Comparative Performance Characteristics of Soft Tissue Fillers

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**Introduction**

**Background:** Soft tissue fillers have gained rapid acceptance as space-occupying devices for the correction of moderate to severe facial wrinkles and folds. More recently, soft tissue fillers for facial volumizing and contouring have been commercialized for the restoration of lost facial volume due to ageing and lipoatrophy.

The objective of this study is to investigate the comparative resistance to deformation, lift capacity and tissue integration profiles of three soft tissue fillers (VYC-20L, HYC-24L+ and RAD) in animal models.
**Test Articles:** VYC-20L, HYC-24L+ and RAD
*VYC-20L and HYC-24L+ contain lidocaine*

**Post-injection time points of analysis:**
- **Resistance to deformation:** Initial, 1, 2 and 9 days
- **Lift capacity:** Initial, 1 day, 1, 2, 4, 8, 12, 25 and 40 weeks
- **Tissue integration:** 1, 4 and 12 weeks
**Method to Assess Resistance to Deformation**

**Canfield 3D Imaging**

**Objective:** Assess the resistance to deformation of soft tissue fillers in an animal model. Resistance to deformation may relate to the injector’s ability to sculpt the product after injection.

**Filler Bolus**
125µl SubQ injection above the skull in a Sprague-Dawley rat

**Force (319 grams) is applied to the bolus using a blunt pestle**

Filler’s resistance to deformation = Percent change in mean height of bolus after application of force → \[ \frac{1}{1} \]

**Four time points of analysis:**
- Initial
- T=1 day
- T=2 days
- T=9 days
**Objective**: Assess the resistance to deformation of soft tissue fillers in an animal model

- VYC-20L and HYC-24L+ were easily deformed after injection relative to the limited deformation observed with RAD.
- VYC-20L was observed to set into the tissue by 2 days and resisted deformation thereafter relative to HYC-24L+. 

*More moldable*

*Less moldable*
**Objective:** Assess the comparative lift capacity of soft tissue fillers in an animal model. Lift capacity refers to the filler’s ability to lift the tissue at the site of injection and sustain this lift over time.

**Canfield 3D Imaging System**

**Filler Bolus**
125µl SubQ Injection above the skull
Sprague-Dawley rat

Lift is analyzed by measuring mean height of bolus by 3D image analysis

**Change in filler lift capacity over 40 weeks**
- Immediately post-injection
- 1 day post-injection
- 4 weeks post-injection
- 40 weeks post-injection
Objective: Assess the comparative lift capacity of soft tissue fillers in an animal model.

Note: 125µl of each filler was initially injected. Differences in lift upon injection relates to the physicochemical properties of each filler.

- **VYC-20L** provides significantly greater lift than HYC-24L+ and RAD at multiple time points throughout the 40 weeks.
- **HYC-24L+** provides significantly greater lift than RAD at multiple time points through 8 weeks.

*Note: Error bars indicate +/- SD, N=14*
Objective: To assess the tissue integration profiles of soft tissue fillers in an animal model.

Method to Assess Tissue Integration

Histological Analysis

- 200μl SubQ injection in a Sprague-Dawley rat
- Explant filler and surrounding tissue at 1, 4, and 12 weeks
- Perform histology on explant (Van Gieson and Colloidal Iron)

Histology Legend:

- Epidermis
- Dermis
- Panniculus carnosus (tan)
- Collagen fibers (pink/red)
- Injected filler bolus (blue)
Tissue Integration
1 week post-injection

- Tissue integration observed with VYC-20L and HYC-24L+ throughout the entire bolus, but limited peripheral tissue integration observed with RAD

Note: Due to lack of tissue integration, the white spaces represent filler displacement during processing for histology (see RAD image above)
Tissue Integration
4 weeks post-injection

- Tissue integration observed with VYC-20L and HYC-24L+ throughout the entire bolus, but limited peripheral tissue integration observed with RAD

Note: Due to lack of tissue integration, the white spaces represent filler displacement during processing for histology (see RAD image above)
Tissue Integration
12 weeks post-injection

- Tissue integration observed throughout the bolus with VYC-20L, HYC-24L+ and RAD

*Tissue integration was also assessed at 24 and 40 weeks post-injection. Observations at these time points are consistent with the 12 week conclusions.
Animal models were utilized to assess the resistance to deformation, lift capacity and tissue integration profiles of VYC-20L, HYC-24L+ and RAD.

**Resistance to Deformation**
- Relative to RAD, both VYC-20L and HYC-24L+ were readily moldable immediately after injection, suggesting the ability to sculpt the products to achieve a desired contour.
- VYC-20L was observed to set into the tissue and resisted deformation thereafter relative to HYC-24L+.

**Lift Capacity**
- Relative to RAD, VYC-20L and HYC-24L+ exhibited improved lift capacity, demonstrating their ability to fill wrinkles and/or provide volume.

**Tissue Integration**
- Compared to the limited peripheral integration observed with RAD at one and four weeks, the early host tissue integration observed with VYC-20L and HYC-24L+ may relate to a natural look and feel observed in the clinic.

Relative to RAD, the performance of VYC-20L and HYC-24L+ in these animal models suggests a favorable clinical profile with respect to their ability to fill wrinkles and/or provide volume.