Shear Stress Test for the Determination of the Optimal Needle Diameter for Injection of Dendritic Cells

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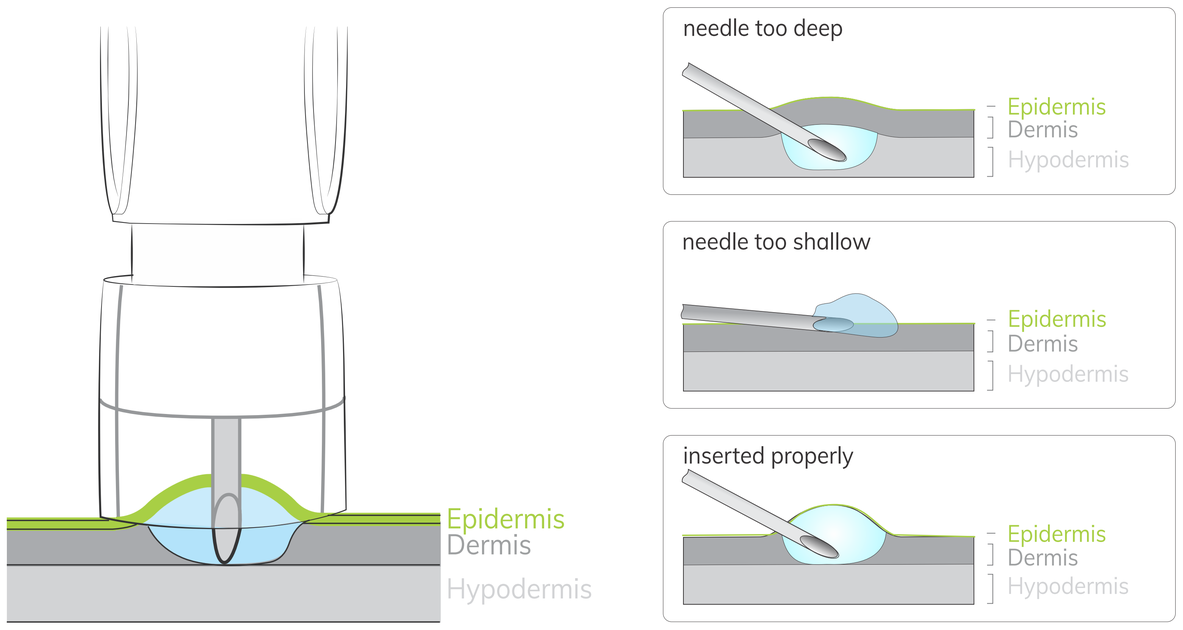
BACKGROUND & AIMS

Recent studies proved the importance of tolerogenic dendritic cells (tolDCs) in autologous cell therapy, including treatments for multiple sclerosis, diabetes type I and rheumatoid arthritis.

For the treatment to be effective, it is important that a large number of viable, functional cells reach the site of action. The main cause of potential cell damage during intradermal injection is shear stress. This will damage the cells, causing a decrease in cell viability and a change in cell phenotype.

This study aimed to determine the optimal needle diameter for intradermal injection of tolDCs to not only avoid shear stress damage but also ensure optimal patient comfort.

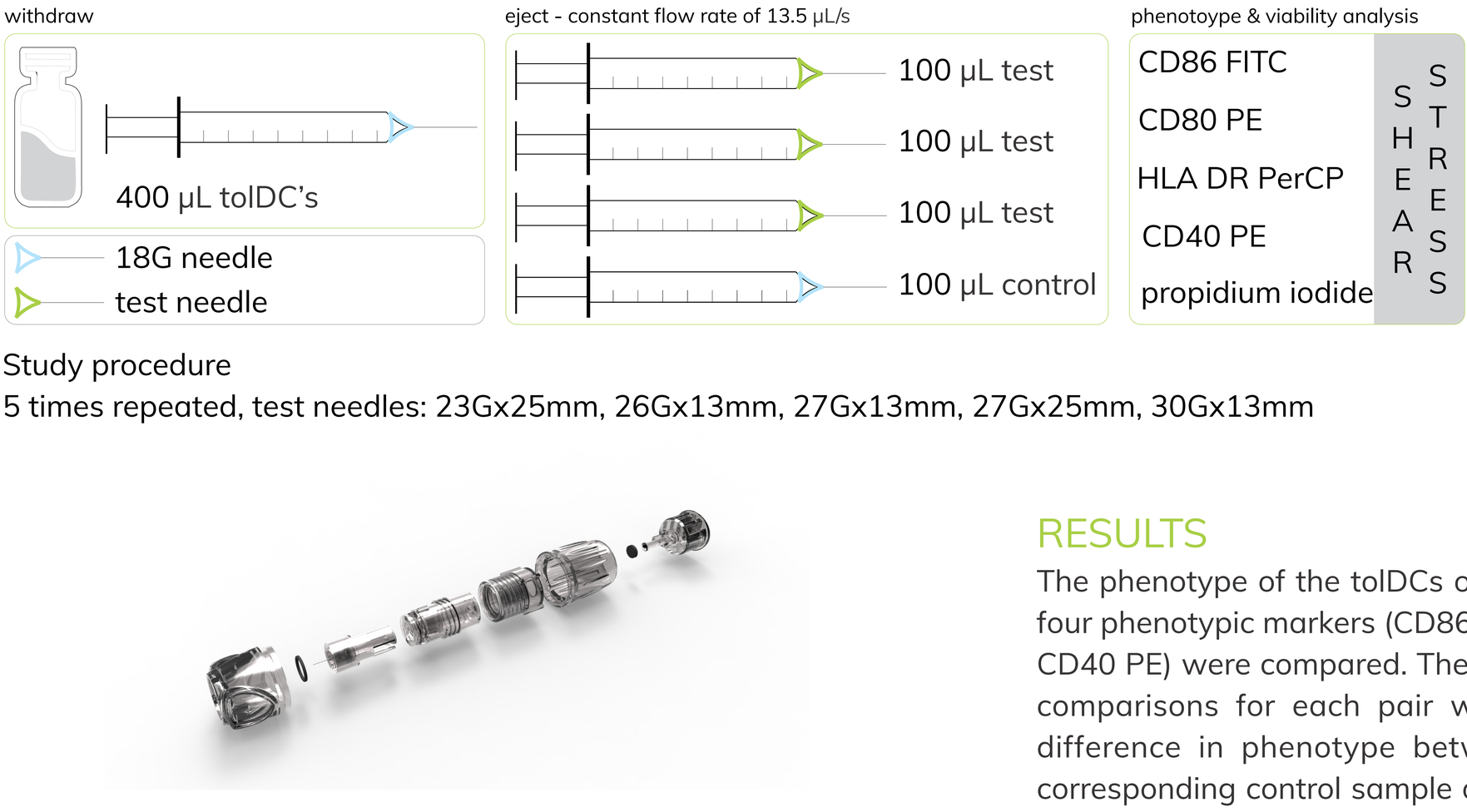


Comparison of injection with CRYO-ID™ and Mantoux Technique

MATERIALS & METHODS

To assess the effect of shear stress in relation to needle diameter, tolDC vaccines were ejected through five different needles (23Gx25mm, 26Gx13mm, 27Gx13mm, 27Gx25mm, 30Gx13mm) at a constant flow rate of 13.5 µL/s to look for the smallest needle that did not have an impact on the viability and phenotype of the tolDCs. The constant flow rate was guaranteed by using a syringe pump.

For every needle tested, a total of 400µl tolDC vaccine was used. 100 µL was used as the control sample and not ejected through the needle. The other 300 µL was ejected per 100 µL, resulting in three test samples per needle. Both the control and test samples were analysed with a flow cytometer for cell viability and phenotype and compared to each other.



35% reduction needle diameter Mantoux vs CRYO-ID™

Study procedure

5 times repeated, test needles: 23Gx25mm, 26Gx13mm, 27Gx13mm, 27Gx25mm, 30Gx13mm

RESULTS

The phenotype of the tolDCs of the test and control samples with four phenotypic markers (CD86 FITC, CD80 PE, HLA DR PerCP and CD40 PE) were compared. The Wilcoxon test with non-parametric comparisons for each pair was used to test for a significant difference in phenotype between the test samples and their corresponding control sample on a significance level of 5%. For all the tested needles, there were no significant differences in phenotype of the tolDCs before and after ejection. Additionally, there was no significant difference in cell viability of the test samples and their control sample on a significance level of 5%. The viability marker for the tolDCs was propidium iodide.

CONCLUSIONS

There is a strong indication that even the smallest needle diameter (30G) doesn't harm the cells and is suited for intradermal injection. The 30G needle significantly improves the patient's comfort compared to the 26G needle that is currently used.

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