HyaFilia

Dermal Filler

A Natural, Safe and Long-lasting Beauty Filler

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What is HyaFilia?

- ***Description***
  - **HyaFilia** is used for **temporary improvement of wrinkles** by injecting it into the skin layer around the facial wrinkles.
  - It is a **colorless** and **transparent gel-type product** with **viscoelasticity** composed of a **stabilized non-animal hyaluronic acid**.

- ***Indications***
  - **HyaFilia** is tissue reconstructive material that intended to be used for **facial tissue augmentation**.
  - It is recommended that the product be used for the correction of moderate to severe facial wrinkles, folds, and acne scars.

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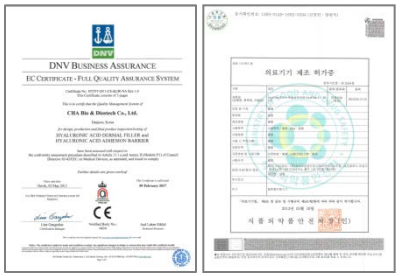
Characteristics of HyaFilia

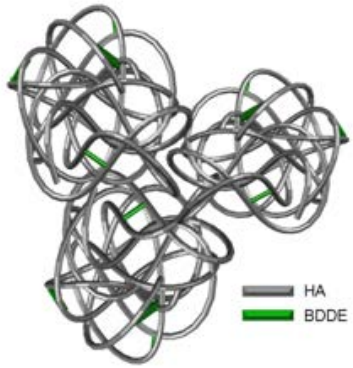
- **CE Mark approval (Feb 9, 2012)**
  - Class Ⅲ
- **KFDA approval (May 16, 2012)**
  - Graft/prosthesis, biomaterial
  - B04230.01(4)



- **Through multicenter clinical trial, safety and efficacy of HyaFilia have been proven.**

- **Non-animal hyaluronic acid**
  - **Usage of HA produced by bacterial fermentation (*Streptococcus equi*)**
  - **Biocompatibility**
    - Non-toxic
    - Non-immunogenic
  - **Biodegradability**
- **BDDE Crosslinked HA**
- **Gel type**
- **Proven safety and efficacy**
- **Medical device**

HyaFilia



- **BDDE cross-linked HA**
  - To overcome the short biodegradability of natural HA
  - Improvement of the sustainability
  - **Biphasic gel**.
  (**Duration : 6-12 Month**)

- **HA Conc.: 20 mg/ml (2%)**
- **High viscosity gel : 2,700,000 cP**
- **Injection Force: 10 N**

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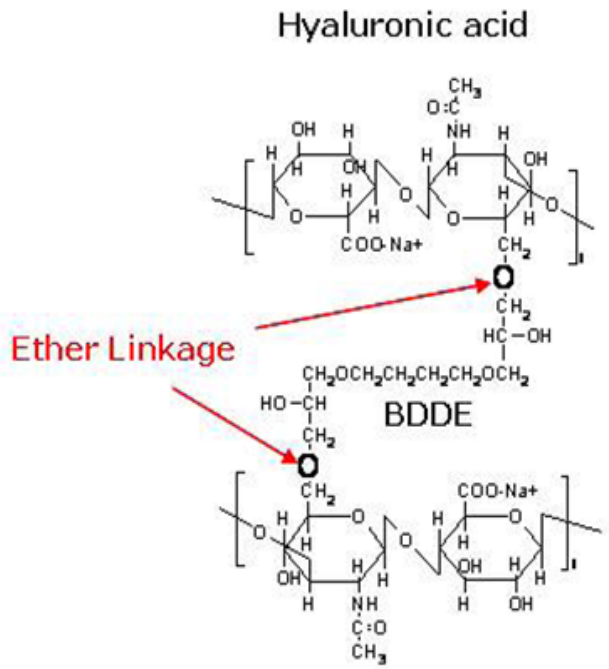
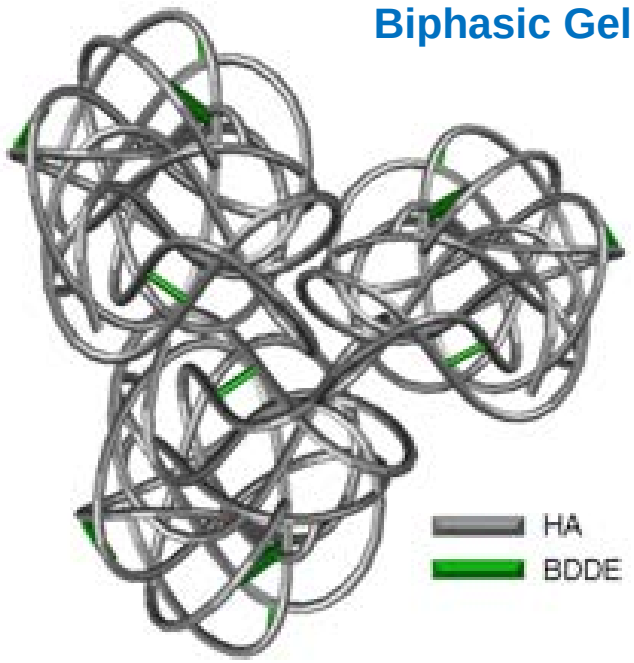
Technology Used for HyaFilia





- ***BDDE cross-linked hyaluronic acid biphasic gel***
  - The half-life of natural HA administered in the body is very short, so **it has to be modified in order to increase the stability *in vivo***.

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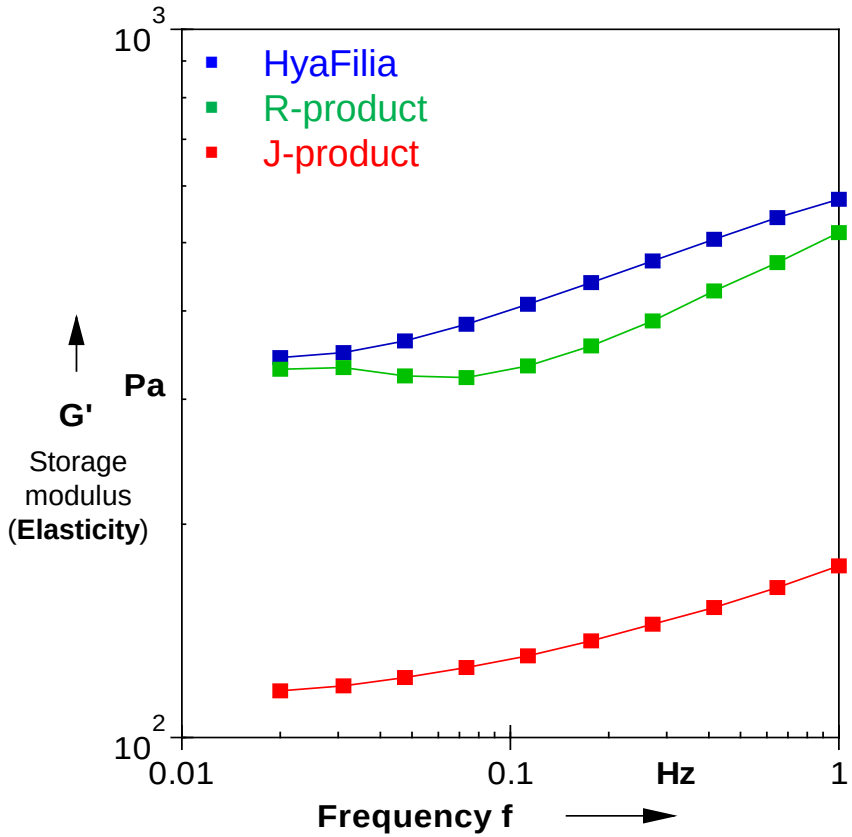
Comparison between HA fillers

classification	HyaFilia	R-product	J-product
Composition	hyaluronic acid	hyaluronic acid	hyaluronic acid
Crosslinking agent	BDDE	BDDE	BDDE
Total HA concentration (mg/ml)	20	20	22~26
Complex viscosity(CP)	2.7 x 10^6	2.8 x 10^6	0.9 x 10^6
Swelling ratio(ml/g)	4	2.8	3.8
Injection force(N)	10	9	13
Endotoxin(EU/ml)	Less than 0.25	Less than 0.5	-

- **HyaFilia has similar chemical and physical features with R-product and J-product which are currently dominating the filler market. However, in the aspect of its swelling degree and enzyme stability, Hyafilia outweighs other products.**

Comparison between HA fillers

- **Result of storage modulus(G') measurement**
  - **HyaFilia had superior elasticity than R-product and J-product. Also, its cross-linking was proved to be stable as it showed steady G' value during the frequency variation.**



➢ **When filler's storage modulus (G') is high…**

- ✓ **Elasticity is excellent**
- ✓ **Supporting power and duration is outstanding** as stability of facial muscle movement is high

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Animal Studies: Safety

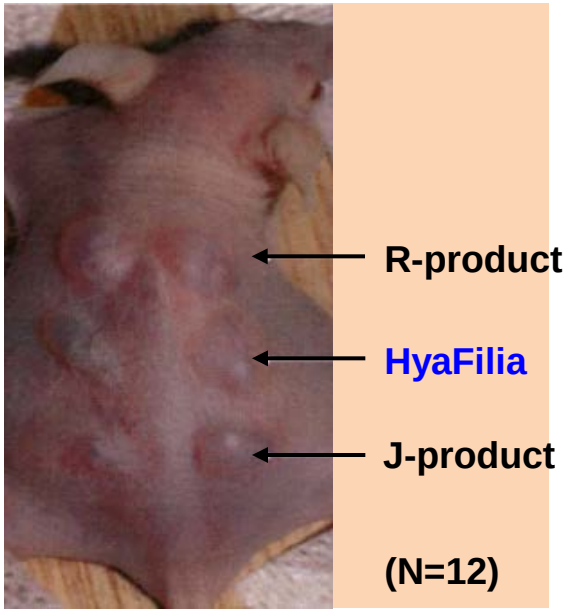
▪ *Safety*

- The following **biocompatibility and toxicology tests** were conducted on HyaFilia.

No	Test Title	Test Number	Test Standards	Test Results
1	**Acute Systemic Toxicity Test**	SNUH 0800401	ISO 10993-11	**Pass**
2	**Subchronic Subcutaneous Toxicity and Implantation Test in Rat - 13 Weeks**	SNUH 0800402	ISO 10993-11, ISO 10993-6	**Pass**
3	**Cytotoxicity Test**	SNUH 0800403	ISO 10993-5	**Pass**
4	**The Guinea Pig Maximization Test**	SNUH 0800404	ISO 10993-10	**Pass**
5	**Hemolysis Test**	SNUH 0800405	ISO 10993-4	**Pass**
6	**Intracutaneous Reactivity Test**	SNUH 0800406	ISO 10993-10	**Pass**
7	**Pyrogen Test**	SNUH 0800407	USP29	**Pass**
8	**Bacterial Reverse Mutation Assay**	SNUH 0800408	ISO 10993-3	**Pass**
9	**In vitro Chromosome Aberration Test**	SNUH 0800409	ISO 10993-3	**Pass**
10	**In vivo Micronucleus Test**	SNUH 0800410	ISO 10993-3	**Pass**
Testing Period	~ November 26th 2009			
Testing Institution	Medical Device Evaluation Center, Clinical Research Institute, Seoul National University Hospital, Korea			

Efficacy Test

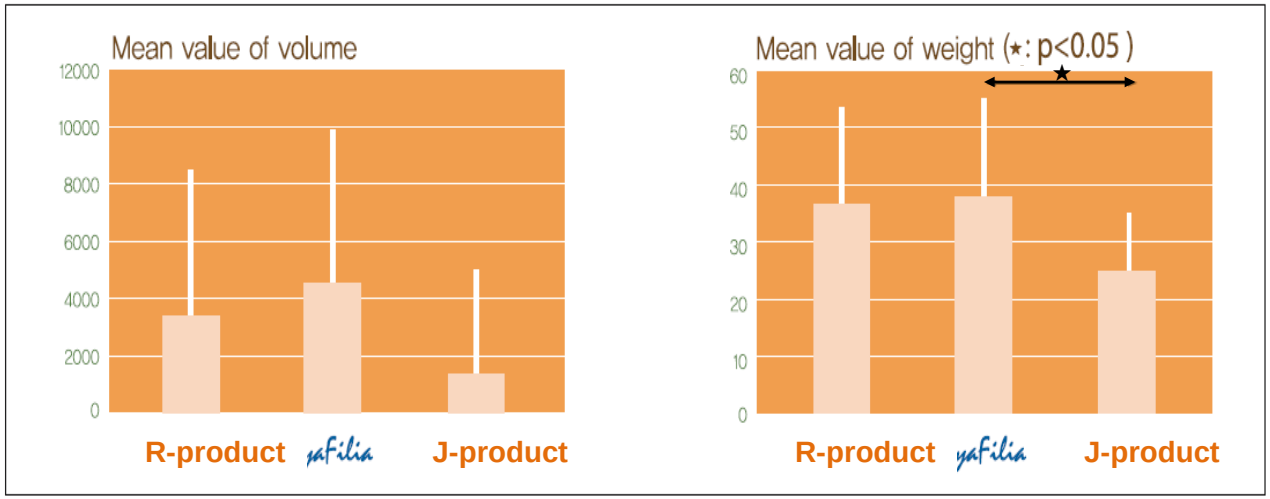
- From the internal duration test using mouse, Hyafilia had longer durability than J-product and similar durability with R-product.
- From the histological test, Hyafilia showed superior result within the material remaining for 4months and connective tissues.

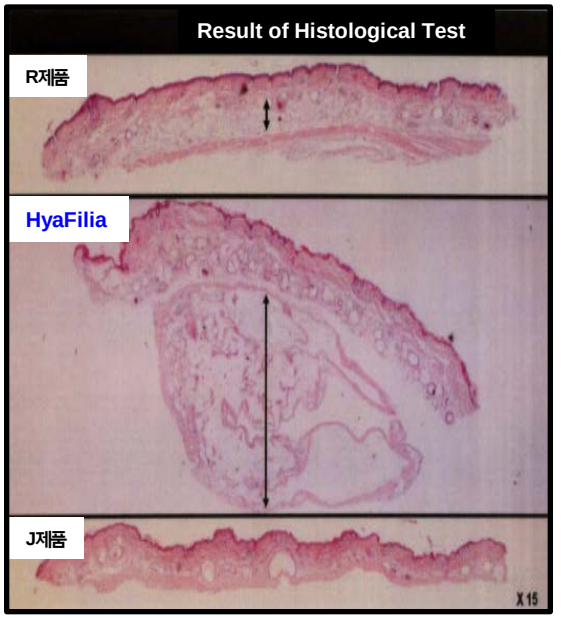


Plastic surgery division of Korea University Medical college (April, 2010)

Internal Duration Test Result

16 weeks after injection





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Clinical Data

▪ Purpose of Clinical Trial

- In order to prove **non-inferiority** of **HyaFilia** compared to **R-product** in the aspect of **Nasolabial fold correction efficacy and safety**.

▪ Clinical Trial Institution

Subject Number	CHA University Bundang CHA Hospital	Korea University Guro Hospital	Catholic University Seoul St. Mary's Hospital
68	20	30	18

Clinical Data

▪ Efficacy Evaluation

- **Primary Efficacy Evaluation : Prove Hyafilia is non-inferior** compared to **R-product**

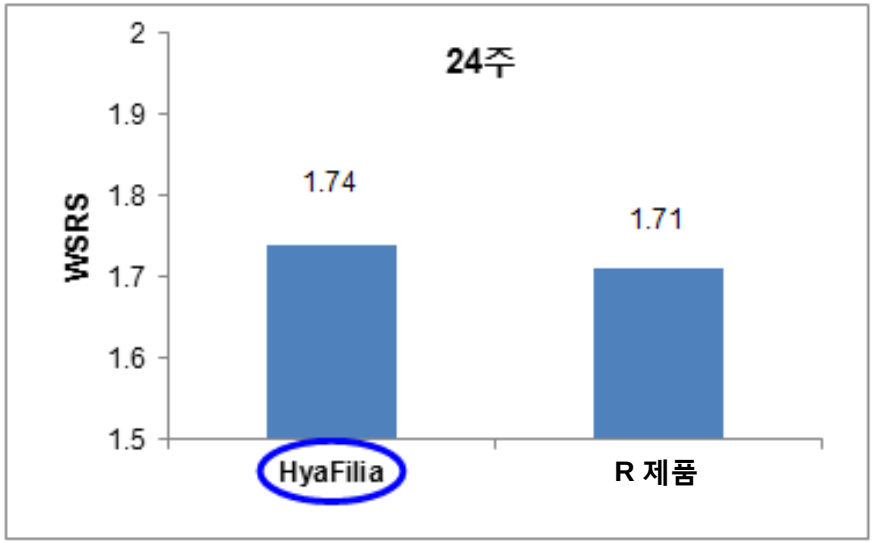
  ✓ WSRS average difference between R-product applied area and Hyafilia applied area was -0.03±0.75 . The lowest value of single one-sided 97.5% confidence interval regarding WSRS result was -0.22. As this was bigger value than -0.29 which was the non-inferiority limit in this trial, Hyafilia's non-inferiority was proved.

Bad

Good

점수	상세 내용
5	Extreme (아주 깊은 주름)
4	Severe (깊은 주름)
3	Moderate (중간 주름)
2	Mild (얕은 주름)
1	Absent (없음)

[Wrinkle Severity Rating Scale (WSRS)]



[독립적 평가자에 의해 평가된 WSRS 평균값 (FAS)]

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Clinical Data

▪ Efficacy Evaluation

• Secondary Efficacy Evaluation

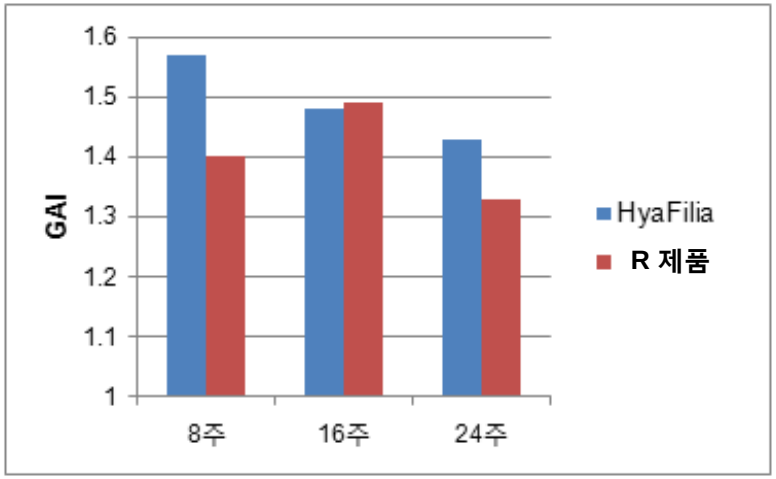
✓ **Patient's Satisfaction Level : Among GAI average value evaluated by subject on the 8th , 16th, and 24th week, Hyafilia's satisfaction level was higher than R-product on the 8th and 24th week. However, it is not statistically meaningful.**

Good

Bad

점수	상세 내용
3	Very much improved (매우 매우 나아짐)
2	Much improved (매우 나아짐)
1	Improved (나아짐)
0	No change (변화없음)
-1	Worse (나빠짐)

[Global Aesthetic Improvement (GAI)]



[각 시점에 피험자에 의해 평가된 GAI 평균값 (FAS)]

▪ Conclusion

- **Hyafilia used to improve nasolabial fold is considered as an effective and safe medical device.**

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