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Introduction: This project is the first in a series to develop a device that decreases the pain of medical needle pricks by applying pressure, vibration and cooling or heating to the skin. The device is premised on the well-established gate theory of pain(1). In children, significant pain and distress can be associated with starting an intravenous, blood sampling or immunization. Children also remember previous painful experiences and learn to anticipate procedures, leading to pre-procedure anxiety(2). When anxiety is severe, a needle phobia can occur, leading to poor compliance with medical and dental procedures(3). This is the first study to complete a thorough, quantitative examination for the optimal pre-applied pressure and vibration to minimize needle pain.

Methods: After local Ethics Committee approval was obtained, 62 healthy consenting adult volunteers were recruited and demographic data collected. Sample size was calculated using data from the literature. An Electronic Von Frey’s Anesthesiometer (EVFA) provided reproducible-mild pain. Subjects learned the verbal rating scale for pain, where 0 is no pain and 10 is the most pain imaginable. The EVFA was placed on the deltoid with an increasing force of 40 grams/sec until 3/10 pain was achieved. The opposite deltoid was then tested and the process completed for 24 measurements over 40 minutes. This established a baseline 3/10 pain score for each person. Subjects then returned to complete the 11 randomized pressure (50-550 torr) and 11 randomized vibration (75-125 Hz) measurements.

Results: The mean force applied by the EVFA causing 3/10 pain was 245±146 grams (N=62,n=1488). There was no difference between measurements taken over the 40 minute test period (F1,23=0.49, P=0.979). Males (256 grams) could tolerate significantly more force than females (218 grams; P<0.0001). Applying external pressure and vibration increased the mean amount of force above baseline by 128±81 (N=48,n=528) and 85±50 (N=48,n=528) grams, respectively. There was a significant difference between the 11 pressure values (F1,10=2.93, P=0.0013) with 400 and 550 torr allowing the greatest amount of force above baseline at 164±161 and 173±138 grams, respectively. There was no single-optimal vibrational frequency (F1,10=0.33, P=0.9730) but 105 Hz produced the highest force above baseline (96 grams). External pressure had a significantly greater amount of force compared to vibration (t=5.62, df=47, P<0.001).

Discussion: The EVFA was verified to be a reliable method to simulate mild needle pain. Both externally applied pressure and vibration allowed a greater amount of force to be applied by the EVFA than compared to baseline. However, external pressure was significantly better than vibration and could be easily incorporated into daily anesthesia practice for needle procedures. In future studies, pressure and vibration will be combined with cooling or heating in adult volunteers. Once optimal values are confirmed, then testing will be completed on pediatric patients.