Comparison of the Effect of Spine Implant Surface Architecture to Quality of Interfaced Bone

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Introduction: Spondylolisthesis, the anterior slippage of a vertebra, is a degenerative condition of the spine that often occurs in patients with osteopenia or osteoporosis. The present study is part of ongoing evaluations of the surface architecture of novel standalone 3D printed interbody fusion devices, using in vitro models. In this study, we compared the effects of implant surface architecture and bone quality on the strength and stability of the inferior aspect of the standalone device at the bone interface.

Methods: Two implant surface architectures were evaluated under simulated physiological loading conditions using composite model bone blocks. Each of the two implant serration designs were tested separately against three synthetic bone models of varying density and surface architecture, specifically; S016: 10 PCF solid rigid polyurethane foam of 0.16 g/cm^3, S008: 5 PCF solid rigid polyurethane foam of 0.08 g/cm^3, C016: 10 PCF cellular rigid polyurethane foam of 0.16 g/cm^3. Two implant surface architectures were simulated using metal blocks; both had 2mm height serrations, one with 45° and the other with 60° angles from the transverse plane of the device. Spondylolisthesis loading was simulated using a custom apparatus within an MTS 858 mini-bionix servo-hydraulic load frame (MTS Systems, Minneapolis, MN). A cyclic load profile with an amplitude of 100N, increasing the maximum force in increments of 100N after every 10 cycles was applied at a rate of 0.5 Hz in a step-wise fashion until failure. Shear implant-bone motion was measured using a D2/200A linear variable differential transformer (LVDT) while force at the interface was recorded by the MTS software. Each implant serration design was tested with three separate bone blocks on each of the three bone analog types, and repeated at both a 30° and 45° test angle. There were thirty-six total experimental trials. Student's t-tests were used to compare the overall dataset (N=36) as well as the differentiated datasets with test angle and bone analog type held constant (N=6).

Results: The max force at the interface ranged from 65 N to 2216 N, varying significantly, depending on foam type and test angle ($p=0.22$). Mean total sagittal migration ranged from 0.29 mm to 1.5 mm for 45° serrations and 0.67 mm to 1.7 mm for 60° serrations ($p=0.06$). Implant serration angle had a much larger impact on stability during the 30° tests. The sagittal displacement was 0.762 mm to 1.16 mm for the 45° serrations and 0.959 mm to 1.64 mm for the 60° serrations at the 30°test angle ($p=0.002$), and the max force at the interface was 726 N to 2067 N for the 45° serrations and 706 N to 1890 N for the 60° serrations ($p=0.007$). As the test angle was increased to 45°, the sagittal migration changed to 0.286 mm to 1.5 mm for the 45° serrations and 0.667 mm to 1.37 mm for the 60° serrations ($p=0.5$), and max force at the interface decreased to 325 N to 1457 N for the 45° serrations and 217 N to 1029 N for the 60° serrations ($p=0.026$). The displacement of the 2mm 60° serrations were significantly larger for the majority of tests, and importantly, was larger for trials with similar max force/duration as the other design. At 500 N, the 60° serration implant migrated 0.48 mm to 1.7 mm while the 45° serration implant migrated 0.16 mm to 0.41 mm. The maximum force at the interface was reliant on serration angle, bone analog type, and plate angle. Maximum force withheld was significantly reduced by changing the angle, ranging from 348N to 2216N using the 30 degree angle, but ranging from 69 N to 1548 N using the 45 degree angle. ($p<0.001$). Additionally, there were significant differences between the max force sustained by the S016 bone analog and both the S008 and C016 bone analog groups ($p<0.001$). When differentiating sagittal displacement by bone analog type, on average, the S016 bone analog at migrated 0.93 mm to 1.6 mm, the S008 bone analog migrated 0.46 mm to 1.6 mm ($p=0.05$), and C016 bone analog migrated 0.29 mm to 1.15 mm ($p=0.002$).

Discussion: Max force sustained at the interface was dependent significantly on surrounding bone analog quality and severity of deformity angle (test angle). Implant design appeared to have a lesser impact on the shear strength changes or max force in the analog bones, and this effect is lessened more at higher angles of deformity. In terms of total sagittal implant migration, the 45° serrations outperformed the 60°. In trials with a similar max force sustained at the interface, the 2mm, 60° implant had consistently higher sagittal displacement. At the 30° test angle, implant serration design played a role in max force sustained at the interface and total migration while bone analog quality was largely involved in max force sustained at the interface. When test angle was increased to 45°, implant serration design no longer played a role in sagittal displacement and had a lesser, but still significant, impact on max force at the interface. Multiple trials at the 45° test angle resulted in near immediate failure at the interface, particularly in the S008 and C016 bone analog models. The results raise concerns regarding the performance of interbody fusion devices when used in poor quality bone and/or high angle of deformity. Failure in these cases with low force-to-failure could result in damage to the bony endplates even with separate methods of fixations such as screws.

Clinical Relevance: At lower angles of spondylolisthesis deformity, implant serration design and bone analog quality played significant roles in implant stability, with the 45° serrations providing greater stability. However, at more severe angles of spondylolisthesis deformity, bone analog quality had near total influence over implant stability.