

## Introduction

The aim of the study was to investigate the epidermal and dermal thickness at the proximal ventral (PVF) and dorsal forearm (PDF) and deltoid in adults aged 18 - 65 years.

This will allow determining the maximum penetration depth and needle characteristics for the development of a platform of medical devices suited for intradermal injection.

## Method

High-frequency ultrasound (VEVO<sup>®</sup>2100, VisualSonics, 40Mhz, 40µm) was used to measure the skin thickness. The PVF & PDF were divided into three to five sections of 4.5cm, each resulting in 90 frames. The distances were measured every 7.5mm. The deltoid region consisted of 1 section of 8 frames. Distances were measured by drawing straight lines perpendicular from the skin surface to the dermal – hypodermal junction (Figure 1).

For each participant a mean and minimum thickness for the PVF & PDF and deltoid were calculated. Correlation with gender, age and BMI was assessed using Mann-Whitney U Test, Spearman correlation and Wilcoxon Signed Ranks Test, respectively.

Characteristics	Men (n=50)	Women (n=49)
Age in years: mean (range)	40.8 (18-64)	40.5 (18-64)
Number per age group		
18 30 year	14	14
31 40 year	10	10
41 50 year	11	11
51 65 year	15	14
BMI: mean (range)*	25.7 (17.9-42.3)	23.1 (18.0-37.8)
Number per BMI group		
< 18.50	1	2
18.50 24.99	24	34
> 25	15	12
> 30	10	1

\* Mann-Whitney U Test: p = 0.003

Table 1: Demographic characteristics of the participants.



Figure 3, Ultrasound equipment: 3D motor and probe. VEVO 2100<sup>®</sup> (Visual Sonics) ultrasound equipment was used, including the 3D motor and MS550D probe (40 MHz). This experimental setup allowed stepwise imaging of skin thickness at the proximal forearm (ventral and dorsal) and the deltoid region. In this case, images of the ventral side of the left proximal forearm were obtained (LPV).

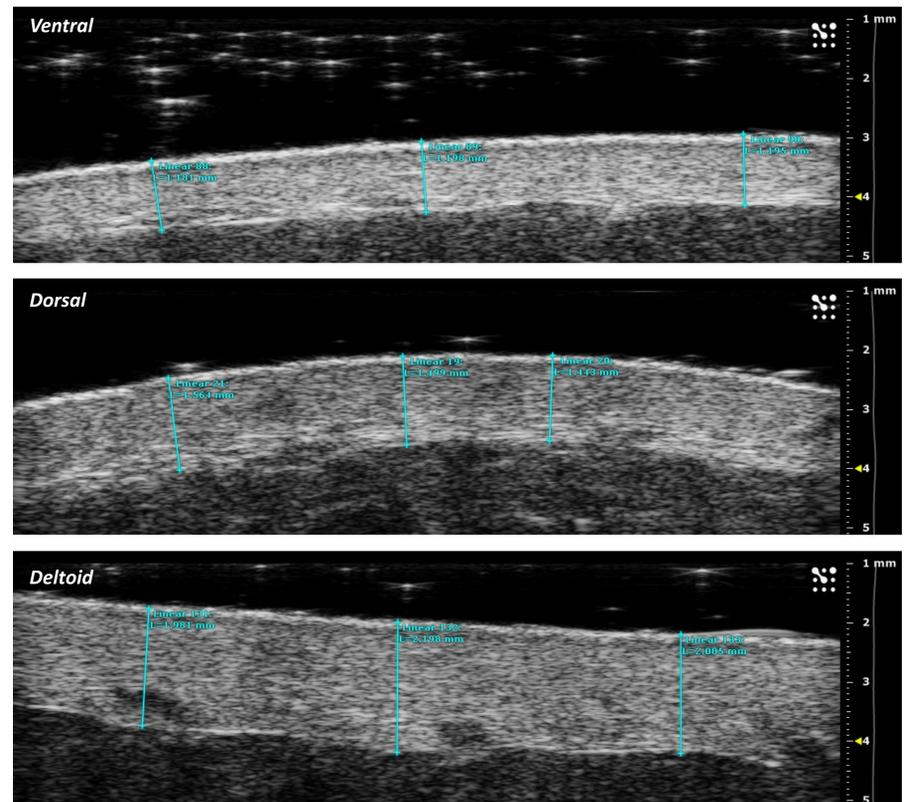
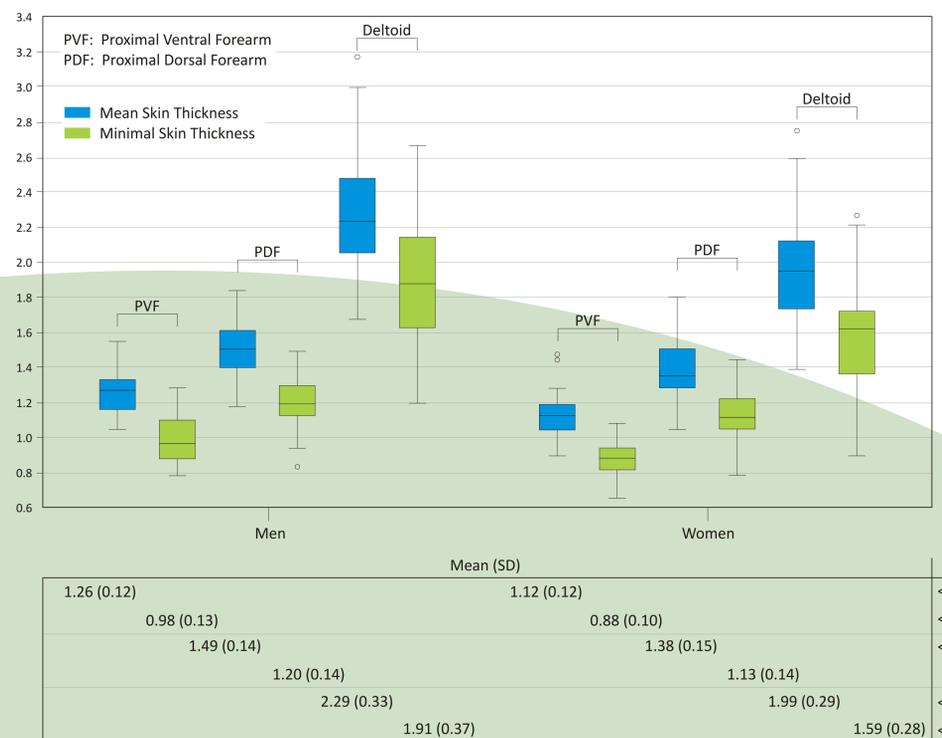


Figure 1: Ultrasound images of proximal ventral and dorsal forearm and deltoid region. Blue bars representing the thickness from the skin surface to the dermal-hypodermal junction.



\* Mann-Whitney U Test

Figure 2: Boxplot showing data on mean and minimal skin thickness by gender.

## Results

Results (n=99 volunteers, Table 1) showed an overall mean skin thickness of 1.44mm (0.78-1.84mm) at the PDF, 1.19mm (0.65-1.55mm) at the PVF and 2.12mm (0.89-3.17mm) at the deltoid.

Mean and minimum thickness of PVF & PDF and deltoid were significantly different for men vs women (Figure 2).

No correlation was seen between age and skin thickness at the PDF and PVF (p=0.095 & 0.087), whereas a significant correlation was found for the deltoid region (p<0.001).

Skin thickness for PDF, PVD & deltoid was significantly correlated to BMI (p<0.001).

## Conclusion

Significant differences in skin thickness were seen for the PVF, PDF and deltoid region for gender, and BMI, but not for age.

Additional multivariate analysis will be done to verify bivariate results in order to set-up needle specifications for the VAX-ID<sup>™</sup> device platform that is being developed by Novosanis.