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Development of biodegradable ϵ -poly(caprolactone) dermal fillers: Comparisons of physical properties and preclinical evaluation

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As the era of population aging approached, people pursue a beautiful life along with a healthy life. Several injectable dermal fillers have been launched and become an increasingly popular option in the treatment for not only aesthetic facial enhancements but also congenital or traumatic facial, body and soft tissue defects. HA (Hyaluronic Acid) filler accounts for 90% of the current market. However, there has been a growing demand for safer and longer-lasting products in the beauty market. In this way, fillers using biodegradable polymers have attracted much attention in the market due to their longer-lasting properties and intrinsic volumizing effect. Unlike HA filler, which maintains the volume of skin with the volume of the product itself, the biodegradable polymer filler regenerates and maintains the volume naturally by inducing the production of collagen as the polymer is biodegraded. Among them, ϵ -Poly(Caprolactone) (PCL) based dermal filler is introduced into the beauty market in 2009 with the properties of biodegradable and safety which has been approved by FDA (Food and Drug Administration) and CE (Conformite Europeenne). In this study, we developed new PCL based dermal filler, SF-01 composed of porous microspheres. The purpose of this study is the comparison of two kinds of PCL based dermal filler (SF-01 with porous microspheres, licensed PCL filler with smooth microspheres) by testing physical properties and performing preclinical evaluation. The values of injectability, rheological properties, initial volume, durability until 24th week, inflammatory/foreign body reaction and collagen formation of SF-01 were tested and compared with licensed PCL filler product. Overall, it is confirmed that SF-01 is superior in durability and shape retention compared to the licensed product and the *in vivo* safety is equivalent. These results suggest our SF-01 would be a promising candidate for dermal augmentation.

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