Although the benefits of adding lidocaine are recognised in terms of relieving the pain experienced upon injection (2,6,7), there are still relatively few studies comparing the effectiveness of adding lidocaine to a given product in a given patient or its impact on potential side effects and on the remanence of the product. Initial comparative studies of this kind carried out in recent years (5-7) generally conclude that the two alternatives produce the same results in terms of tolerance and effectiveness, both immediately after treatment and six months later.

It would appear beneficial to establish the impact of lidocaine within the Stylage® range, the only one to incorporate both an anaesthetic (lidocaine) and an anti-oxidant in the form of mannitol in its cross-linked gel of HA.

In a study published in the Journal of Cosmetic and Laser Therapy, Bernard Mole and Lyliane Gozlan of the Centre Tourville, Paris, wanted to address the following questions:

1. Does this addition offer a real benefit in relation to the basic gel?
2. Could it be the cause of other incidents directly linked to lidocaine?
3. Could it have an impact on the durability of the result?

The single-blind post-CE Marking clinical study included 10 other practitioners. The triple objectives of the study were:

1. To highlight the benefits of adding lidocaine in terms of pain experienced by the patient and for all commonly injected areas of the face;
2. To compare the tolerance of the two products;
3. To compare the degree of aesthetic satisfaction achieved by the cross-linked gel with and without anaesthetic six to eight months after treatment.

**PROTOCOL**

The clinical follow-up was carried out at 11 centres over a period of six to eight months and involved 84 patients aged between 27 and 75 years (with an average age of 50). 96% of them were women. An assessment of the thickness of the skin revealed that 58% of patients had normal skin, 25% had delicate skin and 16% had thick skin.

The injected areas had to be symmetrically aligned on each side of the face for purpose of having comparable areas to assess. Any areas commonly treated with hyaluronic acid-based fillers could be injected. The injector was aware of the product type, i.e. with or without lidocaine, and arbitrarily chose which side to inject, the patient remaining unaware of the distribution of the products.

The assessment was based on three criteria:

- Patient comfort both upon administration of the injection and during the appropriate recommended post-injection massage (on a pain scale of one to 10)
- Any immediate and delayed side effects (oedema, erythema, redness, bruising, etc.) and the intensity thereof (slight, moderate or severe)
- The aesthetic satisfaction achieved after injection: immediately after the injection, five weeks (+/- one week) later and finally six to eight months later.

**RESULTS**

The outcome of the study are as follows:

- A total of seven different areas were injected among the 84 patients. Unsurprisingly, the distribution of injected areas shows the predominance of nasolabial folds and marionette lines (66% of indications).

Stylage® M Lidocaine was just as easy to inject as Stylage® M, confirming that the gel has equivalent physico-chemical properties. The very slight difference observed when using the lidocaine version (90% as opposed to 85% classed as “very easy”) was explained by a reaction specific to some patients who, in just a few seconds after the initial injections, experienced local anaesthesia in the injected areas. The injections, which had been now rendered painless, were more comfortable for the patient and therefore easier for the doctor.

The immediate side effects (experienced a few minutes to a few hours after treatment) were primarily limited to the usual redness or erythema in one third of the cases in both groups, as well as oedemas observed simultaneously. Some indurations were also observed (4-6% of the treated patients). All these side effects were resolved within a maximum of 72 hours after the injection. Bruising, which was more likely to occur when using a gel containing lidocaine, a vasodilator, was nevertheless limited (1%, or just one patient) and no bruising was observed in the group treated with lidocaine-free Stylage® M.

Haematomas were also found in an almost equivalent percentage for both products (14% for Stylage® M Lidocaine and 18% for Stylage® M), which can be explained by the origin of these undesirable effects: rupture of veins and not due to the product itself. An overview of all side effects experienced shows that in 57% of cases without lidocaine and 60% of cases with lidocaine patients suffered no side effects. Consequently, no significant difference was noticed between the products with and without lidocaine in terms of post-injection side effects.

The reported intensity of secondary reactions was low (level I) in the vast majority of cases (intensities: 1 = slight, 2 = moderate, 3 = severe), with only redness being reported as having an intensity of 3 in three patients (two of which had been treated with the lidocaine product and one without).

We summarise the results of a clinical study published in the Journal of Cosmetic and Laser Therapy on the benefits of adding lidocaine to the hyaluronic acid filler Stylage®.
resolved in the hour following the injection, as well as one case of a severe haematoma with Stylage® M. It is also interesting to note that the vast majority of haematomas observed were of low intensity for both products, which tends to confirm the lack of impact of the vasodilatory action of the 0.3% lidocaine in the Stylage® product, as was feared by some. The average intensity of secondary reactions was therefore lower in the lidocaine group.

Finally, no delayed undesirable effects (such as nodules, inflammatory granulomas, hypersensitivity, etc.) were reported, even up to 12-14 months of follow-up. The products are therefore equivalent in terms of tolerance, demonstrating only the usual side effects experienced when receiving filler injections, for a combination of cross-linked hyaluronic acid and mannitol, with or without lidocaine.

More significant was the assessment of the level of pain experienced. This was self-assessed by the patient on a scale of 1 to 10 and was, unsurprisingly, far lower in the lidocaine group, both at the time of injection, with an average scoring of 3.2 as opposed to 5.7, and during the post-injection massage, with an average scoring of 1.8 as opposed to 4. For the purposes of clearer comparison, the results have been organized by 'level of pain' with the following hypotheses:

**Very low level of pain = scores 1-3**

**Average level of pain = scores 4-6**

**High level of pain = scores 7-10**

These results show that 60% of patients claimed to have experienced a "very low" level of pain with Stylage M lidocaine as opposed to only 19% with Stylage® M. Likewise, an analysis of the levels of pain experienced with injections to the lips only, which accounted for 8% of the cases of a severe haematoma with Stylage® M. The overall aesthetic satisfaction remains very high as patients could, perhaps, be explained by the lower level of pain and the more 'relaxed' feeling of the treated area. No asymmetry of correction was reported by either the doctor or the patient, thus confirming that the physico-chemical and volumizing properties of both products are equivalent.

**CONCLUSION**

This study shows that adding lidocaine to a cross-linked hyaluronic acid gel:

1. Does not bring about any increased risk of blood extravasation;

2. Affects neither the quality nor the durability of the result.

However, patient comfort during the injection means that generally-speaking, no nerve block is required, even when treating the lips, an area which is generally much-dreaded as it is extremely sensitive. Although the few seconds it takes to initially insert the product may be uncomfortable, the rest of the injection is far more tolerable. The correction can therefore be refined under much better conditions. This increased comfort throughout the injection process confirms the notion that the addition of lidocaine is still a key step forward in putting the patient at ease and should be applied without limit to all fillers, particularly as real allergies to lidocaine are currently more of a historical nature than a clinical one.

[References]

**STYLAGE®**

**Alma Lasers Receives FDA Clearance for Pixel RF**

Alma Lasers is pleased to announce the introduction of the new Pixel RF fractionated skin resurfacing module for its Accent family of products. Distributed in the UK by ABC Lasers, the Pixel RF uses proprietary InMotion Refractive Radio-frequency Micro Plasma™ Technology, which both ablates and heats the skin through controlled, focused delivery of energy without using disposables. Healthy skin around the treated area helps to accelerate the healing process thus improving results and reducing patient down time by allowing the need for just the targeted tissue to heal and collagen to strengthen. With its high-energy output, the Pixel RF can achieve in as little as one session what would require multiple sessions with other RF technologies. Not only is it highly effective to use on all skin types (Fitzpatrick I-VI) but treatments can be administered year-round with no seasonal restrictions. The Pixel RF causes evaporation, mechanical damage and thermal damage deep beneath the epidermis surface providing significant dermal impact with minimal epidermal disruption.

**Stylage® now available with lidocaine**

Stylage® is now available with lidocaine. Stylage® is the first product on the market which contains cross-linked HA (patented IPN-Like Technology), the anti-oxidant mannitol, which provides less swelling and extended longevity, and lidocaine for comfort and safety for both for patients and physicians. A clinical study conducted by French plastic surgeon Dr Bernard Mole confirmed that the effectiveness of the HA was not compromised by the addition of lidocaine and that the performance and filling capacity or “volumising effect” of gels with Stylage® lidocaine are the same as those without. The study that was carried out on 84 patients with a clinical follow up over a period of six to eight months, concluded that the product does not bring about any increased risk of blood extravasation and affects neither the quality or the durability of the results (see pages 21-22).

**CARLETON MEDICAL**

Carleton Medical will be launching the latest offering from Asclepion, QuadroStar, to the UK aesthetics market next month. The system is the World’s first diode yellow light with a 577nm wavelength, which is the highest absorbency wavelength for oxy and deoxyhemoglobin, meaning it is ideal for vascular treatments. In addition to the 577nm wavelength it also has 532nm, 940 or 980nm wavelengths. The small, compact and light table top device has an iPad interface and a choice of hand pieces as well as a built in scanner and skin cooling for easy handling without cables and there are no running costs.

Applications include vascular lesions; pigmented lesions; laser assisted liposuction; endovascular treatments and surgery. It is due to be launched in March 2013.

**HEALTHXCHANGE**

Healthxchange introduce Obagi® Hydrate™

The latest product from skincare pioneers Obagi® is now available from Healthxchange. Obagi® Hydrate™ is a new facial hydrator that features an innovative technology called Hydromanil which captures and assimilates water into the skin both immediately and lasting due to an advanced multi-capillary process, creating a 2-in-1 response. Clinical results are instant and long-lasting hydration, which helps to enhance skin smoothness, while providing immediate and lasting effects on skin barrier function. In recent clinical trials, the test results reported a 51% improvement in water loss after eight hours and a 92% improvement in the skin’s hydration within two hours (OMP Inc, data on file).