Digital Twin for needle acceleration in an intradermal injection device.

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BACKGROUND & AIMS

The human skin is a complex multilayered material (epidermis, dermis, hypodermis). Its stress-strain curve is hyper-elastic, with a non-constant Youngs modulus (E-modulus).

Also, based on literature, it is known that the failure/breaking strength of human skin is at 10MPa or more. These parameters make it challenging to penetrate the skin with very short and thin needles, as the skin will tent and not break, resulting in failed delivery or leakage of medical substances.

Novosanis' VAX-ID is an injection device suited for perpendicular, accurate and painless drug delivery in the dermis, the layer underneath the epidermis, at a depth of 0.65 to 1.20mm, using needle acceleration to penetrate/break the skin.

Intradermal injection allows for an improved immune response due to its targeted drug delivery. VAX-ID® (Fig. 1) can be used for both prophylactic and therapeutic intradermal vaccination, immunotherapy as well as for anti-allergic drugs, dermatological products and other substances suited for injection in the skin.

The aim of this study was to build a Finite Element simulation (FEA) model to verify acceleration of and kinetic energy in the VAX-ID® needle before it penetrates the skin.

Fig. 1: Novosanis VAX-ID® Gen 2 intradermal injection device.

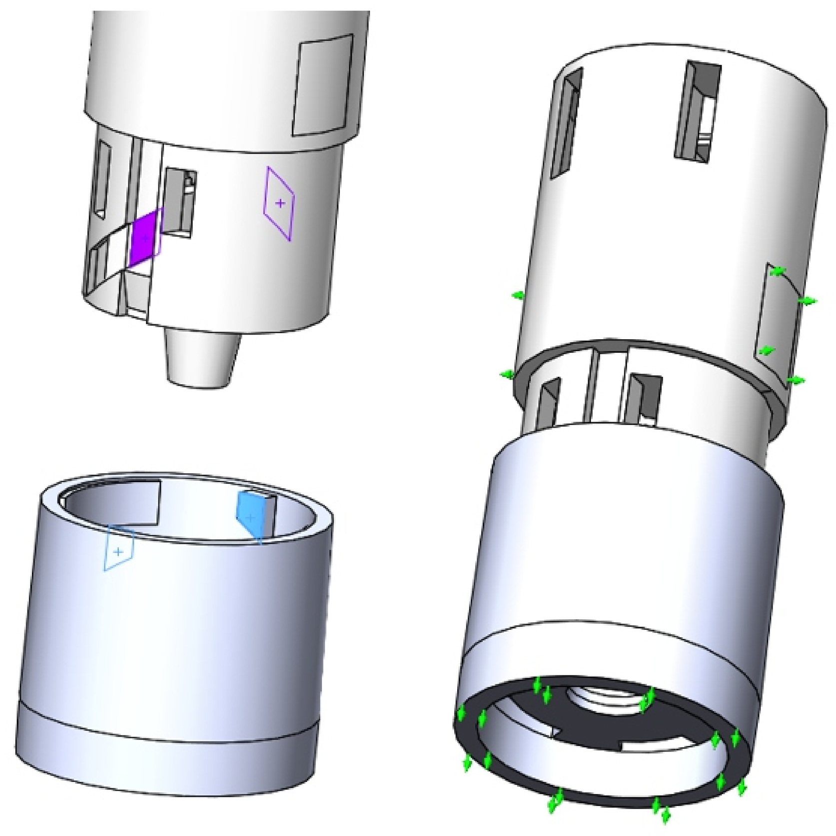

Fig. 2: Simplified CAD geometry of PC housing & PP foot.

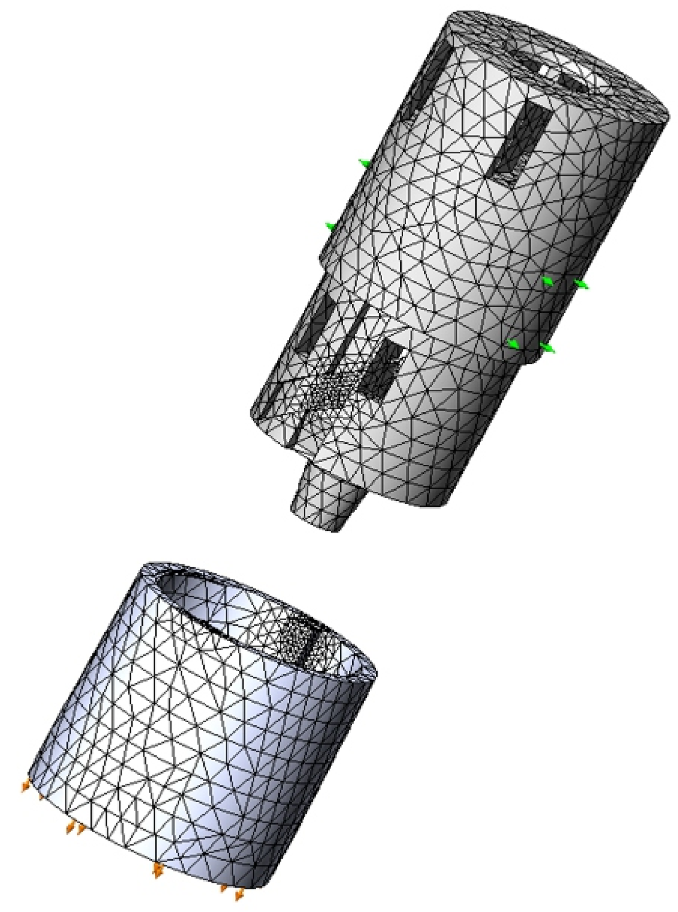

Fig. 3: Tetrahedral Finite Element Mesh.

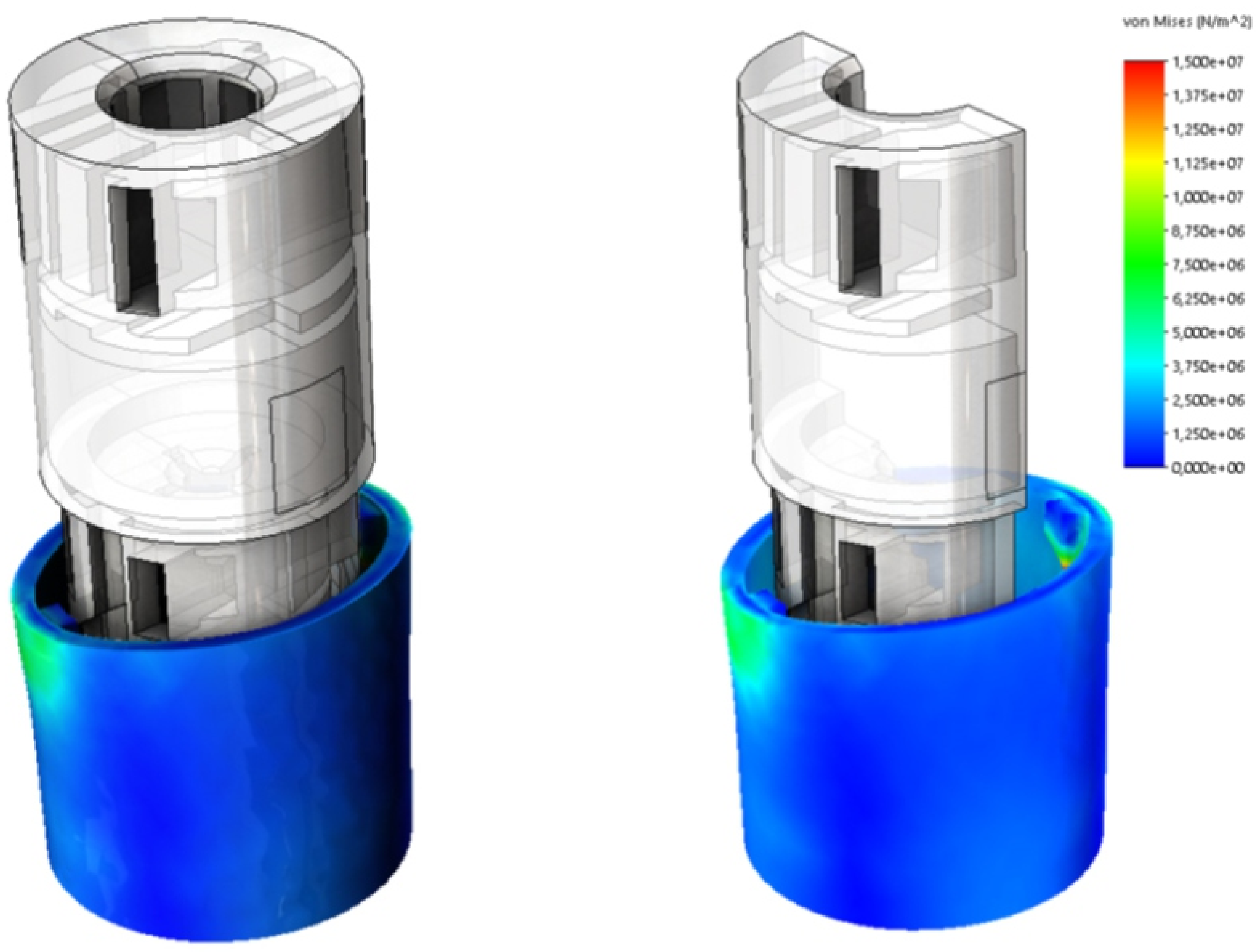

Fig. 4: Von Mises Stress to calculate (i) Friction Force, (ii) Kinetic Energy

MATERIALS, METHODS & RESULTS

A simplified FEA CAD model (Fig. 2) was built of the needle adaptor, interacting with its activation foot. Subsequently, this was the approach:

(i) Empirical test to define the friction coefficient between polycarbonate (PC) adaptor and polypropylene (PP) foot: 0.36

(ii) Programming of material characteristics of PC (Young 2400 MPa, Poisson 0.39) and PP (Young 896 MPA and Poisson 0.41) and contact analysis between both components: shrink fit for prestressing, with roller-slider constraints for skin contact and the administers' fingers

(iii) Tetrahedral meshing of the geometry and simulation solving to acquire Von Mises stress on the foot (Fig. 3)

(iv) Calculation of the Friction Force (5.51N), Kinetic Energy (0.044J) Needle Acceleration and Speed (1.02m/s) (Fig. 4)

CONCLUSIONS

Correlation between prototypes for empirical research and virtual FEA simulation models as digital twin allows for fast and targeted development of injection devices.

(i) This simulation model enables further industrialization and design of new variants of VAX-ID® for intradermal injection

(ii) Needles of 27-33G in diameter, penetrating the skin at 1m/s, carry sufficient kinetic energy to break a skin strength of 10MPA

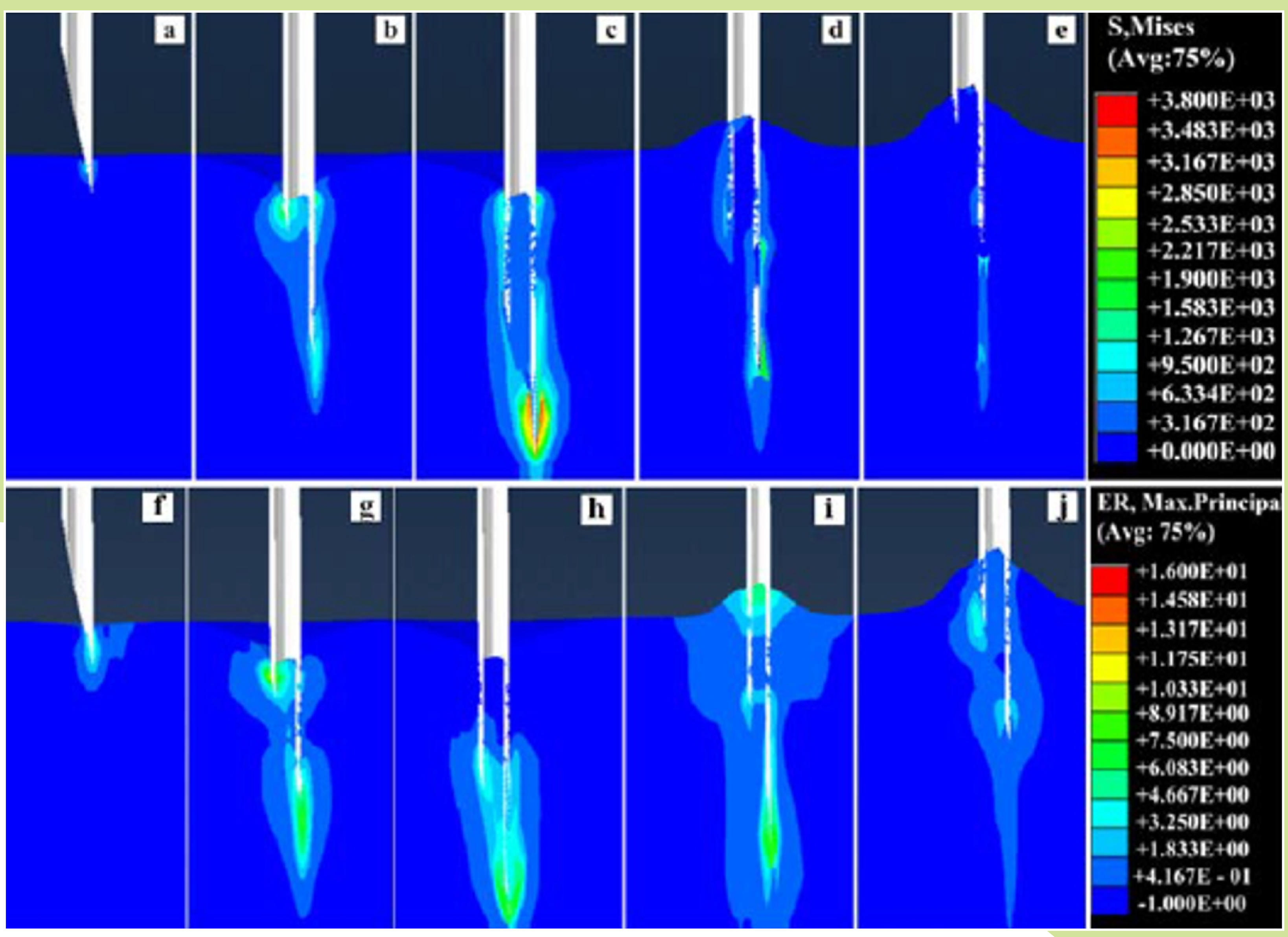

Fig. 5: Stress & Strain distribution of the needle penetration process - Jiang et all 2016

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