GRANULOMETRIC DISTRIBUTION OF PARTICLE SIZES:

A comparison between Merit Bearing nsPVA® Embolization Particles and Boston Scientific Contour™ Embolization Particles

Merit Medical Research & Development

Abstract

The standard manufacturing process of nonspherical polyvinyl alcohol particles starts with the fabrication of a polyvinyl alcohol sponge that is then ground into small nonuniform particles. The resulting shavings are passed through sieves with sequentially smaller holes to separate the particles into various size ranges. Due to the irregular shape of nsPVA particles, this common sieving method results in a percentage of particles that fall outside of specified size distribution ranges.

Objective

This granulometry analysis study was performed to compare the granulometric size distribution of Merit Bearing nsPVA Embolization Particles and Boston Scientific Contour Embolization Particles.

The following embolization particles and equipment were used:

- Merit Bearing nsPVA Embolization Particles (Fig. 1)
- Boston Scientific Contour Embolization Particles (Fig. 1)
- Camsizer® XT particle analyzer (Fig. 2)

Method

Seven size ranges (45-1180 µm) of Contour particles were purchased from Boston Scientific for this study. Merit tested the seven equivalent Bearing size ranges for this study.

The Camsizer XT particle analyzer performed an optical measurement analysis. Free-falling particles were illuminated by two pulsed LED light sources and their images were captured by two digital image processing cameras, each one specialized in a specific size range.

A method was specifically developed for each size range where image processing and calculations are relative to the dimensions, the velocity, and the sharpness of the particles. The Camsizer XT software stores and processes images of individual particles and can detect agglomerated particles and exclude them from the results.

The Camsizer XT performed an analysis on the number of particles that fell within and outside the stated size range.

Figure 1: Embolization Particles

Figure 2: Camsizer XT

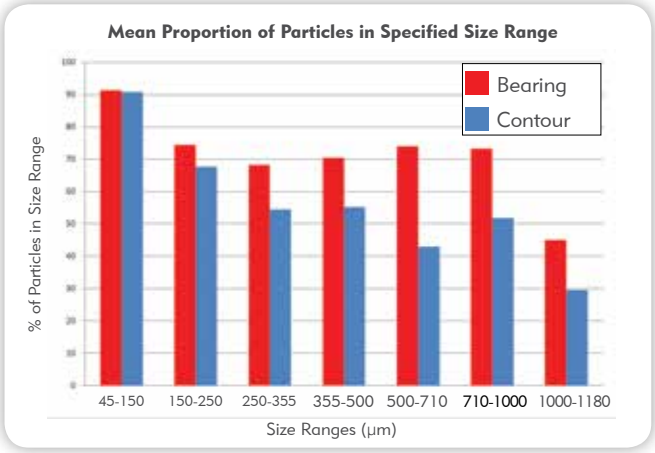
RESULTS

The following charts indicate that the tested samples of Merit Bearing nsPVA® exhibited a greater percentage of particles consistently within the specified size ranges when compared to Boston Scientific Contour™.

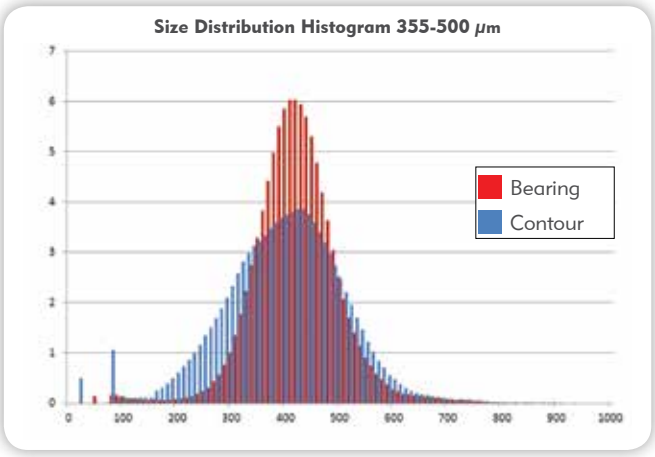
CONCLUSION

This study demonstrates that the size distribution of Bearing nsPVA particles is more tightly calibrated than Contour particles.

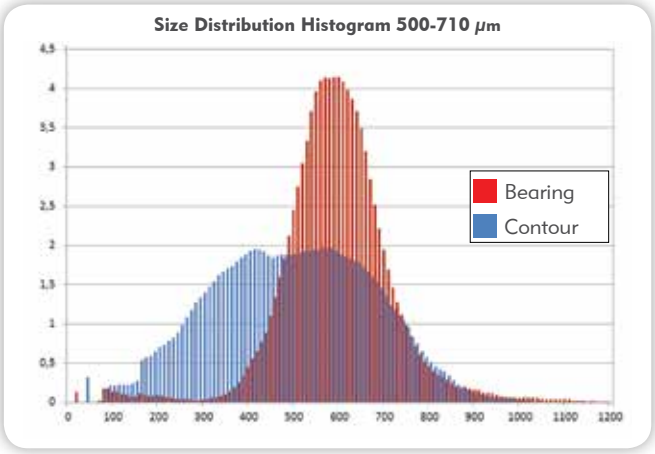
Disclaimer:
The tests described in this document were laboratory bench tests conducted by Merit Medical in 2012-2013. Granulometry analysis was performed with calibrated imaging equipment (Camsizer XT) on at least 6100 particles. These tests were conducted using the following lots of Contour™ product: 14945627, 14959129, 14999768, 15228667, 15837033, 14792749, 15857804, 14860137, 15808410, 15008956, 15193505, 15855152, 14621269, 14996550, 15842238. Every effort was made to report accurate, verifiable results. No conclusions are drawn regarding the translation of bench data to the clinical model.



For all seven size ranges, on average, **Bearing nsPVA** had **33%** more particles in the specified size ranges than Contour.



In the 355-500 µm size range, **Bearing nsPVA** had **71%** and **Contour** had **51%** fall within range.



In the 500-710 µm size range, **Bearing nsPVA** had **72%** and **Contour** had **38%** fall within range.

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