

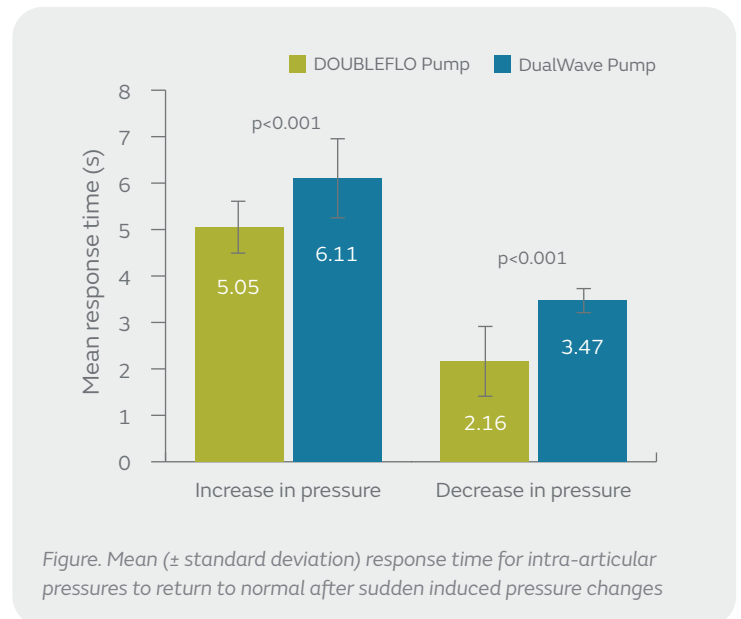
Performance testing comparing the time taken for the new DOUBLEFLO[◇] Inflow/Outflow Pump and DualWave[™] Pump to respond to sudden changes in intra-articular pressure

Overview

- This summary describes the findings of testing conducted by Smith+Nephew to compare the time taken for the DOUBLEFLO Pump and DualWave Pump (Arthrex Inc, Naples, FL) to respond to sudden changes in intra-articular pressure
- Pumps were attached to an artificial joint with a system to change and measure pressure
- Testing consisted of measuring the time taken for intra-articular pressure to return to normal values (a stable range within 11mmHg of pre-test values) following induced positive and negative pressure changes
- Fifteen samples were used for each pump
- Positive and negative pressure changes were induced at steady state joint pressures of 50, 75, and 100 mmHg for each sample
- Mean response time was calculated as the mean time taken for intra-articular pressure to return to normal values across all samples and pressure settings

Results

- In terms of mean response time, the DOUBLEFLO Pump responded significantly faster to changes in intra-articular pressure than the DualWave Pump ($p < 0.001$; Figure):
 - 38% faster to respond to a decrease in pressure
 - 17% faster to respond to an increase in pressure
- The DOUBLEFLO Pump responded to both increases and decreases in intra-articular pressure significantly faster than the DualWave Pump at all tested pressure settings (50, 75 and 100mmHg; $p < 0.05$)



Conclusions

In performance testing, the DOUBLEFLO Pump responded to both increases and decreases in intra-articular pressure significantly faster than the DualWave Pump.

Considerations

This study was conducted by the Smith+Nephew Research & Development team in a laboratory and used an artificial joint; further investigation may be necessary to determine the clinical applicability of these findings.

Data on file: Smith+Nephew 2020. Testing Protocol/Report Form: 15009773 Rev A.