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Case Report

A Clinical Case Series: Australian Validation of Liquid Polycaprolactone Injectables

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Abstract

Objective: To validate the use of a fully-liquid form of Polycaprolactone (Gouri) collagen stimulator on facial skin rejuvenation in Australia.

Background: For decades, different fillers types are used for augmentation of volume loss and improvement of skin quality [1]. Polymer-based collagen stimulators are characterised by their long duration of action and biostimulatory properties.2 Polycaprolactone (PCL), a biodegradable and bioresorbable aliphatic polymer, has been used in aesthetics improving facial aging features such as fine wrinkles, contour laxity and volume loss. Polylactic acid (PLLA) and polyglycolic acid (PGA) also both belong to the same chemical family [2-5]. Multiple studies on PCL in the form of microspheres suspended in carboxymethyl-cellulose gel carrier have been described [2,3,5-7]. However, they only act locally where it is injected. Commonly associated with injection technique, nodule and granuloma formation occurs due to localised overabundance of product or immune response to an isolated hypermobile region where facial muscle animation can accumulate the product together [8]. theoretically, this can be minimised by a fully-liquid form of collagen stimulator. Hence, fully-liquid polycaprolactone has been recently developed which naturally spreads on the entire face and increases the collagen synthesis rate with minimal risk of granuloma and nodule formation [9] While the use of this product has been trialled and validated overseas, to the best of our knowledge, the treatment protocol has not been trialled for use or validated in Australian patients.

Methods: Two Australian adult females who have not had any collagen stimulating products injected previously have been included in this descriptive case study. Liquid PCL was injected on 10 injection points on the face as per product protocol established overseas. The procedure was then repeated 4 weeks later. Photos taken before injection, 4 weeks and 12 weeks post injection were compared and evaluated using Global Aesthetic Improvement Scale (GAIS) accordingly using both patients' and two independent aesthetic practitioners scores.

Results: Both patients achieved significant improvement on their skin quality and fine wrinkles using the GAIS. They both tolerated the treatment procedure without major complication. Minor facial swelling occurred on one of the subjects, which was resolved by taking oral steroids. Both patients were satisfied with the treatment outcome.

Conclusion: This case report validates the effectiveness of the established protocol in Australian patients. The 2ml of product, delivered by needle into 5 injection points on each side of the face in sequential treatments spaced 4 weeks apart, demonstrate a safe treatment protocol with no long-term adverse effects noted. Forthcoming data from further investigations will reinforce knowledge of the product including its long-term outcome and safety.

Introduction

Collagen, a major component of the extracellular matrix (ECM) providing essential structural support, is a functional protein interacting at different cellular levels. In skin, fibrillar collagen type-I (85%) and type-III (10%) are predominant. However, reduction of fibrillar collagen which is well-described using histological approaches, is a characteristic feature of chronologically aged skin [1]. With aging, changes in fat, bone, muscles, and ligaments, loss of collagen, its disorganization and fragmentation, all play a central role in the associated skin changes accompanied by changes in other components of the ECM. The fragmentation of the collagen fibres impairs its interaction with the fibroblasts, inducing modification of the cell morphology, thus reducing mechanical forces. Collagen decrease is accompanied by an increase in metalloproteinase levels. The collagen-related aging process has been extensively investigated and reviewed [1]. Aging signs can be improved through volume restoration and collagen stimulation in multiple soft tissue layers by using hyaluronic acid or non-hyaluronic acid fillers. Successive dermal fillers made available were all designed to provide improved safety and longer action duration (e.g., collagen, free or uncross-linked hyaluronic acids, cross-linked hyaluronic acids and collagen stimulators). Collagen stimulators, i.e. polymer-based products have the longest action duration compared to hyaluronic acid-based fillers [2,3].Collagen stimulators are characterized by their long duration of action and biostimulatory properties [4] In 2009, a novel collagen stimulator (Ellansé®, Sinclair Pharma, London, UK) was introduced in Europe [5]. Ellansé® is composed of PCL microspheres (30%) suspended in an aqueous carboxymethyl cellulose (CMC) gel carrier (70%), which provides an immediate but temporary filling effect [5]. The PCL microspheres contribute to long-term volume by stimulating new collagen production. As the CMC gel is absorbed in the first 6-8 weeks, the loss in volume from the carrier gel is gradually replaced by the newly formed collagen because of the PCL-induced neocollagenesis [5-7]. It is indicated for subdermal implantation in the face for improvement of facial age-related conditions and hand rejuvenation. Further development of PCL leads to regeneration of new collagen without the use of microparticles. This liquid-type PCL spreads on the entire face forming new collagen and achieving full facial skin rejuvenation and theoretically minimises the risk of granuloma and nodule formation.7 However, no report has been described regarding its short or long-term effects. This case report aims to describe the short-term treatment outcome of this product in Australia.

Materials and Methods

The product injected was Gouri, a microparticle-free liquid polycaprolactone dermal filler. Each syringe contains 1mL and 0.2mL is injected to the deep dermis using a 31G needle. A bolus technique consisting of 10 injection points on the face is used according to the product general protocol. Each subject received 2mL of the product (1mL per side of face). The use of this technique minimises the variation between subjects and ensures that the injection point does not touch the vital structures [8].

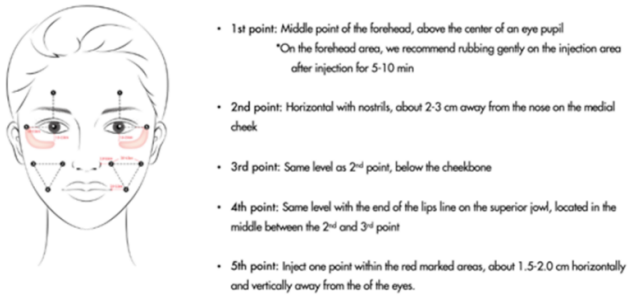

Figure 1: Gouri General Protocol.

Two female volunteers aged 28 and 32 with moderate facial fine lines and requesting restoration were included in this case report. Pre-treatment photos were taken for documentation (Figure 2a and 2b) including skin markings for injection on the patient (Figure 3). Both patients took a dose of antihistamine Loratidine 10mg po before treatment as per product recommendation.7 A post treatment telephone interview was carried out day 1 post injection and immediate response to treatment were recorded. Second treatment was performed 4 weeks later following the same protocol. Patients were encouraged to report to the authors any unusual findings or response at any time during and after the treatment. Photos were taken pre-treatment, 4 weeks and 3 months post treatment. Global Aesthetic Improvement Scale (GAIS) was used to measure the extent of improvement of the subjects (Figure 4). Both patients and two independent aesthetic practitioners provided the scoring of GAIS.

Figure 2: Pre-treatment photos of patient 2.

Figure 3: Skin markings for Gouri injection sites according to general protocol.

	Degree	Description
1	Exceptional improvement	Excellent corrective result
2	Very improved patient	Marked improvement of the appearance, but not completely optimal
3	Improved patient	Improvement of the appearance, better compared with the initial condition, but a touch-up is advised
4	Unaltered patient	The appearance substantially remains the same compared with the original condition
5	Worsened patient	The appearance has worsened compared with the original condition

Figure 4: Global Aesthetic Improvement Scale (GAIS).

Results

Both patients tolerated and completed the 2 session procedures. Both also developed temporary (i.e., less than 48 hours) of localised swelling on the injection sites with surrounding erythema (Figure 5). First patient's swelling subsided spontaneously without requiring intervention. However, second patient's swelling after her second session required non-steroidal anti-inflammatory drug and a short 3-day course prednisolone 10mg po per day which then resolved her swelling. There was no bruising, visible or palpable lumps, discolouration, signs of vascular occlusion, granuloma/ nodules or infection noted. Photo comparison of both patients' pre-treatment, 4 weeks and 3 months post treatment is presented in Figure 6. The average GAIS for both patients is 4 and for both independent aesthetic practitioners is 3. Overall average GAIS is 3.5.

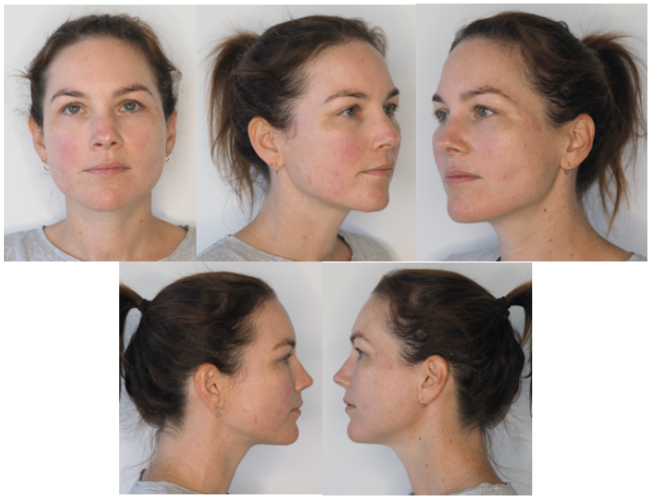

Figure 5: Immediately after injection. Note transient erythema surrounding the injection sites.

Figure 6: Comparison pre-treatment, 4 weeks and 3 months post-treatment.

Discussion

PCL-based dermal filler has been used for over a decade and it has shown advantages over traditional hyaluronic acid and carbon hydroxyapatite-based fillers because it presents with more stable and durable results [2,3,4]. The use of the PCL-based dermal filler has not been limited to the subcutaneous and supraperiosteal levels of the face; increase in skin thickness was shown in a

study using a particular off-label techniques [9]. The response to injection of the product, as with any injection, that creates an injury triggers a tissue repair process. The collagen induced by the PCL filler follows the healing cascade characterized by three main phases: inflammation, proliferation and remodelling; granulation tissue formation and early appearance of collagen type-III is followed by long-term collagen type-I production and deposition, in the remodelling phase [10,11]. Recent progress of PCL has led to development of liquid PCL. This product is the first of its kind and utilises CESABP (collagen enabled solubised active and biodegradable polymer) technology which enables regeneration of collagen and rejuvenates skin without the use of microparticles [8]. Liquid PCL naturally spreads and regenerates collagen on the entire face giving sustainable results preventing skin aging through deep skin rejuvenation. It restores the collagen synthesis rate which has decreased due to skin aging and rejuvenates the skin [8]. This limited case report of 2 patients has photographically demonstrated an improvement in difficult to treat areas (e.g., accordion lines) without granuloma formation. Traditional hyaluronic acid fillers are generally not indicated in these regions as adding volume in these locations can be associated with more heaviness and therefore more ageing facial features. An established overseas protocol is utilised in this study on Australian patients have proven good efficacy (i.e. improvement of fine wrinkles) with minimal complications (i.e. short-term swelling). The short-term benefits of using a fully liquid PCL were the absence of nodules or granuloma formation. However, detailed evaluations with larger cohort of patient over time would be required to fully access this.

Conclusion

The field of aesthetics is constantly evolving and ongoing development of creating an innovative, safe and long-lasting collagen stimulator is continuously being pursued. After decades of its first synthesis, polycaprolactone or PCL, a well-known polymer, has proven its role in improving aesthetics. The first liquid PCL shows satisfactory results in this case report when using established protocol volumes and techniques. The participants experienced no granuloma or nodule formation; the benefits hypothesized with a fully liquid PCL. Further studies including long-term outcomes, measurement of skin extensibility and viscoelasticity can be conducted.

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