

# Post-market Evaluation for the Safety of the Current Local Practices of Injectable Dermal Filler

## Study Category:

- Post-market evaluation study (دراسة تقييم سريري)
- Risk analysis study (دراسة تحليل مخاطر)

## BACKGROUND

Recently, Injectable dermal filler has been widely used in Saudi Arabia. Injectable dermal filler is classified as a medical device. It is a gel-like substance that is injected underneath the skin. It is a minimally invasive esthetic procedure that helps to reduce facial lines and wrinkles and restore fullness and volume in the face, creating a smoother appearance. Moreover, it can enhance the lips and increase their volume. Despite the benefits of injectable dermal fillers, the number of complications has been increased due to the widespread use of injectable dermal fillers [1,2]. This study aims to evaluate the safety and the current local practice of using injectable dermal filler, and to evaluate the awareness of approved uses for injectable dermal fillers. In addition, evaluating the awareness of the healthcare providers about reporting adverse events of injectable dermal filler to the SFDA.

## EVALUATION OUTCOMES

### Part I: Methodology

An online survey approach was developed in order to evaluate the safety and current local practice of injectable dermal filler in Saudi healthcare providers. A survey was prepared and sent to healthcare providers around KSA including public, private, and other types of healthcare providers.

### Part II: Results

The significant findings of this study indicate that Hyaluronic Acid is the most common type of filler used by healthcare providers. All used injectable dermal fillers have Medical Device Marketing Authorization (MDMA). Healthcare providers use dermal fillers as intended by the manufacturer. However, few healthcare providers need further investigation as they have applied it in the other areas of the body, such as 15% for body contouring or enhancement and 8% is applied in the breast and buttocks. 54% of healthcare providers stated that patients experienced common complications after injectable dermal filler. 85% of healthcare providers report the complications of dermal fillers to the Saudi FDA (National Centre for Medical Devices Reporting (NCMDR)). Furthermore, most healthcare providers have a policy and

procedures for allergic tests for patients before receiving injectable dermal fillers. Only 15% of healthcare providers do not have a policy and procedures for the allergic test. In addition, 15% of healthcare providers do not have a specific age for patients to receive injectable dermal fillers. Finally, all healthcare providers do not use needle-free devices to inject dermal filler.

### **Part III: Conclusion**

In conclusion, the injectable dermal filler has many advantages for different applications. However, it should be used according to the manufacturer's instructions for use to avoid any safety complications that may occur. Moreover, the results showed the importance of increasing the awareness level of reporting any incidents/complications that may occur to the National Centre for Medical Devices Reporting (NCMDR).

### **SFDA RECOMMENDATIONS**

Based on the study findings, the following actions are recommended:

#### **SFDA regulation action:**

- Develop safety communication for all medical beauty centers / clinics that use injectable dermal filler including the following:
  - Healthcare providers must use the approved injectable dermal fillers by Saudi FDA.
  - Healthcare providers must use injectable dermal fillers as indicated by the manufacturers.
  - Healthcare providers must be specialized, trained, and qualified to use injectable dermal fillers.
  - Healthcare provider must inform the patient of all possible complications of injectable dermal fillers and the specific product they intend to use.
  - Healthcare providers must report the incidents or complications of the injectable dermal fillers to the Saudi FDA through the National Center for Medical Devices Reporting (NCMDR).
  - Healthcare providers must have a policy and procedure for allergic tests for patients before receiving injectable dermal fillers.

For more information about the SFDA Safety Communication, please [click here](#).

- Awareness materials about the injectable dermal filler devices for public by SFDA.

## ACKNOWLEDGMENT

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For further information or inquiries related to this study, you may contact us at: [cia.md@sfda.gov.sa](mailto:cia.md@sfda.gov.sa)

## REFERENCES

- [1] FDA, "Dermal Fillers (Soft Tissue Fillers)," 2021. [Online]. Available: <https://www.fda.gov/medical-devices/aesthetic-cosmetic-devices/dermal-fillers-soft-tissue-fillers>.
- [2] "Dermal filler," American society of plastic surgeons, 2022. [Online]. Available: <https://www.plasticsurgery.org/cosmetic-procedures/dermal-fillers>.