

# A SINGLE CENTRE COMPARATIVE STUDY OF Juvéderm® ULTRA SMILE AND RESTYLANE Lipp FOR LIP ENHANCEMENT AND AUGMENTATION

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## INTRODUCTION

Lip augmentation is an increasingly popular aesthetic procedure which can be performed both surgically and non-surgically. The lip augmentation can be used to improve both the fullness and outline of the lips. To this end, Hyaluronic Acid (HA) fillers are a well established non-surgical treatment option. Though there are a wide range of HA fillers on the market, key differences do exist. These differences include: the presence or absence of pre-incorporation of lidocaine, the smoothness of injection and whether or not they are particulate in nature. A new HA filler with pre-incorporated lidocaine, Juvéderm® ULTRA Smile (Allergan, Irvine, CA) is an addition to the Juvéderm® ULTRA range of HA fillers which, collectively, demonstrate a unique homogenous smooth 3D matrix and which compare favourably to other, older, particulate technologies such as Restylane® and Restylane® Lipp™ that do not incorporate lidocaine.

## OBJECTIVE

The purpose of this study was to evaluate whether differences exist in patient comfort and aesthetic result for two HA fillers, one with and one without pre-incorporated lidocaine when used to augment the lips.

## MATERIALS

This was a single centre, prospective, open label comparison of Juvéderm® ULTRA SMILE, 24mg/ml HA gel with pre-incorporated lidocaine (HA + lidocaine) and Restylane® Lipp™, 20mg/ml HA gel without pre-incorporated lidocaine (HA alone).

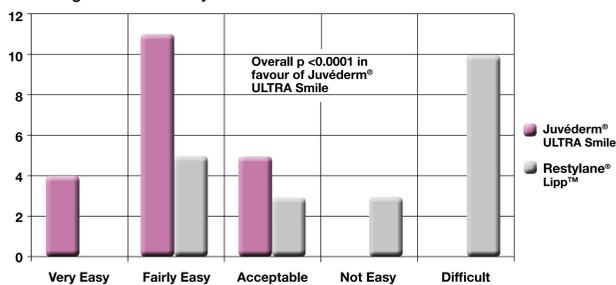
## METHOD

Patients were randomised to receive either one of the two treatments. They were initially not offered any form of anaesthesia. After initiation of the treatment, if the patient experienced a high degree of discomfort, a rescue anaesthetic was administered in the form of a nerve block or topical cream. Patient pain scores were measured during and after the treatment on a 10 point pain scale. The injector was asked to rate each treatment on: ease of injection, ease of sculpture, aesthetic effect and smoothness.

## RESULTS

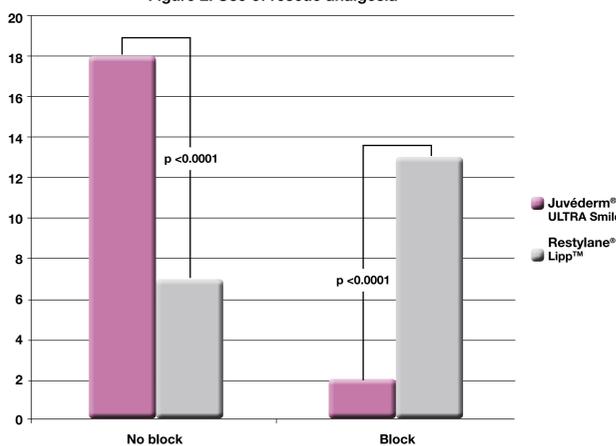
Twenty patients received each treatment. The patients were matched for age, previous injections and injected products. Both groups received similar volumes of the study treatments (mean vol 1.08ml: Juvéderm® ULTRA Smile and 1.01ml: Restylane® Lipp™).

Figure 1: Ease of Injection before block or at the start of treatment



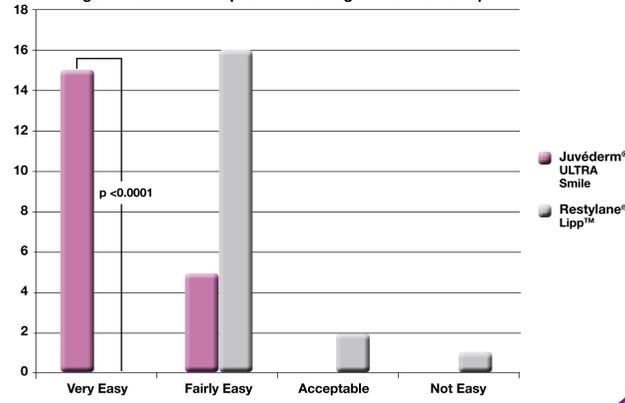
The majority (75%) (15/20) of treatments with Juvéderm® ULTRA Smile were rated as very or fairly easy; In contrast, most (53%) (10/19) of treatments with HA alone were rated as difficult (Figure 1). There was a highly statistically significant difference between Juvéderm® ULTRA Smile and Restylane® Lipp™ when looking at how easy it is to inject the filler in the lip before the block or at the start of the treatment (p<0.0001). **Juvéderm® ULTRA Smile was easier to inject than Restylane® Lipp™.**

Figure 2: Use of rescue analgesia



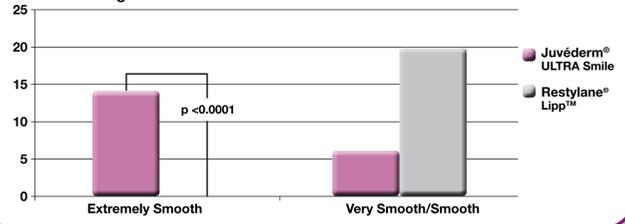
By the end of the treatment, 65% (13/20) (95% CI: 41%,85%) of the Restylane® Lipp™ group did not tolerate their treatment and required rescue anaesthetic block for comfort (Figure 2). In comparison only 10% (2/20) (95% CI: 1%,30%) of patients treated with Juvéderm® ULTRA Smile required block anaesthesia, however, in both cases these patients requested a block prior to treatment due to previous painful experience of lip injections. The reduced event rate of patients requiring a rescue anaesthetic seen with Juvéderm® ULTRA Smile compared to Restylane® Lipp™ was highly statistically significant (p<0.0001). **The addition of lidocaine to Juvéderm® ULTRA Smile negated the need for additional anaesthesia.**

Figure 3: Ease of sculpture or massage of filler in the lip



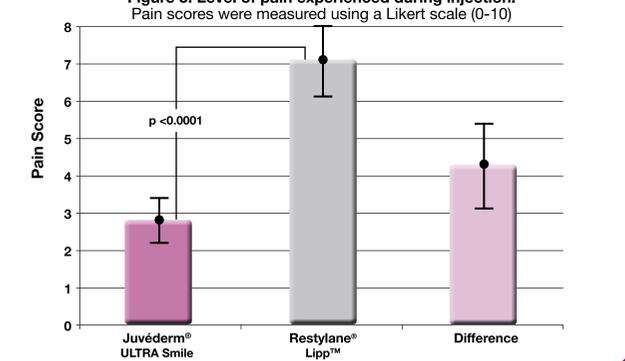
Sculpture or massage of the filler in the lip was 'very easy' in 75% (95% CI: 51%,91%) of patients injected with Juvéderm® ULTRA Smile (Figure 3). None of the procedures involving Restylane® Lipp™ were described as 'very easy'. This difference is highly statistically significant p<0.0001. **It was easier to sculpt or massage Juvéderm® ULTRA Smile whilst in the lip than Restylane® Lipp™.**

Figure 4: Smoothness of result after treatment



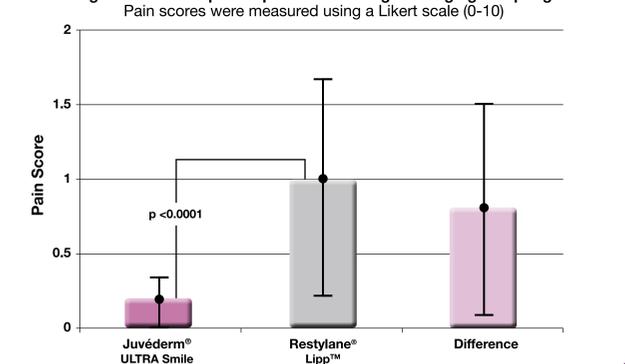
In 70% of patients (95% CI: 46%, 88%) the results with Juvéderm® ULTRA Smile were judged to be extremely smooth (Figure 4). This difference is highly statistically significant (p<0.0001). It was found that no patients treated with Restylane® Lipp™ had an extremely smooth result. **The injection of Juvéderm® ULTRA Smile was smoother than Restylane® Lipp™.**

Figure 5: Level of pain experienced during injection.



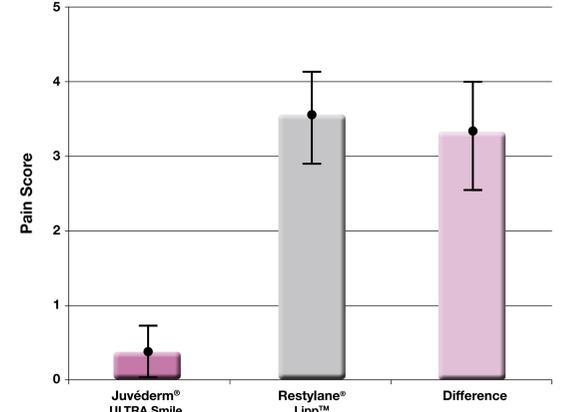
Patients receiving Juvéderm® ULTRA Smile had a mean pain score of 2.8 (95% CI: 2.2,3.4) compared to 7.1 (95% CI: 6.1,8.0) (Figure 5). This difference was highly statistically significant (p<0.0001). The mean difference of pain score using Restylane® Lipp™ is 4.3 (95% CI: 3.1,5.4) greater than when using Juvéderm® ULTRA Smile. **Injection with Juvéderm® ULTRA Smile was more comfortable than with Restylane® Lipp™.**

Figure 6: Level of pain experienced during massaging/sculpting



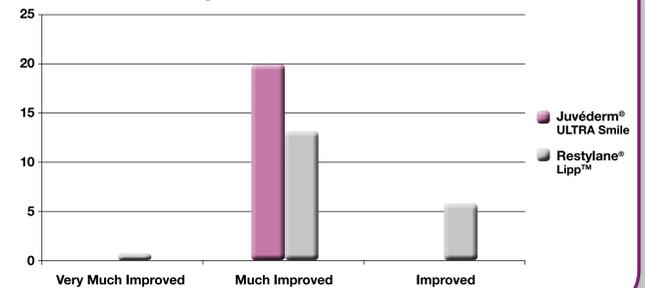
Patients receiving Juvéderm® ULTRA Smile had a mean pain score of 0.2 (95% CI: 0,0.4) compared to those patients on Restylane® Lipp™ who reported a mean pain score of 1.0 (95% CI: 0.2, 1.7) (Figure 6). The mean difference in pain score when using Restylane® Lipp™ is 0.8 greater than when using Juvéderm® ULTRA Smile. This difference was statistically significant (p<0.0001). **Patients experienced less pain during sculpting if they received Juvéderm® ULTRA Smile than if they received Restylane® Lipp™.**

Figure 7: Level of pain experienced 5-10mins after treatment



Patients on Juvéderm® ULTRA Smile had a mean pain score of 0.3 (95%CI:0,0.8) whereas patients on Restylane® Lipp™ had a mean pain score of 3.6 (95% CI: 2.9,4.2) (Figure 7). The mean difference of pain score when using Restylane® Lipp™ is 3.3 (95% CI:2.5,4.0) greater than when using Juvéderm® ULTRA Smile. This difference is highly statistically significant (p<0.0005). **Patients suffered significantly less discomfort after treatment with Juvéderm® ULTRA Smile than after treatment with Restylane® Lipp™.**

Figure 8: Aesthetic result



The aesthetic result was rated as much improved in all (20/20) patients in the Juvéderm® ULTRA Smile group compared to only 65% (13/20) in the Restylane® Lipp™ group. The difference in aesthetic result between Juvéderm® ULTRA Smile and Restylane® Lipp™ did not reach statistical significance. No adverse events were reported in either group.

## DISCUSSION

The results above show that the lip augmentation can be a very uncomfortable experience for the patient. The requirement to add in rescue anaesthesia may increase the time of the procedure and involved additional injection. Often, the lip augmentation is accompanied by massage to produce an even feel to the treatment and also shape the product for optimal aesthetic appearance of the lips. This massage may also add additional pain to the procedure and, itself, may necessitate the addition of rescue anaesthesia to the procedure. The advantages in time and patient comfort of not needing to resort to rescue anaesthesia are clear. Juvéderm® ULTRA Smile demonstrated a reduced need for rescue anaesthesia in a device that is specifically designed for lip augmentation.

## CONCLUSIONS

**The addition of lidocaine to Juvéderm® ULTRA Smile negated the need for additional anaesthesia.**  
**Juvéderm® ULTRA Smile was easier to inject than Restylane® Lipp™.**  
**The injection of Juvéderm® ULTRA Smile was smoother than Restylane® Lipp™.**  
**It was easier to sculpt or massage Juvéderm® ULTRA Smile whilst in the lip than Restylane® Lipp™.**  
**Injection with Juvéderm® ULTRA Smile was less painful than with Restylane® Lipp™.**  
**The difference in aesthetic result between Juvéderm® ULTRA Smile and Restylane® Lipp™ did not reach statistical significance.**  
**Injection with Juvéderm® ULTRA Smile was more comfortable than with Restylane® Lipp™.**  
**Patients suffered significantly less discomfort after treatment with Juvéderm® ULTRA Smile than after Restylane® Lipp™.**