Biomechanical Evaluation of CONCORDE™ Bullet and PEEK Verte-Stack® Capstone® Vertebral Body Spacer

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The CONCORDE™ Bullet device (DePuy Spine, Inc., Raynham, MA) was designed to facilitate ease of insertion and improve resistance to migration while maintaining the proven clinical benefits of the existing CONCORDE product line. This biomechanical study demonstrates the reduced insertion force, greater resistance to migration, and larger bone graft area of the CONCORDE Bullet as compared to that of its competitor: The PEEK Verte-Stack® Capstone® Vertebral Body Spacer (Sofamor Danek, Memphis, TN).

IMPROVED EASE OF INSERTION

The CONCORDE Bullet was designed with a bulleted nose to improve its ease of insertion. Bench-top testing using simulated vertebral body anatomy under physiologic loading showed that the insertion force required with the CONCORDE Bullet was 8% less than that of the PEEK Verte-Stack Capstone Device (Figure 1).

The tapered tip of the CONCORDE Bullet transiently distracts during insertion thereby significantly reducing: 1) the required insertion force, 2) the risk of posterior lip fracture, and 3) the risk of damage to the bony endplate.

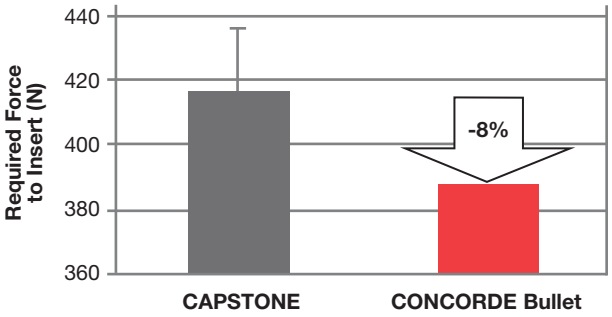

Figure 1: Force required to insert each device. CONCORDE Bullet required a significantly lower insertion force than Verte-Stack Capstone ($p<0.05$).

GREATER RESISTANCE TO MIGRATION

Once implanted, resistance to migration is critical to clinical success. To evaluate this attribute, bench-top testing was performed using recent protocols defined by Goel et al[1]. These tests demonstrated that the CONCORDE Bullet, when compared to the Verte-Stack Capstone device, maintained a statistically equivalent resistance to posterior migration while displaying significantly greater resistance to anterior migration (Figure 2). This key benefit is due to the device's novel pyramidal teeth design (Figure 3).

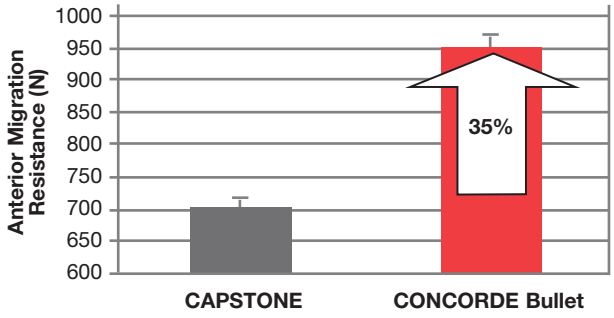

Figure 2: Resistance to migration once implanted. CONCORDE Bullet had a significantly greater resistance to anterior migration as compared to the PEEK Verte-Stack Capstone device ($p<0.05$).

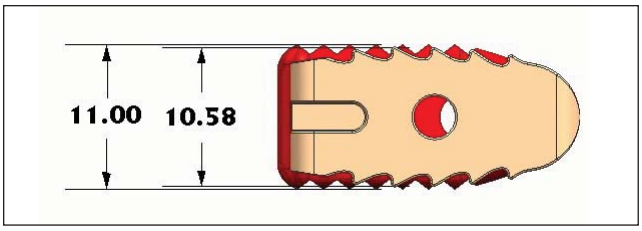

Figure 3: Comparison of the pyramidal teeth design of the CONCORDE Bullet (outlined in red) to the teeth on the PEEK Verte-Stack CAPSTONE device (outlined in yellow). The pyramidal teeth have been shown to increase the resistance to anterior migration.

BENEFIT OF CFRP

Similar to its predecessor, the CONCORDE Bullet is made of carbon fiber-reinforced polymer (CFRP). CFRP is composed of 70% PEEK and 30% Carbon Fiber. This material has been shown to sustain loads 100% greater in compression and tension than 100% PEEK alone[2]. However, strength by itself is not sufficient to enable fusion. Moderate stiffness is also required so that the load is shared across the bone graft bed. This is demonstrated by Wolff's law which states that bone formation within a given bone bed does not occur unless that particular site is subjected to loading.

Only CFRP has the ability to allow for both – great strength and moderate stiffness. Large lateral openings decrease the overall stiffness of the construct while the CFRP material itself, through its inherent material properties, can sustain significantly greater loads than PEEK. This combination of great strength yet moderate stiffness could not be achieved with a PEEK device molded with large lateral holes. This is simply due to the PEEK polymer not being strong enough and thus not being able to withstand the type of loads experienced in the spine. In fact, PEEK devices can only be designed with very small lateral openings.

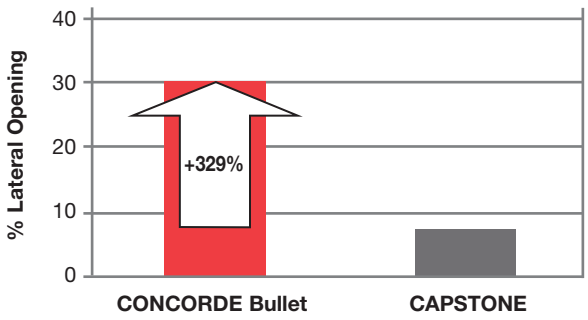

Figure 4: Percent open area in lateral wall. Lateral openings are critical for load sharing, placement of graft material, and diffusion of nutrients and oxygen to the graft site - functions that are optimized in the CONCORDE Bullet design.

An evaluation was done to compare the percent of lateral openings in the CONCORDE Bullet to that of the PEEK Verte-Stack Capstone device. The percent of lateral openings was measured by dividing the surface area of the lateral openings by the total lateral surface area. The Verte-Stack Capstone device has openings in only 7% of its total lateral area while the CONCORDE Bullet has 30% of its total lateral area occupied by openings (Figure 4). The Verte-Stack Capstone, made entirely of PEEK, resembles a "closed" device when compared to the CONCORDE Bullet.

In addition to the benefit of load sharing, the large lateral openings provide more room for bone graft material and diffusion of nutrients and oxygen to the graft material.

INCREASED BONE GRAFT AREA

For bone formation, devices alone are not sufficient, but require bone graft or bone graft replacements. Similarly, bone graft materials alone, for example, iliac crest bone, bone marrow-based or BMP-based grafts, will not ensure a fusion. A fusion requires an effective bone graft, along with a device with optimal biomechanics. This fact has been shown indirectly when BMP-based grafts were implanted with femoral rings: high failure rates and subsidence were observed in these cases. Investigators reported that BMP-based grafts increased the rate of resorption of the femoral rings, thus creating mechanical instability. Without proper biomechanics, new bone could not form and those cases went on to failure[3].

CONCORDE Bullet was designed to contain as much graft material as possible while maintaining optimal biomechanical properties. The use of CFRP allows for enlarged lateral openings which are more than 3x larger than those in PEEK devices. This allows increased volume of bone graft material that can be placed inside the devices and improved diffusion of nutrients and oxygen to the graft material. This fact was highlighted in a study by Okuda et al., in which 101 patients were evaluated at the 3-year post-operative time point, following posterior lumbar interbody fusion. In this publication, the authors attribute a large bone graft volume and preservation of the osseous end plate during discectomy to the prevention of subsidence and to the overall success of the interbody arthrodesis procedure[4].

In Figure 5, the surface area available for new bone formation through the CONCORDE Bullet is presented and compared to the PEEK Verte-Stack Capstone. By utilizing the 100% greater peak compressive loads afforded by carbon fiber-reinforced polymer (CFRP), as shown by William et al[2], the CONCORDE Bullet provides 33% greater graft volume than the PEEK Verte-Stack Capstone.

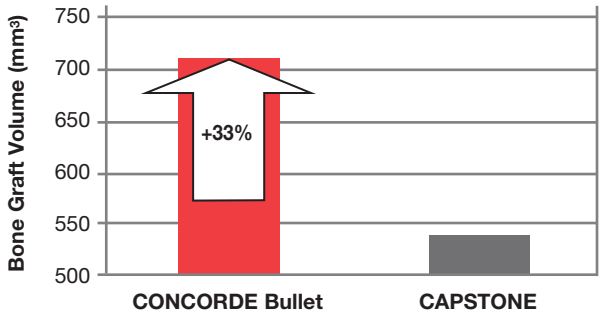

Figure 5: Volume available within the device for bone graft material and new bone formation.

CONCLUSION

The CONCORDE Bullet device was designed to leverage the proven clinical history of CFRP devices[5] while improving ease of insertion and resistance to migration. This biomechanical evaluation showed that through its bulleted nose, pyramidal teeth, and large lateral openings, the CONCORDE Bullet significantly improved ease of insertion without sacrificing the force needed to resist migration or the volume available for bone graft material and new bone formation.

REFERENCES

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