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Technical Bulletin

Cobalt Chrome Screws (CoCr) Test Report Summary

Background

Plating systems such as those for the wrist and elbow currently use 2.7 mm and 3.5 mm hexalobe locking and nonlocking titanium alloy (Ti) screws for fixation. To address patient considerations and market demand, CoCr screws were developed. Material properties and manufacturing process improvements led to the hypothesis that CoCr screws could demonstrate lower insertion and removal torque, and higher torsional yield than that of Ti screws.

This technical bulletin provides a summary of the mechanical testing performed on both 2.7 mm and 3.5 mm locking and nonlocking CoCr Hexalobe Screws and their Ti counterparts.

Test Method

1. ASTM F543-17 guidelines (in conformance with the requirements of YYT 0018-2016 and ISO 6475-1989)
   - Torsional yield strength and maximum torque per Annex A1 of ASTM F543-17
   - Insertion and removal torque per Annex A2 of ASTM F543-17

2. Equivalence tests were performed, using Ti screws as predicate
   - Insertion and removal torque of 10 Nm (2.25 lbf) axial load to depth of 10 mm in 30 PCF foam blocks
   - Torsional strength of 10 Nm (2.25 lbf) axial load or less with torque, rotation, and time recorded at minimum data acquisition rate of 50 Hz

Results

CoCr screws consistently saw lower insertion and removal torque levels than equivalent Ti screws. This means that CoCr screws require less force for placement and/or removal, facilitating and quickening the procedural process.

Table 1 – Test Results of Insertion and Removal Torque

Insertion (Avg Nm at 10 mm depth)	CoCr Screw	Ti Screw
2.7 mm	0.229	0.344
3.5 mm	0.236	0.368
Removal (Avg Nm at 10 mm depth)		
2.7 mm	0.234	0.330
3.5 mm	0.240	0.392

Additionally, CoCr screws saw higher torsional yields and peak load levels than equivalent Ti screws. This supports the assumption that CoCr screws are stronger and can withstand greater rotational torque without breaking or stripping compared to Ti versions.

Table 2 – Test Results of Torsional Yield and Peak Load

Torsional Yield (Avg Nm)	CoCr Screw	Ti Screw
2.7 mm	1.431	1.202
3.5 mm	3.529	2.542
Torsional Peak Load (Avg Nm)		
2.7 mm	1.942	1.633
3.5 mm	4.740	3.420

Conclusion

All testing of the CoCr screws passed acceptance criteria, thus demonstrating improved ease of insertion and removal, and increased screw strength compared to Ti screws.

References

1. ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws. 2017, ASTM International: West Conshohocken, PA.
2. YYT 0018-2016, Product Technical Requirements for Bone Screws.
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4. *Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway;* Final Guidance for Industry and Food and Drug Administration Staff; Document issued on December 11, 2020.
5. Hickok, M. D., Marklin, R. W., Nagurka, M. L., & Simoneau, G. (2014). Screwdriver Bit Head Design – Effect of Phillips, Straight, and a Hybrid Design on Torque, Axial Force, and Effort Ratio. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting,* 58(1), 1580–1584. https://doi.org/10.1177/1541931214581329
6. TP-011360 – ASTM F543 Verification Testing of 2.7 mm L/NL CoCr Hexalobe Screws
7. TP-011362 – ASTM F543 Verification Testing of 3.5 mm L/NL CoCr Hexalobe Screws
8. TR-011471 – ASTM F543 Testing of 2.7 mm L/NL Ti Hexalobe Screws
9. TR-010641 – ASTM F543 Screw Test - 3.5 mm Locking Hexalobe
10. TR-011643 – ASTM F543 Annex 1-3 Verification of 2.7 mm L/NL CoCr Hexalobe
11. TR-011644 – ASTM F543 Annex 1-3 Verification of 3.5 mm L/NL CoCr Hexalobe
12. TR-011733 – ASTM F543 Annex 2 Ins Testing for CoCr Screws (30pcf)

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