The Consulting Room
Keeping Aesthetic Practitioners Informed
Edition 132 May 2014

Feature Article

'Comfortably Numb'
The Lowdown on Topical Anaesthetic Products

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‘Comfortably Numb’

The Lowdown on Topical Anaesthetic Products

Topical anaesthetics have a history going back to the end of the 19th century, when cocaine was first applied topically during eye surgery. However cocaine came with risks and it is reported that its use in anaesthesia claimed 13 deaths and 200 cases of systemic toxicity within 7 years of practical use in the 1880s. Yet it was almost another hundred years before any safe and effective topical products became widely available with the introduction of procaine and tetracaine in the early 20th century.

A late comer, Lidocaine, was synthesised by a Swedish chemist Nils Löfgren in 1943, under the name Xylocaine. He sold the rights to Astra AB (a founding company of AstraZeneca) and the drug was first marketed in 1948. Despite the development of other anaesthetic agents since then, lidocaine has remained the most widely used.

The first topical agent available to anaesthetise the skin was a combination of 0.5% tetracaine, 0.05% adrenaline (epinephrine) and 11.8% cocaine, known as TAC. Due to the safety concerns over cocaine toxicity, plus the cost and regulations, the cocaine was replaced and a far more common combination became 4% lidocaine, 0.1% epinephrine and 0.5% tetracaine, known as LET, as well as 20% benzocaine, 6% lidocaine and 4% tetracaine, known as BLT. LET and BLT can be compounded by pharmacies but are not commercially manufactured brands.

As research has progressed, more and more different agents have been formulated and brought to market in a number of commercially available topical applications. The most famous of which is EMLA, which stands for Eutectic Mixture of Local Anaesthetics. EMLA, launched in Europe in 1985, represents the first major breakthrough in topical anaesthesia products for intact skin and the birth of the batch produced topical anaesthetic product.

Pain and Anaesthetics

There are main different types of pain which have now been defined by scientists, but in its simplest form humans feel pain most commonly from situations which are thermal (heat, such as a burn, or cold), mechanical such as crushing, cutting, grazing or chemical such as lemon juice in a cut or chilli in your eye.

At the end of our nerves we have pain receptors; the stimulation of these receptors causes sodium to enter the area which in turn causes an electrical signal to amass in the nerve, once big enough the electrical signal makes its way to the brain and the signal is interpreted as what we know as a sensation of pain.

Substances used to anaesthetise a targeted area aim to temporarily block this pathway so that signals are not created, nor sent onwards to the brain. They do this by blocking the sodium channels and stopping the sodium from entering the nerve ending where the pain would be being felt. No sodium equals no electrical signal build up, which means no pain alert is sent to the brain along the fibres of the nerve.

Intradermal injections of local anaesthetics have been used for many years, but these can come with their own problems, not least that the pain (albeit brief) of administering the anaesthetic, both the needle puncture and the diffusion of the agent into the skin can be uncomfortable for the patient. Similarly injections of anaesthetic are known to cause oedema. Nowadays more and more topical products have come to the market which provide cosmetic practitioners with improved options for anaesthesia when performing superficial dermatological and cosmetic procedures.

Topical Anaesthetic Composition

All topical anaesthetic cream products on the market today use derivatives of the natural chemical of cocaine which comes from the leaves of the coca plant that is native to South America. The properties of cocaine mean that amongst other things it blocks sodium channels so interferes with the sending of pain signals, and also causes

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vasoconstriction so reduces bleeding on a small scale. All of this has made it a well studied and synthesised chemical. It is also known for its properties as a class A recreational drug, which has meant that it is no longer used directly as an anaesthetic ingredient due to toxicity safety concerns.

Cocaine derivatives, available in a variety of concentrations and combinations are contained within well known topical brands and include benzocaine, butamben, lidocaine, prilocaine, tetracaine (previously called amethocaine in the UK), pramocaine and dibucaine (which are both commonly used in OTC haemorrhoid preparations).

The most common derivative is of course lidocaine (formerly also known as lignocaine in the UK) and this is the key anaesthetic ingredient used in topically applied creams.

Although many products can be compounded generically, by pharmacists, there are many who argue that this is not advisable practice as incorrect concentrations, additions of other ingredients, poor quality ingredients and mislabelling have been known to occur and can cause adverse effects. Sticking to strictly controlled, batch produced commercially approved products is the preferred best practice.

Clinical Concerns

The key considerations with any topical anaesthetic product include the mode of action used for penetration of the anaesthesia, the practical application for the practitioner, the time taken until onset of effect, the duration of pain relief achievable, as well as safety for the recipient in terms of subcutaneous toxicity and levels of absorption of ingredients into the body, alongside minimising the potential for adverse effects.

In a clinical paper published in Dermatologic Surgery by doctors **Joseph Sobanko, Christopher Miller and Tina Alster** which reviewed topical anaesthetics for dermatologic procedures, it was noted that despite widespread use of lidocaine-containing products for superficial dermatologic, aesthetic and laser procedures, "*comprehensive reviews are lacking regarding their relative safety profiles and appropriate dermatologic use*". The authors concluded that in order to reduce the risk of side effects from the use of these products clinicians should consider the amount of the product used, the location on the body where it is being used, the size of the surface area and the duration of application of the product. Their literature review noted cases of adverse outcomes from the use of topical anaesthetics on excessively large skin surface areas during laser hair removal treatments.

Although topical anaesthetic formulations are generally considered to be safe, occurrences of allergic reaction, systemic absorption and even death have been reported with their use. All products, which are designed for use on intact skin, should also be used with extra care in the proximity of the eyes to avoid the risk of corneal lesions and other known adverse eye complications.

Problems are especially noted with OTC products and their use by the public without medical supervision. So much so that in 2007, the U.S. FDA had to issue **public health advice** following the deaths of two separate women who had used over the counter purchased topical anaesthetic products, on their legs, occluded under cling film prior to appointments for laser hair removal.

Penetration

In order to be effective as a numbing cream a topical anaesthetic needs to be able to get through the superficial layers of the skin (stratum corneum) so that it can block the pain signals at the nerve endings which are located within the dermis.

As well as the composition of the cream, including its pH level, there are other practical operations which can be done by the clinician to remove or reduce the thickness of the stratum corneum and prepare the area to aid this process, such as cleansing and tape stripping. Similarly the processes of heat and occlusion can help the product to penetrate into the skin. Skin cleansing with benzoyl peroxide should be avoided as it can decreased the absorption of the anaesthetic.

Newer products to the market claim that their use of liposomes provides an improved delivery mechanism through the stratum corneum as they resemble the naturally found lipids in the tissue so can freely move and penetrate through the epidermal barriers with the anaesthetic encapsulated on its journey to the targeted area.

One interesting area of recent research is in the use of pre-treatment with lasers to enhance the absorption of topical anaesthetics. British doctor, Georgette Oni, a research fellow at the Department of Plastic Surgery at the University of Texas Southwestern Medical Center has co-written two papers in 2012 and 2013 which looked at this area.

The **first** questioned whether fractional lasers could enhance the transdermal absorption of topical lidocaine in an in vivo animal model (porcine). In the study a 4% lidocaine product was applied to the pigs under occlusion and then blood serum levels were tested at various intervals. A week later the experiment was repeated but the pigs were treated with an Er:YAG laser at 500, 250, 50 and 25 µm ablative depths before the topical anaesthetic was applied. The results of the study showed that the laser pretreatment significantly increased the absorption of the topical lidocaine so that it could be detected in the blood and that the manipulation of the laser settings had an effect on the levels of absorption.

The **second** paper assessed the safety and efficacy of laser pretreatment in the transdermal delivery of a topical anaesthetic (BLT) for facial rejuvenation. The 10 subjects were split into two groups, both groups were given the anaesthetic cream for 20 minutes, it was removed and bloods drawn, then one group was pretreated with an ablative laser and the other with a fractional laser across the full face. Both groups were then given more topical anaesthetic for a further 20 minutes. Both groups then received their full ablative or fractional treatment, with blood being drawn again at 60, 90, 120, 180 and 240 minutes after the initial application of the anaesthetic cream for analysis of lidocaine absorption. The resulting data demonstrated some differences in pain scoring across the groups, alongside differing serum levels of lidocaine but concluded that topical anaesthetic for facial rejuvenation can be enhanced with laser pretreatment while maintaining safe blood serum levels. The authors noted that further studies should examine optimal application amount and time to allow safe multipass facial rejuvenation without the need for invasive nerve blocks.

Occlusion

To occlude or not to occlude is often the question. In the case of topical anaesthetics the process of occlusion normally involves the application of a covering or dressing on top of the applied cream to seal it against the skin and away from the surrounding air; this is normally facilitated with the use of plastic wrap such as cling film.

In most cases occlusion will speed up and increase the penetration of the anaesthetic, although occlusion is not always necessary depending on the area being targeted, the treatment being performed afterwards and the topical anaesthetic formulation being used.

A new product launched to the market claims to self-occlude, thus creating a flexible film like structure, once the applied cream has dried on the skin, which can then be just peeled off at the end. This, it is claimed, results in a speedier time of onset and also a quicker overall process for the practitioner as there is no mess or time added on for product removal once the anaesthetic effect is achieved.

Time to Onset

Both the penetrative qualities of the anaesthetic product and the use of occlusion, or not, will have a bearing on the time to onset needed for the anaesthetic effect to be in place.

In many busy medical practices, the desire for a fast acting solution which results in shorter waiting periods between treatment prep and actual treatment are desirable, both for patients and practitioners. For a practitioner, choosing a product which is both safe and effective is one thing, but the choice of one (from the many which are already known to be safe and effective) may well come down to one with a faster time to onset.

Duration of Pain Relief

The primary role of a topical anaesthetic is to ‘numb the area’ so that no pain is felt by the recipient when a treatment is performed on the targeted area. Depending on the type of procedure being performed, and the time needed to complete it, this will have an effect on the duration of anaesthetic or pain relief required to maintain comfort from start to finish of the treatment.

Additionally, depending on the aggressive level of trauma which the treatment produces as an end point, there may well be post-treatment pain which could be managed in the immediate after hours by a longer acting topical anaesthetic, before other forms of pain relief are required by the patient. Thus the duration of pain relief provided by a product may influence the decision to use one for one type of treatment and another, longer acting product for a more invasive procedure.

Toxicity

One of the potential complications with the use of topical anaesthetics is lidocaine toxicity. Both prolonged application, application over large areas and improper use of concentrations which are too high (particularly with compounded products) can all increase the risk of increased serum levels of lidocaine in the blood.

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Use over a whole limb (upper or lower leg) or over half a torso in one application is considered unsafe practice. If pain reduction is needed for a larger treatment area, other options such as ice packs, air cooling devices and distraction methods should be considered for increased patient comfort.

Practitioners are advised to always read the pack inserts of the specific products which they intend to use on a patient and to be familiar with its individual properties and unique characteristics, as not all products are the same or are applied in the same way. If training is available from a supplier or distributor then it is recommended that you avail yourself of it. Caution should be taken to not exceed guidelines on the amount of product used as this can cause toxicity, the signs and symptoms of which practitioners should be aware of and be able treat rapidly should they occur. Similarly repeated us or cross use of products can have a cumulative effect on toxicity.

Signs and symptoms of lidocaine toxicity increase with the amount of lidocaine in the blood stream but start with lightheadedness, numbness around the mouth and a metallic taste in the mouth, moving on to rapid eye movement, slurred speech, localised muscle twitching and tremors and in the worst case seizures, difficulty breathing and coma.

Special consideration to the type of topical anaesthetic ingredients contained in a product should be given to those who present with existing liver, kidney or heart concerns. Also, their use is generally not recommended in pregnant or breast feeding mothers due to the transfer of small amounts of the agents through the placenta and into breast milk.

Similarly most of the clinical papers available which look at serum levels of lidocaine following the application of a variety of products, on otherwise healthy individuals, show a marked difference in lidocaine metabolism between individuals and not just differences between sexes or ethnicities. Some also argue that the risk of toxicity is increased with the use of occlusion so extra caution should be taken with this practice and each individual treated according to their profile.

It is also noted that liposomal delivery methods allow both improved penetration into the skin but also protect the drug from being metabolised by the body quite so quickly. This concept and the safety of the mechanism was demonstrated in a paper by **R Fisher et al** in 1994 which looked at the absorption rates of liposome encapsulated tetracaine versus non-encapsulated in rabbits by measuring blood serum levels after application. The paper concluded that "*liposome encapsulation of topically applied local anaesthetics might reduce the potential systemic toxicity caused by rapid absorption of these compounds*".

Some other useful papers on the subject of lidocaine toxicity include:

- **Systemic toxicity from topically applied lidocaine in conjunction with fractional photothermolysis.**
- **Comparison of five commonly-available, lidocaine-containing topical anesthetics and their effect on serum levels of lidocaine and its metabolite monoethylglycinexylidide (MEGX).**
- **Serum lidocaine levels and cutaneous side effects after application of 23% lidocaine 7% tetracaine ointment to the face.**
- **Effect of 4% topical lidocaine applied to the face on the serum levels of lidocaine and its metabolite, monoethylglycinexylidide.**

Brands

There are several topical anaesthetic products, now available to the aesthetic professional, which all have differing ingredient compositions and unique properties. The following gives a summary of each of the major brands widely available in the UK through wholesale pharmacies.

Ametop®

Ametop®, manufactured by Smith & Nephew is a topical anaesthetic gel used for dermal analgesia on intact skin, particularly indicated for use prior to venepuncture or venous cannulation. It contains 4% tetracaine and sodium hydroxide, sodium methyl-p-hydroxybenzoate, sodium propyl-p-hydroxybenzoate, monobasic potassium phosphate, xanthan gum, sodium chloride and purified water.

Ametop increases the size of blood vessels in the region where it is applied, having a vasodilating effect, which can cause temporary redness or erythema in the area. However this property can be seen as an advantage in cases where intravenous access is being sought, as less vasoconstriction is seen compared to other topical anaesthetics such as EMLA, leading to **less painful cannulation**. This may be a useful topical anaesthetic for use in Platelet Rich Plasma (PRP) treatments, for needle sensitive patients, for example, which require the drawing of a blood sample from a vein for the production of the PRP product which is ultimately used in the facial rejuvenation treatment.

The gel should be applied, under occlusion, for 30 – 45 minutes for the best effect and numbness will remain for four to six hours.

For more information on Ametop, please consult the **SPC**.

EMLA™ (Eutectic Mixture of Local Anaesthetics)

EMLA™ or Eutectic Mixture of Local Anaesthetics is a local anaesthetic for topical application, developed to anaesthetise intact skin by AstraZeneca and marketed since 1985. Its primary marketed use is for preventing pain associated with needle insertion, intravenous cannulation, and superficial surgery on skin.

EMLA contains 2.5% lidocaine and 2.5% prilocaine, plus a thickening agent carbomer 974P, emulsifying agent polyoxyethylene hydrogenated castor oil, sodium hydroxide and distilled water with a pH of 9.4 in a cream form.

EMLA makes the blood vessels smaller in the region where it is applied, having a vasoconstricting property, which can cause a temporary whiteness or blanching in the area after application.

Ideally the product should be applied for 60 minutes under an occlusive dressing for the best effect and numbness should last for up to two hours. It can be applied for up to 5 hours without adverse effect.

The manufacturers note that prilocaine in high doses may cause an increase in methaemoglobin plasma levels, particularly in conjunction with methaemoglobin-inducing agents. This is however rare, effecting less than 1 in 1,000. They therefore note that with large doses of EMLA, consideration should be given to the risk of additional systemic toxicity in patients receiving other local anaesthetics or agents structurally related to local anaesthetics, since the toxic effects are additive. This is born out by a clinical paper by **Dr Garcia-Saura**, published in Spain in 2013 which described the case of a 21 year old female with methaemoglobinemia after using EMLA cream for laser hair removal.

For more information on EMLA, please consult the **SPC**.

LMX 4®

LMX 4® Cream is a topical local anaesthetic with an approved indication to produce surface anaesthesia of the skin prior to venous cannulation or venipuncture (in adults, the elderly and children) or the administration of painful topical treatments on larger surface areas of intact skin (in adults only). The marketing authorisation holder is Ferndale Pharmaceuticals Ltd who market and distribute LMX4 in the UK and also promote it through their aesthetic division, AesthetiCare.

LMX 4 contains 4% w/w lidocaine with liposomes. Ingredients include benzyl alcohol, carbomers, cholesterol, phospholipon 80H (hydrogenated soy lecithin), polysorbate 80 (Tween 80), propylene glycol, trolamine, vitamin E acetate and purified water.

According to the manufacturer, the liposomes provide an improved delivery system through the stratum corneum as

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they resemble the naturally found lipids so can freely move and penetrate through the epidermal barrier layers with the lipophilic lidocaine anaesthetic encapsulated. The liposomes thus help facilitate the rate and extent of penetration. This also means that it can achieve an anaesthetic effect in a sho rter time frame to EMLA and without the necessary requirement for occlusion; (although it is generally recommended to occlude as it can dry on the skin if not occluded and can require wetting to aid removal).

LMX4 cream should be applied for between 30 and 60 minutes with or without occlusion to achieve the anaesthetic effect. It can be applied for up to 5 hours (under occlusion) without adverse effect.

Clinical data from 2006 by **MS Nestor** concluded that moderate amounts (30g and 60g) of occluded LMX4 were safe; the test subjects showed no evidence of clinical toxicity and blood levels showed no evidence of significant lidocaine or lidocaine metabolites. LMX4 is approved for use of up to 180g on areas of 900cm^2 in adults.

Common side effects (> 1 in 100) as stated in the SPC include irritation, redness, itching or rash. LMX 4 contains propylene glycol which may cause skin irritation. The manufacturer claims that the use of liposomes enables only lidocaine to be used and clinical studies can demonstrate that this results in less skin balancing than prilocaine containing EMLA Cream or topical anaesthetics containing tetracaine, which has a greater vasodilator effect, such as Pliaglis or Ametop.

For more information on LMX4, please consult the **SPC**.

Pliaglis®

Pliaglis®, manufactured by Nuvo Research Inc. and distributed worldwide by Galderma claims to be the first, self-occluding topical anaesthetic cream available for use prior to a wide range of dermatological procedures, providing proven safety and efficacy for rapid onset and sufficient, lasting pain relief for patients.

Pliaglis does have some history to tell. Within clinical literature it is widely referred to as the ‘S-Caine Peel’ with Pliaglis being the marketed and trademarked brand name, which came later. The first iteration of the product, then manufactured by ZARS Pharma (which was **acquired by Nuvo Research** in April 2011) was discontinued in September 2008 due to manufacturing issues which led to an inability to obtain consistent product viscosity, (this was not related to product safety). The manufacture of the product was thus transferred to facilities at Galderma where improved manufacturing was available and it was relaunched with **European Marketing Authorisation** in July 2011 and **US FDA approval** in October 2012. The product was then launched into the European market in April 2013.

Pliaglis contains the highest concentrations of anaesthetic ingredients on the market in a topical product with 7% lidocaine and 7% tetracaine plus calcium hydrogen phosphate, anhydrous, purified water, polyvinyl alcohol, white soft paraffin and sorbitan monopalmitate. It also contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may cause delayed allergic reactions in some cases.

The product should be applied to intact skin for 30 minutes for procedures such as laser hair removal, pulse dye laser treatment, non-ablative laser skin resurfacing, dermal filler administration or for access to veins and for 60 minutes for laser tattoo removal and laser ablation of leg veins.

The following clinical papers looked at the use of Pliaglis alongside many of these specific aesthetic treatments:

- **Thirty-minute application of the S-Caine peel prior to nonablative laser treatment.**

- **Lidocaine/tetracaine peel in topical anesthesia prior to laser-assisted hair removal: Phase-II and Phase-III study results**

- **Two randomized, double-blind, placebo-controlled studies evaluating the S-Caine Peel for induction of local anesthesia before long-pulsed Nd:YAG laser therapy for leg veins.**

- **60-minute application of S-Caine Peel prior to 1,064 nm long-pulsed Nd:YAG laser treatment of leg veins.**

- **Evaluation of the S-Caine Peel for induction of local anesthesia for laser-assisted tattoo removal: randomized, double-blind, placebo-controlled, multicenter study.**

- **The S-Caine Peel: A Novel Topical Anesthetic for Cutaneous Laser Surgery** (pulsed dye laser treatment for telangiectases and port wine stains).

- **Evaluation of a novel topical anesthetic agent for cutaneous laser resurfacing: a randomized comparison study.** (CO_2 laser skin resurfacing).

It is said to have a long lasting effect of up to 9 hours which aids in the management of post-treatment pain from more aggressive procedures such as laser ablation.

Once applied in a thickness of 1mm, the Pliaglis cream dries to form an occlusive barrier upon exposure to air. The cream adheres to the skin and as it dries, releases the lidocaine and tetracaine into the skin for the anaesthetic effect. Once the time frame for onset is complete, the Pliaglis cream is simply peeled away prior to treatment. Some minor residue may remain which can be cleansed with ease. It is important to not occlude the cream before its removal as it has self-occluding properties.

There were no reports of methemoglobinemia in the trials of Pliaglis. However the manufacturer notes that caution should be exercised to ensure that the doses, areas of application, and duration of application are consistent with those recommended by them.

Patients should also be advised to take extra care to avoid inadvertent trauma to the skin (through scratching, rubbing or exposure to extreme temperatures) whilst under the local anaesthetic effects of Pliaglis.

Unlike other products on the market, the safety of its use in children has not been evaluated so it must only be used on adults. Its safety has however been proven in geriatrics (over the age of 65) according to this paper by **AK Schecter**.

During clinical trials of the product, localised skin reactions (erythema and skin discolouration) at the site of application were a very common adverse event, but were generally mild and transient in nature, effecting over 10% of patients, with skin oedema also quite common. These do not appear to interfere with the clinical outcome of treatments.

According to **Dr Tina Alster** in a paper in which she reviewed all published studies which looked at Pliaglis; "*studies comparing the Lidocaine/Tetracaine (LT) peel with placebo or a 1:1 eutectic mixture of local anaesthetics (EMLA) cream have shown the LT peel to have superior anaesthetic efficacy in adult patients undergoing a variety of cutaneous procedures*".

The following paper by Dr Alster entitled **Review of Lidocaine/Tetracaine Cream as a Topical Anesthetic for Dermatologic Laser Procedures** also provides additional data on Pliaglis and some comparison remarks.

[Note: Dr Tina Alster receives no funding or sponsorship from Galderma.]

Preliminary data from a non-interventional study at four European clinics evaluating efficacy and safety in daily practice use of Pliaglis was presented at the 22nd EADV meeting in October 2013. It revealed that the majority of patients were very satisfied or satisfied with the pain reduction and 90% would like to receive Pliaglis again as a topical anaesthetic and would recommend it to family and friends.

Additionally 69% of the participating patients who had previously had the same dermatological procedure performed in the same area stated that the anaesthesia obtained with Pliaglis was better when related to the previously used anaesthetic.

For more information on Pliaglis, please consult the **SPC**.

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Comparison Data

What is great to see in this area of aesthetic medicine, and perhaps more so due to its relevance to more general medical practices is that there is much more of an abundance of comparative clinical data for the various products available. As we know this isn't always the case when we look at other aesthetic devices and technologies.

In a paper published in 2012 by **M Fraczek and A Demidas**, the authors compared the efficacy of three topical anaesthetics, **EMLA, LMX4 and Ametop**. The aim of the study was to compare the purported advantages of Ametop gel and LMX4 gel with EMLA cream using an objective and repeatable method. Ametop and LMX4 were administered, under occlusion, for 30 minutes and compared to EMLA cream applied for 30 and 60 minutes on the intact upper lip skin of 15 volunteers.

After evaluating the results, the **authors concluded that LMX4 and Ametop appeared to be faster acting than EMLA**. Their results also showed the **30-minute application of LMX4 and Ametop under occlusion to be equivalent to 60-minute administration of EMLA**. Ametop, in contrast to the rest, provided very good anaesthesia for up to 60 minutes. They noted that **the application of EMLA cream under occlusion over only 30 minutes cannot guarantee appropriate effects**.

Similarly in another paper published in 2014 by **P Gahalaut et al**, the authors compared the use of **EMLA and Pliaglis** in a split-side trial on 40 patients who were having skin tags removed using radiofrequency ablation. The topical anaesthetics were both applied for 30 minutes under occlusion (self and manual) prior to treatment. The results showed that the **pain severity** experienced by the patients in terms of visual analogue scale score was **significantly less for Pliaglis as compared to EMLA** and proved the efficacy of Pliaglis when applied for a short time of 30 minutes.

The same conclusion was drawn in a paper by **Dr. Tina Alster** which compared a double-blinded 30 minute application of **EMLA** (occluded) **and Pliaglis** for CO_2 laser skin resurfacing and noted that **pain scores were significantly lower in the group treated with Pliaglis as the EMLA required a longer application time**.

It is worth noting however that the SPC for EMLA clearly recommends that the product be applied for 60 minutes so it is possible that a fuller anaesthetic experience would have been produced in the Gahalaut and Alster trials if the product was applied as directed. Such trials were mostly aimed at proving the rapid time to onset of the Pliaglis brand at the expense of EMLA which is known to take longer to onset.

Conclusion

The road to choosing a topical anaesthetic for your clinical practice is not, at first glance a simple process. A clinician needs to assess which of the treatments they perform most likely require the application of a topical anaesthetic for increased patient comfort. How big the treatment area is, how long the anaesthetic will need to be active for (including post-treatment pain management), the known product side effects on patients, and how quickly they need the anaesthetic to 'work' in their busy clinic environment. It may be that the 'one size fits all' approach is not ideal and a clinician may choose different topical anaesthetics for use with different aesthetic treatments.

Similarly, as with all things, in what is ultimately a business, cost is another consideration. EMLA and LMX4 come in at a fairly comparable price, both under £15 for 30g, whereas the self-occluding technology and higher concentration of ingredients in Pliaglis ups its price tag considerably (approx. £23 for 15g). It remains to be seen if the perceived benefits of the 'quick to remove' film and longer lasting anaesthetic effect of Pliaglis will be enough of an advantage to make aesthetic clinicians take the added cost on board.

Other Bibliography References: **Topical anaesthetics in dermatology, by Rod Tucker**

Lorna Jackson

Lorna has been Editor of The Consulting Room™, the UK's largest aesthetic information website, for over a decade, since 2003. She has become an industry commentator on a number of different areas related to the aesthetic industry, collating and evaluating statistics, plus researching, investigating and writing feature articles, blogs, newsletters and reports for The Consulting Room™ and various consumer and trade publications, including *Cosmetic News, Journal of Aesthetic Nursing, Body Language*, *PMFA News*, *Aesthetic Medicine* and *Aesthetic Dentistry Today.* Lorna has also been asked to present at various industry events, including Smart Ideas, BACN and Merz Aesthetics Business Workshops, the FACE Conference and the Clinical, Cosmetic & Reconstructive Expo.

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(1376)

Date: March 2016

Certificate No: A001823

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PRESCRIBING INFORMATION

LMX4 Lidocaine 4% w/w Cream is a topical anaesthetic containing 4% w/w Lidocaine in a liposome base. **Indication: Venous cannulation or venipuncture:** Adults including the elderly and children over one month of age. Local anaesthetic for topical use to produce surface anaesthesia of the skin prior to venous cannulation or venipuncture. **Dose and method of use:** Apply 1 to 2.5g of LMX4 Cream to the area of the skin where the procedure will occur. No more than 1g of cream should be applied to children under 1 year of age. 1g of cream equates to approx. 5cm of cream squeezed from the 5g tube or approximately 3.5cm of cream squeezed from the 30g tube. The LMX4 Cream should remain undisturbed on the skin and can be covered with an occlusive dressing to prevent disturbance. Adequate anaesthesia should be obtained after 30 minutes, but the LMX4 Cream can be applied for up to 5 hours under a dressing. Shortly before starting the procedure the LMX4 Cream should be removed with clean gauze and the procedure site prepared in the usual manner. Maximum application time for 1 year and above should not exceed 5 hours. Maximum application time for 3 month up to 12 month infant should not exceed 4 hours and maximum application time for 1 month up to 3 month infant should not exceed 60 minutes. **Indication: Painful topical treatments on larger surface areas of intact skin:** Adults, including the elderly. Local anaesthetic for topical use to produce surface anaesthesia of the skin prior to painful topical treatments on larger surface areas of intact skin. Apply approx. 1.5g to 2g LMX4/10cm² of skin up to a maximum of 900cm². Apply until response is achieved which is generally between 30 to 60 minutes. Typical estimated quantities are 30-40g/200cm² (approx. 10cm x 20cm or covering a face), 45-60g/300cm² (approx. 10cm x 30cm or covering an arm), 135g-180g/900cm² (approx. 30cm x 30cm, or covering torso or back). The LMX4 Cream should be applied evenly at the specified dose with a uniform thickness across the area where the treatment will occur. Measures may be taken to ensure the cream remains undisturbed. Shortly before starting the topical treatment the LMX4 cream should be removed and the site for treatment prepared in the usual manner. **Contraindications:** Hypersensitivity to Lidocaine, or any of the amide-type local anaesthetics, or any of the excipients. **Precautions and warnings:** For external use only. Do not apply to irritated skin or if excessive irritation develops. Avoid contact with eyes. Do not use in large quantities or for longer times than those recommended. LMX4 Cream should not be applied to wounds, mucous membranes, or on atopic dermatitis as there is no clinical data relating to its use on such areas. Lidocaine should not be used in any clinical situation in which its penetration or migration beyond the tympanic membrane into the middle ear is possible. Repeated doses of Lidocaine may increase blood levels of Lidocaine. Patients with severe hepatic disease are at greater risk of toxic plasma concentrations of Lidocaine. Production of surface anaesthesia can block all sensations in the treated skin and trauma to the treated area such as exposure to extreme temperatures should be avoided until complete sensation returns. **Interactions:** Lidocaine should be used with caution in patients receiving Class 1 anti-arrythmic drugs. **Pregnancy and lactation:** LMX4 should be used during pregnancy only if clearly necessary. Caution should be exercised when LMX4 is administered to a nursing mother.

Undesirable effects: Application of Lidocaine can cause transient local blanching followed by transient erythema and other effects can include irritation, redness, itching or rash of the skin. In rare cases local anaesthetics have been associated with allergic reactions including anaphylactic shock. Systemic toxicity is unlikely but signs of systemic toxicity are blurred vision, dizziness, difficulty breathing, trembling, chest pain or irregular heart beat. **Basic NHS Price:** LMX4 5g £2.98, LMX4 30g £14.90. **Legal classification:** P **MA number and holder:** PL 20685/0034, Ferndale Pharmaceuticals Ltd, 12 York Place, Leeds, LS1 2DS. Prescribers should consult the Summary of Product Characteristics for further information. **Date of revision:** July 2013.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to
Ferndale Pharmaceuticals Ltd. contact details below

Ferndale Pharmaceuticals Ltd, Unit 740 Thorp Arch Estate, Wetherby, West Yorkshire, LS23 7FX. Phone: 01937 541122. Fax 01937 849682. email info@ferndalepharma.co.uk

REFERENCES

* LMX4 Summary of Product Characteristics (Date of Revision 28 June 2013)
† Taddio et al, CMAJ 2005;172(13):1691-1695

Date of preparation: July 2013 **Item code:** LMX4ACare0713

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