

Distal Radius Sterile Kit: Non-Inferiority Testing of 2.4mm vs. 2.7mm Cortex Screws for Distal Radius Plate Use

DePuy Synthes offers the most comprehensive portfolio to meet your distal radius needs with a sterile single-use solution and comprehensive non-sterile sets offered in stainless steel and titanium.¹

The DePuy Synthes Distal Radius Sterile Kit is designed to address up to 80% of distal radius fractures currently treated with plates.² The single-use, streamlined core kit of instruments and implants is designed to optimize work flow efficiency in your operating room and drive repeatable, more consistent procedures and processes.

Introduction

For more than 10 years, distal radius constructs have been composed of 2.4mm VA and 2.4mm cortex screws or 2.4mm VA and 2.7mm cortex screws. Surgeons preferring 2.7mm cortex screws in the plate shaft require two sets of instrumentation to implant screws into the plate. To increase procedural efficiency in a sterile solution, the Distal Radius Sterile Kit is streamlined to implant 2.4mm screws. This simplifies the management of instruments and implants during the surgical procedure.



Figure 1 - 2.4mm Construct



Figure 2 - 2.7mm Construct



Figure 3 - Test Setup

Test Rationale and Setup

To investigate the strength of a 2.4mm Distal Radius construct, testing was conducted to compare peak load strength of constructs with 2.4mm cortex screws versus constructs with 2.7mm cortex screws in the plate shaft. The test constructs were chosen to represent components available in the sterile kits while maintaining like constructs for a valid comparison. The compared constructs and the test setup are shown in Figures 1-3.

Result³

The test showed that peak load strength of a distal radius construct with 2.4mm cortex screws in the shaft is non-inferior to a construct with 2.7mm cortex screws in the shaft with a non-inferiority margin of less than 5%. Testing evaluated mean peak load and no screws broke at the peak load.

Note: The plates and screws used in this test were stainless steel. Since screw strength is proportional to cross-sectional area, it can be concluded that the relative difference of the two constructs are expected to be the same for Titanium 2.4mm vs 2.7mm cortex screws.

References

1. Analysis of leading distal radius competitors 2017
2. The VA LCP® Two-Column Distal Radius Plates are the best-selling radius plates of DePuy Synthes. The remaining 20% of cases may require the use of alternate implants depending on the complexity. (Internal Global Sales Analysis 2015).
3. Data on file at DePuy Synthes, Windchill #0000271005