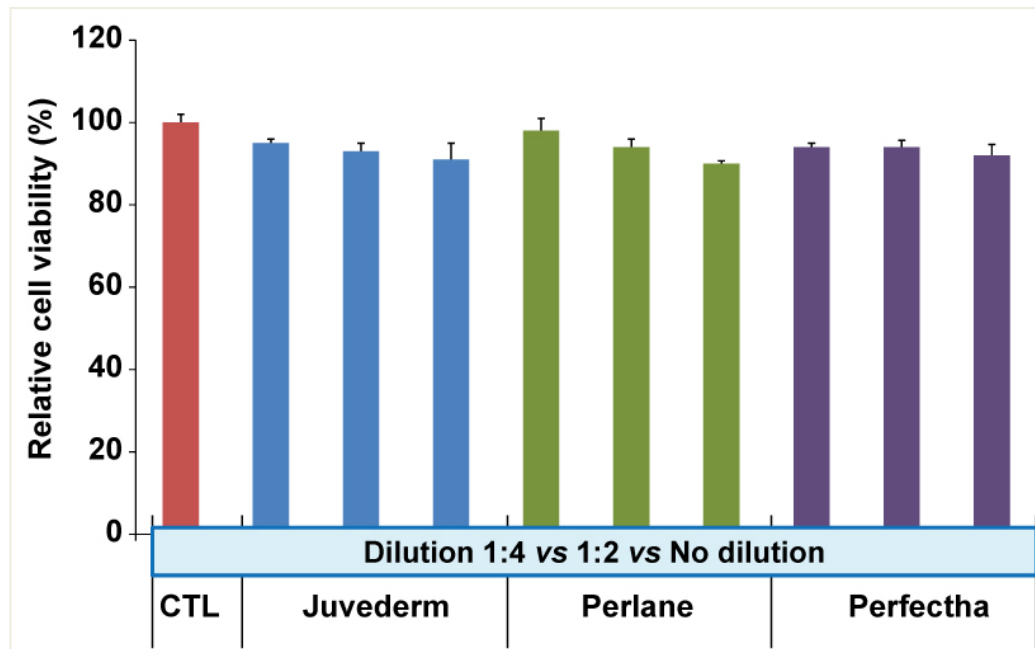
Particle morphology analysis:

- particle sizes evaluated by scanning electron microscopy (SEM) . HA gels immersed in corn oil and particle morphology investigated by optimal imaging with a folliscope.

PERFECTHA PRODUCT CHARACTERISTICS

In vitro cytotoxicity assay.

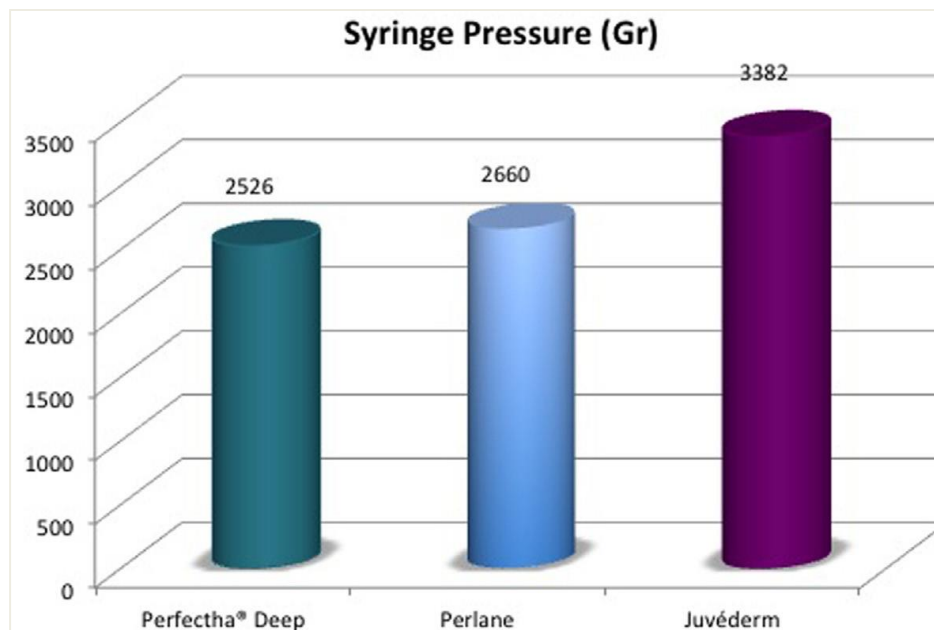
No significant cytotoxicity in any of the tested fillers. All tested fillers showed greater than 90% cell viability.



PERFECTHA PRODUCT CHARACTERISTICS

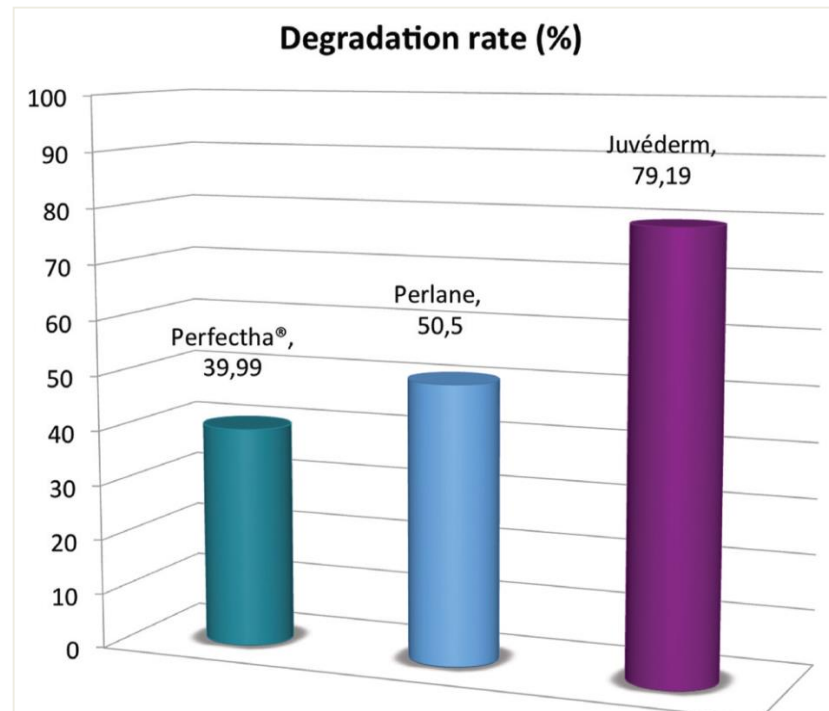


Measurement of syringeability. Greater injection power needed for the monophasic filler than the biphasic fillers.



PERFECTHA PRODUCT CHARACTERISTICS

Resistance to enzymatic degradation. The two biphasic fillers PERFECTHA and Perlane were more resistant to degradation by hyaluronidase than the monophasic filler.

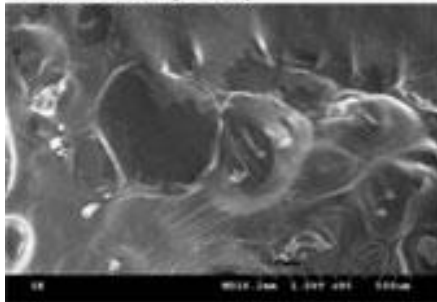


PERFECTHA PRODUCT CHARACTERISTICS

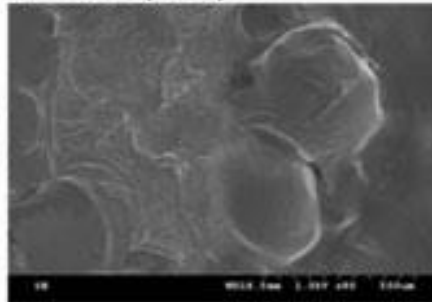
Morphological assessment with SEM.

Two biphasic fillers showed uniformly sized particles, while the monophasic filler showed unevenly sized and agglomerated particles

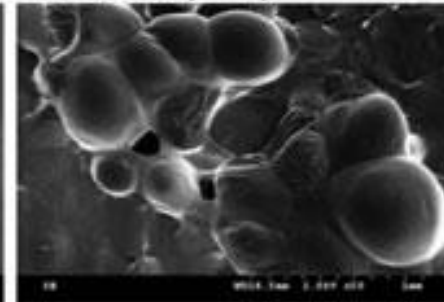
Perfectha (90 X)



Perlane (90 X)



Juvederm (50 X)



PERFECTHA PRODUCT CHARACTERISTICS

Biphasic HA fillers have some advantages in :

- Hyaluronidase resistance,
 - Better application for syringe injection (syringeability)
 - Lower risk for overcorrection, through localizing ability
 - So should be better for wrinkle restoration
-
- Monophasic HA fillers may be more suitable for volume augmentation possibly due to spreading capacity.

PERFECTHA PRODUCT CHARACTERISTICS

Perfectha Deep characteristics:

- Perfectha is non cytotoxic
- Perfectha is more resistant to enzymatic degradation than a monophasic
- Perfectha lower injection force needed than for a monophasic

COHESIVITY OF DIFFERENT TYPES OF HAS



2013

Communication

Rheological characteristics of hyaluronic acid-based dermal fillers before and after flowing through needles

Características reológicas de preenchedores dérmicos à base de ácido hialurônico antes e após passagem através de agulhas

ABSTRACT

Hyaluronic acid-based dermal fillers are currently among the most commonly used substances in cosmetic procedures. The present study aims at identifying alterations in the rheological properties of different types of fillers containing hyaluronic acid, before and after flowing through needles. The same analysis is carried out with fillers with and without hyaluronidase.

Keywords: *hyaluronic acid; dermis; esthetics.*

RESUMO

Os preenchimentos dérmicos à base de ácido hialurônico constituem procedimentos estéticos dos mais utilizados atualmente. Este trabalho teve como objetivo identificar alterações nas propriedades reológicas dos diferentes tipos de preenchedores com ácido hialurônico antes e após sua passagem pelas respectivas agulhas e, nesta última situação, adicionados ou não de hialuronidase.

Palavras-chave: *ácido hialurônico; derme; estética.*

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² Dermatology Specialist Candidate at the Dermatology Service of the Pontifícia Universidade Católica de Campinas (PUC-Campinas), Campinas

COHESIVITY OF DIFFERENT TYPES OF HAS

Objective:

- Rheological differences between biphasic and monophasic Has before and after injection

Products :

- Non cross linked : Teosyal Meso
- Cross-linked biphasic : Restylane /Perfectha Derm
- Mono/mono : Stelis® Basic
- Mono/poly : Teosyal® Ultra deep

Study : 3 drops of toluidine + 0,5mL syringe

- 0,5mL syringe plus needle
- 0,5mL syringe + needle + 40UI hyaluronidase



Photos

30'
2hs30'
24hs
48hs
72hs
96hs
168hs

COHESIVITY OF DIFFERENT TYPES OF HAS

Tempo	TEOSYAL® MESO			PERFECTHA DERM®			RESTYLANE®			ESTELIS® BASIC			TEOSYAL® UTRADEEP LIN		
D0 (30 minutes)															
D0 (2 horas e 30 minutos)															
D1															

COHESIVITY OF DIFFERENT TYPES OF HAS

Tempo	TEOSYAL® MESO			PERFECTHA DERM®			RESTITANE®			ESTELIS® BASIC			TEOSYAL® UTRADEEP LINE		
D0 (30 minutos)															
D0 (2 horas a 30 minutos)															
D1															
D2															
D3															
D4															
D7															
Seringas	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C

COHESIVITY OF DIFFERENT TYPES OF HAS

Conclusion:

Cross-linked biphasic Has have a better final cohesivity

Cross-linked Monophasic HAs have an accentuated gravimetry in contact with hyaluronidase (DO- 30 mn)