

Bioretec Research and Development

Comparison between ActivaScrew™ and titanium compression screws: biomechanical compressional force and force relaxation after implantation

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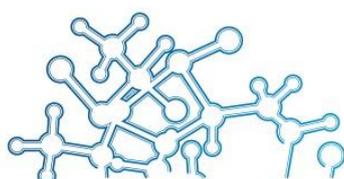
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1 Literature review

Adla et al. studied several mini bone screws and compressive forces they can achieve in closed cell foam simulating cancellous bone. The Herex C70-200 foam (Impag) had density of 200 kg/m³, tensile strength of 6.6MPa, compression strength of 4.8MPa and shear strength of 3.5 MPa. The screws under comparison were Mini-Acutrak screw, Herbert Whipple screw, 2.0mm AO screw, cannulated 3.0mm AO screw with 5.5 mm washer. The screws were inserted half turn at a time with 5 s interval until compressive force did not get any bigger. The maximum compressive force was measured and also monitored up to 10 minutes. Cannulated 3.0 mm AO screw obtained maximum compressive force of 86N which had decreased to 70N after 400 s (81% from the maximum force). The rest of the screws achieved maximum compression forces between 44 N and 57 N and the decrease percent after 400 s from the maximum force was between 84%-89%. [1]

Bailey et al. studied several cannulated compression screws and their compression properties. 3 mm Herbert screw, 3 mm Herbert Whipple screw, 3.5 mm Acu-trak, 4 mm Asnis and 4 mm Little Graftor screw were being compared. Grade 10 foam (Sawbones) was used as test substance with density of 0.16g/cc, compressive strength of 2.2 MPa, tensile strength of 2.1 MPa and shear strength of 1.6 MPa. The screws were inserted in foam half turn at a time and the compressive force was measured after 30s of each half turn until the screw failed. Maximum compressive forces were as following: Acu-trak 38 N, Asnis 33 N, Little Graftor 32 N, Herbert 22 N and Herbert Whipple 20 N. [2]

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Gruszka et al. was investigating different compression screws in cadaver scaphoids. 3.5 mm Acumed Acu-trak 2 Mini, 3.2 mm Stryker Twinfix, 3.0mm Synthes Headless compression screw and 2.0 Synthes AO screw were compared. The screws were inserted in scaphoids with compressional force measurement until no change after 5 s of partial rotation happened in the force. The maximum force was measured and monitored while the screw and the scaphoid was in immersed in physiological saline in +37°C. The results were following for each screw at maximum compression and after 12 hours: Stryker Twinfix from 226N to 141 N (62%), Acumed Acu-trak 2 Mini from 191 N to 121 N (63%), Synthes Headless compression screw from 137 N to 78 N (60%) and Synthes AO screw from 72 N to 32 N (44%). [3]

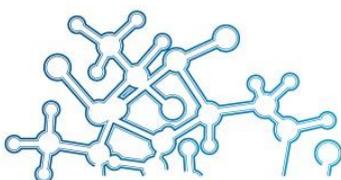
2 Experience with Bioretec ActivaScrew™-products

Compression generation of 4.5 mm ActivaScrew™ LAG was compared biomechanically to Synthes 6.5 mm AO screw. The test setup was made using porcine fibulas. The fibula was cut in half and the supported proximal portion was attached to the supported distal portion with a LAG screw. The LAG screw was tightened and the compressive force applied between the distal and the proximal end of the fibula was measured until the screw or the bone failed. The mean maximum force (n=3) for the 6.5 mm Synthes screw was 440±100 N and for the 4.5 mm ActivaScrew™ LAG 402±50 N. With both implants, the bone was the weakest and broke in the end.

The stress relaxation of the ActivaScrew™s was tested by gripping the screws from the thread and the head under physiological saline in +37°C. The distance between the grips were increased to create compressive force simulating clinical use of the screw. The tensional force was monitored for several weeks. For 2.0 mm ActivaScrew™s the initial tensile force was 50 N. After 400s the force level was 48 N (96%) and after 12 hours it was 35 N (68%). At 2 weeks the tensile force level was 28 N (56%). For 3.5 mm ActivaScrew™ LAG the initial tensile force was 200 N. After 400s the force level was 190 N (95%) and after 12 hours it was 105 N (53%). At 3 weeks the tensile force level was 70 N (35%)

Compression generation in vitro was compared between 3.5 x 40 mm ActivaScrew™ and Synthes 3.5 x 40 mm cannulated metal screw. Grade 10 foam (Sawbones) was used and the screws were tightened in physiological saline in 37°C until maximum compressive force. Then the compressive force was monitored for 4 days. The obtained maximum compression after 30s of final tightening for ActivaScrew™ was 54 N where for Synthes 3.5 mm cannulated screw it was 36 N. The higher compression of ActivaScrew™ decreased faster than Synthes metal screw but after one day it remained at the same level of 21 N while Synthes metal screw was reducing the compression from 18 N after one day to 16 N after 4 days. (Figure 1)

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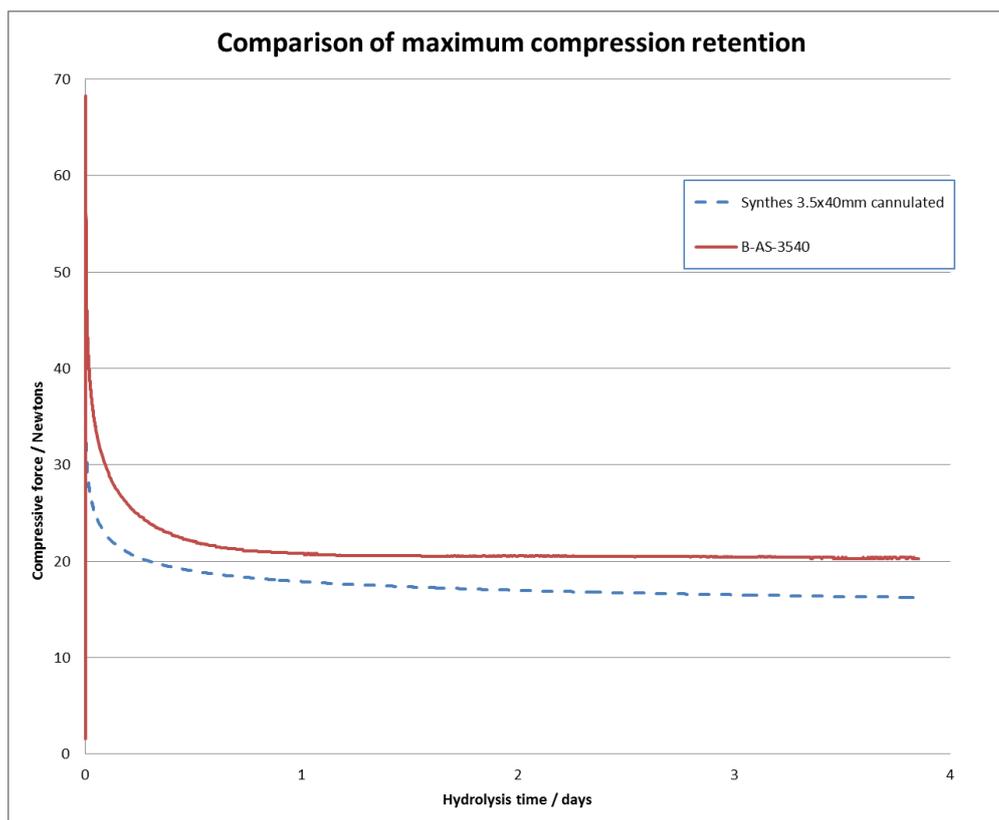


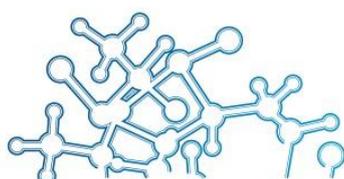
Figure 1. Comparison of compression force retention for 3.5 mm ActivaScrew™ and 3.5 mm cannulated metal screw.

3 Conclusions

The biomechanical compressional force test for 4.5 mm ActivaScrew™ LAG demonstrates that it is possible to achieve similar compressional forces with the ActivaScrew™ as with the metal screws. The foam model comparison of 3.5 mm ActivaScrew™ to Synthes 3.5 mm cannulated metal screw or metallic headless compression screws of similar size from Bailey et al. study support this observation. The maximum compression for 3.5 mm ActivaScrew™ was 54 N where it was 20 N – 38 N for the metal screws of similar size in the similar test setup; Acu-trak 38 N, Asnis 33 N, Little Graftor 32 N, Herbert 22 N and Herbert Whipple 20 N. [2]

The stress relaxation studies are difficult to compare because the test setups and density of test substances are different but the comparison of Bioretec 3.5 mm ActivaScrew™ and Synthes 3.5 mm cannulated metal screw have identical test setup and it shows that compression of metal screw seems to be reducing faster after the stabilized compression level. The relaxation of polymeric ActivaScrew™s secures the foam (and the bone) from being relaxed or remodeled irreversibly. The relaxation of the ActivaScrew™ is partially reversibly due to Auto-compression property and it is maintaining the compression better.

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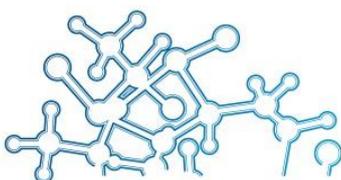


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