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JongSeo Kim

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Tumescent anesthesia for reducing pain, swelling, and ecchymosis during polycaprolactone filler injections in the face

JongSeo Kim

Kim-JongSeo Plastic Surgery Clinic, Seoul, Korea

ABSTRACT

PCL filler can be injected in two major ways to control pain. One such method involves mixing 0.3cc of PCL filler with lidocaine, and the other is the method introduced in this report, which involves pre-injection with a tumescent solution. It is hard to reduce pain effectively with pre-mixing PCL filler with lidocaine because there may be not enough time to act lidocaine solution effect immediately for pain control. The pre-mixing method changes the properties of the original filler, especially the property of the CMC portion. Therefore, in my simple and novel technique, tumescent solution is injected, followed by PCL filler which preserves the original CMC property. This is done after sedation of the tissue by the tumescent solution and dissection of soft tissue to create a space for the ensuing PCL injection. After pre-injection with tumescent solution, histological analysis indicated that the tissue did not become irritated in response to the foreign body material (PCL filler) or the mechanical trauma caused by the needle. That is the key mechanism of the tumescent injection method for reducing tissue reaction and that may reduce pain and swelling during and after PCL filler injections.

Introduction

Ellanse™ is composed of polycaprolactone (PCL) microspheres suspended in a solution of aqueous carboxymethyl cellulose (CMC) (1). PCL-based injectable fillers contain 70% CMC and 30% PCL by volume. Millions of PCL fillers are used in clinics globally, but the most immediate unwanted adverse effects are edema, pain, and ecchymosis, as many doctors have experienced and still hesitate to choose PCL filler for these reasons. PCL filler can be injected in two major ways to control pain (1). One such method involves mixing 0.3cc of PCL filler with lidocaine, and the other is the method introduced in this report, which involves pre-injection with a tumescent solution and is referred to as tumescent anesthesia injection method. It is difficult to reduce pain effectively by premixing PCL filler with lidocaine because not enough time may be available for the lidocaine solution to act and produce an immediate effect on pain control. The most important step in this method is the pre-mixing, which can change the properties of the original filler, especially that of the filler’s CMC constituent. Properties of CMC gel are decided by the proportions of water and glycerin. If water proportion is increased, gel viscosity must be decreased and its original function as carrier gel is lost. Depending on time, temperature, and pH, a CMC gel is easily contaminated by microbes or molds and few studies proving the safety of adding normal saline to CMC gels are available. Therefore, in my simple and novel technique, tumescent solution is injected, followed by PCL filler which preserves the original CMC property. This is done after sedation of the tissue by the tumescent solution and dissection of soft tissue to create a space for the ensuing PCL injection. After pre-injection (test injection or hydro-dissention injection) with tumescent solution, histological analysis indicated that the tissue did not become irritated in response to the foreign body material (PCL filler) or the mechanical trauma caused by the needle. That is the key mechanism of the tumescent injection method for reducing tissue reaction and this may reduce pain and swelling during and after PCL filler injections. 10 minutes after injection of tumescent solution, the solution will undergo spread and volume change will be minimized. Therefore it is not necessary to worry about volume change after by tumescent solution.

PCL is a material commonly used in surgical sutures, wound dressings, and surgical mesh. PCL is a well-known, totally bi-resorbable, soft medical polymer (2). According to the manufacturer; PCL is completely biodegradable over time, with the rate of degradation depending on the length of the PCL polymer chains in the microspheres at the time of implantation (3). Shorter chains degrade faster than longer chains, which means that the clinical duration of the effect can be controlled by shortening or lengthening the polymer chains (4). The product is available in various formulations S, M, L, and E by length of the polymer chains, with effects from one (S formulation) to four (E formulation) years. Ellanse™-M formulation was used in this study.

Materials and methods

Patients

A total of 30 patients (mean age of women was 42.3 years) were observed and were followed up from February 2013 to
January 2017. PCL filler gels (Ellansé M: AQTIS Medical, Utrecht, the Netherlands) were injected to faces of the patients using a 50-mm 23-G cannula (Figure 1). The right sides of patients’ faces were injected with pre-mixed PCL filler with lidocaine (1cc of PCL filler was mixed with 0.3cc of lidocaine). The left sides of patients’ faces were injected with pre-filled PCL filler after pre-injection of 1-3cc tumescent solution. The tumescent solution was composed of 100cc normal saline (N/S), 30cc of lidocaine and 0.3mg of epinephrine. Pain, swelling, and ecchymosis were also compared between the right and left sides of the faces of all 30 patients.

A biopsy was performed to compare tissue reactions (by histologic cell counting) after PCL injections in a 38-year-old woman who had a planned scar revision operation on the chin (Figure 1).

On the left side of her forehead, nasolabial fold, and chin, 3cc of tumescence was injected with a 50 mm-23G cannula after making entry points using a 23-G sharp needle. Ten minutes after tumescence injection, swelling induced by tumescent solution had subsided and PCL injection was performed. 0.75cc of PCL filler was injected into the sub-muscular layer to augment the patient’s left forehead. 0.75cc of PCL filler gel was injected into the subdermal layer on the left cheek area and left chin area to improve skin tightness. 0.5cc of PCL filler was injected into the subdermal layer to treat the left nasolabial fold using a 50mm-23G cannula. 10 minutes after tumescent anesthesia, anesthesia solution-induced swelling was subsided with the application of mild compression. A total of 2cc of PCL filler gel was used for the patient’s left side (Group 1).

In comparison, 2cc of PCL filler was mixed with 0.6cc of dental lidocaine for treating the right side of her face. (The ratio for pre-mixing solution of PCL filler and dental lidocaine was 1:0.3cc.) 0.975cc of pre-mixed PCL filler (0.75cc of PCL filler and 0.225cc of dental lidocaine) was injected on the right side of her forehead, 0.975cc of the mixture was injected on the right side of cheek and chin areas, and 0.65cc of mixture (0.5cc of PCL filler and 0.15cc of dental lidocaine) was injected into right nasolabial fold using a 50-mm 23-G cannula at the same depth.

Finally, 4cc (left side 2cc and right side 2cc) of PCL filler was injected on both sides. One day (21 hours) after the injection, the scar excisional operation was performed on her chin area. Two biopsy specimens were obtained from her left and right sides of the chin near the scar. To compare tissue reaction after PCL injection, a quantitative histological analysis was performed. Histologic cells or inflammatory cells were counted on each of the 10 slides. The histologic cells were counted only around PCL particles on each slide, and the cell counting numbers were divided by number of visible PCL particles (microspheres). The number of histocytes per PCL particle on left (tumescent anesthesia first) and right (pre-mixing method) sides was compared.

**Assessment of pain, edema, and ecchymosis**

The level of pain, swelling, and ecchymosis experienced by the patients was compared between the right and left sides of the face, the next day using a five-point scale ranging from very low to severe, for all subjects.

**Biopsy study**

A scar revision operation was planned for a 38-year-old woman, and she was treated with PCL filler for facial augmentation one day before the operation (Figure 1). Two biopsy specimens (left and right sides of the chin scar) were obtained from her chin area during scar revision (21 hours after PCL injection) to compare the tissue reaction through a quantitative histological analysis. Each of the 10 slides was stained with Hematoxylin & Eosin (H&E). It was hypothesized that severe swelling and ecchymosis would correspond to a greater abundance of histocytes or inflammatory cells around the PCL particles, and that the absence of a response involving tissue damage and irritation would correspond to less inflammation. The number of histocytes only around PCL particles on each slide, and the cell counting numbers were divided by number of visible PCL particles (microspheres). The number of histocytes per PCL particle on left (tumescent anesthesia first) and right (pre-mixing method) sides was compared.

**Scanning electron microscopy**

The individual particles of PCL filler were visualized with a scanning electron microscope (SEM) in order to confirm the data provided by the manufacturer about the shape, surface, and diameter of the particles. Diameter of PCL particles was measured by SEM.
Results

Assessment of pain, edema, and ecchymosis

Important differences in, pain, edema, and ecchymosis were observed between treatment by PCL Injection after pre-injection with tumescent solution (left side of face) and pre-mixing PCL filler with lidocaine (right side of face). There were severe swelling (mean score, 4.8), pain (mean score, 4.7), and ecchymosis (mean score, 4.2) after premixing PLC with lidocaine on the right side. Most injected areas on the left side showed fewer signs of swelling (mean score, 3.2), pain (mean score, 2.4), and ecchymosis (mean score, 2.7) (Table 1, Figure 1). Swelling, pain, and ecchymosis were significantly reduced in the area injected PCL filler after tumescence anesthesia in the left side, and the tumescence anesthesia method prevented edema and pain after the injection of PCL filler.

No significant long-term differences were observed between the left and right sides, but there were differences in initial swelling and ecchymosis. Thus, it may be concluded that the efficacy of Ellansé was not compromised by this new method, and that it was associated with a less intense immediate tissue reaction and a reduced inflammatory reaction, as confirmed by the histological analysis of biopsy samples and clinical findings.

Biopsy study

Significant histological differences were noted between right and left sides. Large numbers of histocytes were observed around the PCL particles on the right side one day after the injection of the PCL filler. In contrast, the specimens from the left side showed relatively fewer histocytes around PCL particles (Figure 2). The number of histocytes in direct contact with PCL particles was significantly different one day after injection. The number of histocytes around PCL particle was calculated and was divided by the number of PCL particles. (The number of histocytes/number of PCL particles.) The mean of histocytes per PCL particle on the right side was 3.2798, and the number of histocytes on the left side was 1.4235 (Table 2).

Scanning electron microscopy

On SEM imaging, the particles of PCL filler were found to be fully round and very smooth (Figure 3). Mean diameter of PCL particles that were fully visible (were not hidden by other PCL particles) was 39.42 microns.

Discussion

Various concentrations of lidocaine solution or epinephrine can be mixed with the calcium hydroxyapatite (RADIESSE™) (1). PCL dermal fillers (Ellansé™) could also be prepared using this same method. Many previous studies have found that it is safe to use a mixture of a calcium hydroxyapatite filler (CaHA) and lidocaine or lidocaine/epinephrine solution. With 10 to 20 strokes, the lidocaine solution can be hand-mixed with a PCL or CaHA dermal filler, resulting in a homogenous blend described in many publications (1). But the viscosity, elasticity, and extrusion force have been shown to decrease with increased volumes of lidocaine (1,5). However, this pre-mixing technique has some potential problems, such as contamination, the potential uneven distribution of the particles, and changes to the original properties of the CMC component. This pre-mixing technique could potentially disrupt neocollagenesis due to unfavorable distances among the PCL particles and Loss of function of the CMC gel. For reducing pain only, premixing method has serious adverse effects such as contamination, changing property of CMC, changing or disruption of each particle, uneven distribution of PCL particles, and uneven mixing CMC.

After making an entry point with a 23G needle, sufficient quantities (1cc or 2cc) of the tumescent solution was injected using a 23G cannula. The tumescent syringe was then replaced with a prefilled PCL filler syringe, maintaining the same cannula in the entry point. Once the 23-gauge cannula is inserted through the entry point during application of tumescent anesthesia, PCL filler can be injected via the same cannula without removing it. To reduce bias by initial volume changes due to tumescent solution, mild compression can be done for 10 minutes.

Before this study, the author had injected 0.5cc PCL filler only on the right side of the nasolabial fold on his own face via a 23G 50mm cannula after tumescent solution anesthesia to experience any effects on pain and swelling reduction. After injection of Ellanse using tumescence, the author was able to return to work immediately afterward, with no significant ecchymosis or swelling, and could strongly recommend the use of tumescent anesthesia prior to PCL filler injection.

There are other advantages in using tumescent anesthesia method with the injection of PCL filler.

Firstly, it is much safer from adverse effects, such as vascular problems and embolisms, than injection of Ellanse™ itself. After injection of the tumescent solution, Firstly, it is much safer from adverse effects, such as vascular problems and embolisms, than
injection of Ellansé™ itself. During injection with the tumescence (test injection with tumescence), if there is bleeding, the risk of vascular problem would be higher and the filler materials can breach the vessels through the damaged vascular wall. During this period, the physician may notice embolisms in the area, or torn vascular structures even when using a cannula. Therefore, if the bleeding was seen after tumescence injection, filler injection should be postponed to another day. The author had experienced an unfortunate case of skin necrosis on temple area even after injecting tumescence injection. The author had injected tumescence first on temple area with 23-G cannula, but moderate bleeding was seen from the entry point. After compression of the temple area for five minutes, the author injected CAHA filler gel but this resulted in unwanted adverse events. Filler should not have been injected as tissue trauma was already apparent and could risk vascular problems. The following day, swelling was seen on temple area. After two days, the skin color had changed to dark reddish, and the patient had suffered from pain on temple area. A 2-cm necrotic area of the skin occurred, even though the patient was hospitalized for further treatment. Therefore, the use of cannulas does not always protect from vascular problems.

Secondly final result can be confirmed and predicted by injection of tumescent solution. Right after the injection of tumescence, I show the volume change made by only tumescence to patients. Then patients and injector can also predict final result. After test injection with tumescence anesthesia, the patient can decide if she wishes to proceed with fillers and the injector can adjust the amount of filler gel injected by estimating the volume of tumescent solution in the shape produced.

Table 2. 3 histocytes were counted around 1 PCL particle on the right side of the face (red bar). 1 histocyte was counted around 1 PCL particle on the left side of the face (blue bar).

![Comparison of histological findings between left (tumescence anesthesia) and right sides (pre-mixed PCL injection with dental lidocaine)](image)

The mean number of histocytes per PCL particle

![Bar graph showing the mean number of histocytes per PCL particle](image)

Figure 2. Comparison of histological findings between left (tumescence anesthesia) and right sides (pre-mixed PCL injection with dental lidocaine) (left). There were relatively less histocytes around PCL particles in specimens from the specimen of left side, in which the tumescence anesthesia method was used (right). In contrast, on the right side of the patient, relatively excessive amounts of histocytes or inflammatory cells are present around the PCL particles (white circle showing that the diameter was about 40 microns) after the injection of premixing PCL filler with lidocaine. Histocytes were counted around PCL particle and the number of histocytes was divided by PCL particles in each of the 10 specimens.

![Figure 3. Scanning electron microscopy views of PCL particles in Ellansé filler. (A) The particles size was 39.42 microns in the study. (B) The surface of the particles was smooth, and the shape was fully round.](image)
Thirdly, the injection with the tumescence can create a safe space for filler injection by hydro-dissection and facilitate easier injections with lower syringe pressure. Lower pressure on the plunger during filler injection produces safer injections and lowers the risk of vascular complications and other adverse effects.

This simple tumescence anesthesia method was very easy to perform and effectively prevented swelling, pain, bruising, and even vascular problems when injecting the PCL filler. In contrast, a pre-mixture of PCL filler with dental lidocaine did not effectively prevent pain during the injection in this study. PCL filler mixed with lidocaine was also unable to prevent ecchymosis because not enough time was left for the vessels to shrink and for the tissue reaction to be inhibited. This technique also did not reduce swelling. In contrast, most of the patients who underwent the tumescence anesthesia technique were able to return to work immediately after the injection, because they experienced less swelling and discomfort. The tumescence anesthesia method employs an extremely simple mechanism for reducing swelling: namely, the inflammatory cells are sedated such that the patient’s soft tissue does not respond to irritation from the material injected (PCL filler) or tissue trauma.

Outcomes of augmentation and wrinkle improvement were similar in both the groups. The tumescence anesthesia method is only advantageous in terms of recovery time, relief of pain (during and after injection of PCL filler), reduction of ecchymosis, and safety from vascular problems. Safety from vascular problems and welfare of patients must be seen as paramount. Since injections of tumescence anesthesia result in pain and swelling, many doctors avoid using it. However, with the method introduced in this study, tumescence anesthesia before PCL filler injection could become a very simple and effective procedure.

PCL filler has not been approved by the US Food and Drug Administration (FDA), but was approved by the Korean FDA at the end of 2012. The author has used hundreds of syringes of PCL filler (Ellanse) for treating forehead wrinkle and augmentation, treating the neck fold, and performing hand rejuvenation, nose augmentation, cheek rejuvenation, and nasolabial fold treatment. Another report by the author has demonstrated that a thin layer of collagen and a tiny area of scaffolding around the PCL micro-particles have been observed 13 months after injection (6). PCL filler increases effects by stimulating new collagen formation. In that article, the new tissue around the PCL particles contained not only collagen I but also collagen III. A sufficient amount of collagen will take place approximately one year after the injection.

CMC itself stimulates tissue reaction for one month, and the author observed giant cells the CMC component of the filler (unpublished data). Since 70% of Ellanse by volume is CMC, an overall decrease in volume takes place due to resorption after one month. Ultimately, approximately 50% of the original CMC volume is replaced by new vascular tissue and connective tissues, resulting in volume loss one month after PCL filler injection (6). CMC in Radiesse filler caused redness and excessive tissue reaction in some cases several years ago but in 2016 and 2017, excessive tissue reaction was never found after Radiesse injection. The author believes that the CMC component in Radiesse® has improved. However, the CMC component of Ellansése fillers is different to that in Radiesse®, in the author’s opinion. CMC are not all of the same quality.

With regards to collagen formation after filler (stimulator) injection, the amount of neovascular formation depends on the patient and the injection area. The volume graph provided by AQTIS (now Sinclair Pharma) was not correct for most patients because the initial volume loss of CMC portion (CMC gel is absorbed 1 or two months after injection) was not reflected in the company’s data. Some physicians demonstrated with computer scanning programs that the volumization effect was maintained over 1 year but this was not the usual clinical progression of the procedure. CMC could not be replaced by soft tissues after injection in the author’s own studies (6). The author is conducting further analysis of PCL fillers with H&E, PSR, Herovici’s stain, and immunochemistry antibody stain will be introduce in next articles by author. The key to maintaining volume after the injection of PCL filler is the formation of new vascular tissue and stimulation of collagen production. Booster injections with PDRN or PRP can promote vascular tissue stimulation, but initial volume loss after injection must have occurred as the CMC portion can be absorbed even while new collagen or soft tissues are growing.

To confirm manufacturer’s data, PCL particles were studied with electron microscopy. The surface of the microsphere particles and their size were confirmed via electron microscopy. PCL particles were fully rounded and had very smooth surfaces. Moreover, the tissue reactions around particles of PCL fillers was studied histologically. PCL filler is both a good dermal filler and a stimulating filler (6).

ORCID
JongSeo Kim http://orcid.org/0000-0003-1428-5898

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