

## A Novel Mesh-free Model For Accurately Simulating Material Damage During Orthopaedic Screw Pull-out Per The Astm F543-17 A3 Standard

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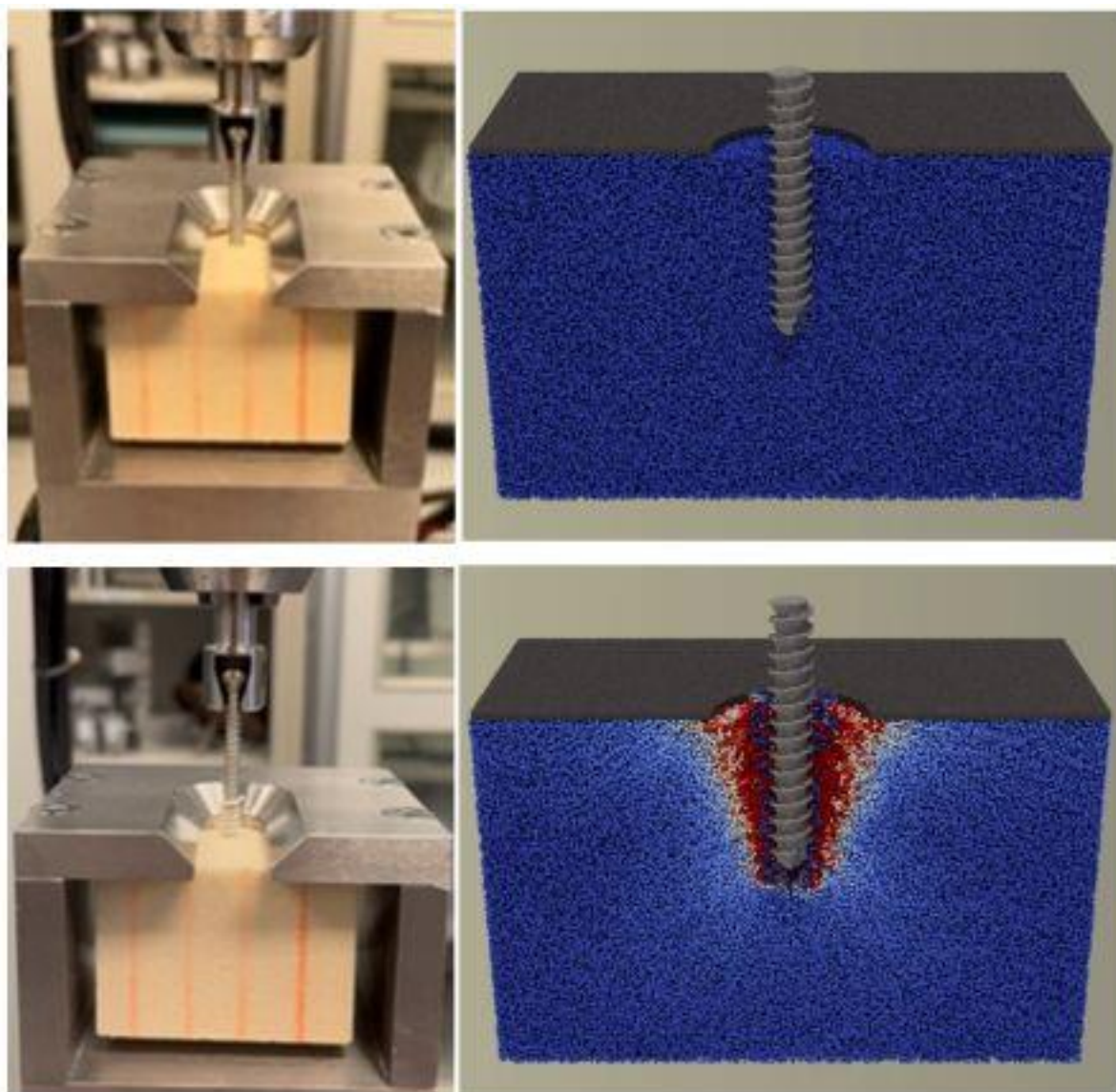
**Introduction:** Mesh-free computational models of ASTM F543-17 A3 (screw pull-out) were generated using a novel simulation software system and its predictions were compared to physical experimental test results.

**Methods:** Generic HA 3.5, HA 4.0, and HA 4.5 bone screws were fabricated (316L stainless steel, ISO Fine tolerance, n=3 each), inserted into pilot holes in the PU foam, and then pulled out while recording force vs. displacement data. Blocks of solid rigid polyurethane foam measuring 58 x 65 x 40 mm were prepared from 20 PCF foam (n=3 for each screw design), and 15 PCF foam (n=3 for HA 4.5 screw only). Models of the implant and foam blocks were constructed in the novel mesh-free computational modeling system at a resolution of 200  $\mu\text{m}$ /particle and simulated pull-out tests were performed.

**Results:** The maximum peak pull-out loads of the HA 3.5 screws from 20 PCF foam were 692 N (average) and 706 N in the physical and simulated tests, respectively. For the HA 4.0 screws the maximum pull-out loads were 816 N (average) and 713 N from 20 PCF foam in the physical and simulated tests, respectively. For the HA 4.5 screws the maximum peak pull-out loads were 509 N (average) and 508 N from 15 PCF foam in the physical and simulated tests, respectively; maximum pull-out loads were 798 N (average) and 820 N from 20 PCF foam in the physical and simulated tests, respectively. The average CCC (concordance correlation coefficient) between simulation and experiment maximum pull-out loads was >0.90, suggesting excellent concordance, however the simulations over-predicted loads following the peak. Computational time on a 32-core cloud-computing instance was less than 12 hours for each simulated test.

**Discussion:** The novel mesh-free computational modeling system in the present study can accurately predict the maximum pull-out loads of several typical orthopedic screws in two common PU foam grades per ASTM F543-17 A3, suggesting that this system can be used to quickly predict the likelihood that a candidate design will pass without the need of a physical prototype or testing laboratory.

**Significance/Clinical Relevance:** This novel particle-based ASTM F543-17 A3 model can be used to quickly predict the likelihood that a candidate design will pass, supplementing or replacing the need for a physical prototype to be fabricated and tested under laboratory conditions.



Cover image

Table 1. Deviations between physical and simulated testing protocols and the published ASTM standard

| Test Setup Parameters/Procedures |  | ASTM F543-17 A3 standard method  | Physical test  | Simulation   |
|----------------------------------|--|--|--|--|
| Test setup procedures            | Load fixture   | Slot to capture the head of the screw without contact being made with the screw's shaft  | Slot to capture the head of the screw without contact being made with the screw's shaft  | No simulated load <u>fixture</u> ; screw head is removed since only the screw's shaft interacts with the foam  |
|                                  | Test block clamp's grip span                                 | Minimum of five times the major diameter of the bone screw   | Minimum of 16 mm   | Minimum of 16 mm   |
|                                  | Test block (polyurethane foam in accordance with ASTM F1839) | Discretion of the user   | 15 or 20 PCF   | Scaled according to manufacturer's 15 or 20 PCF compression data   |
|                                  | Foam block size (width x length x height)                    | Height should be more than 20 mm   | 58 x 65 x 40 mm  | 58 x 65 x 40 mm  |
|                                  | Screw insertion  | 3 rpm into a foam block pre-drilled with a pilot hole using a drill size specified by the screw manufacturer (and tapped if specified) | Manually and slowly inserted the screw into a pre-drilled foam block with pilot hole 0.1 mm smaller than the screw's core diameter | No simulated insertion; Boolean difference operation was performed to create a cavity with the same profile as the screw. The screw model was then positioned in the cavity. |
|                                  | Screw insertion depth  | 20 mm  | 20 mm  | 20 mm  |
|                                  | Sample size  | Usually, n=5 minimum per case  | n=3 per case   | n=1 per case   |
| Parameters                       | Tensile load rate  | 5 mm/min   | 5 mm/min   | 1 m/s (Table 2)  |
|                                  | Data collection time interval                                | Suitable to continuously record load versus load fixture displacement  | 0.05 s   | $1 \times 10^{-9}$ s   |
|                                  | End point (displacement)                                     | The maximum load is reached during the test method   | 6 mm   | 6 mm   |
|                                  | Resolution (specific to simulation)                          | Not applicable   | Not applicable   | 200 $\mu$ m  |

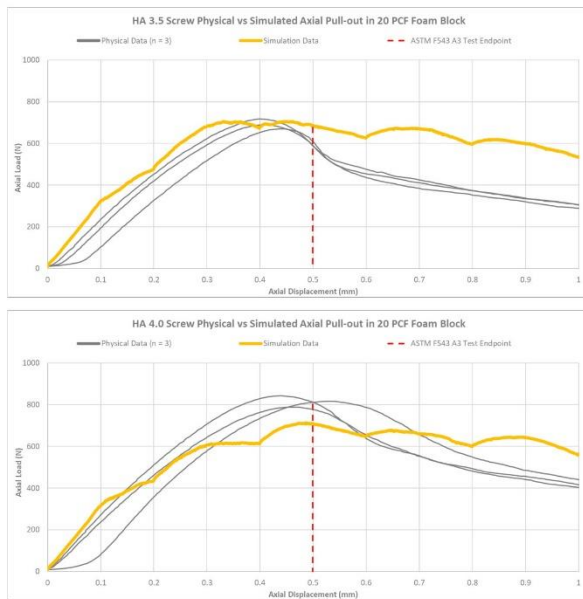


Figure 1A. Load-displacement curves from the physical experiment ( $n = 3$ ) and the simulated (half-sized / symmetric across YZ-plane) axial pull-out tests of HA 3.5 (top) and HA 4.0 screws (bottom) in 20 PCF polyurethane foam blocks up to 1 mm pull-out displacement

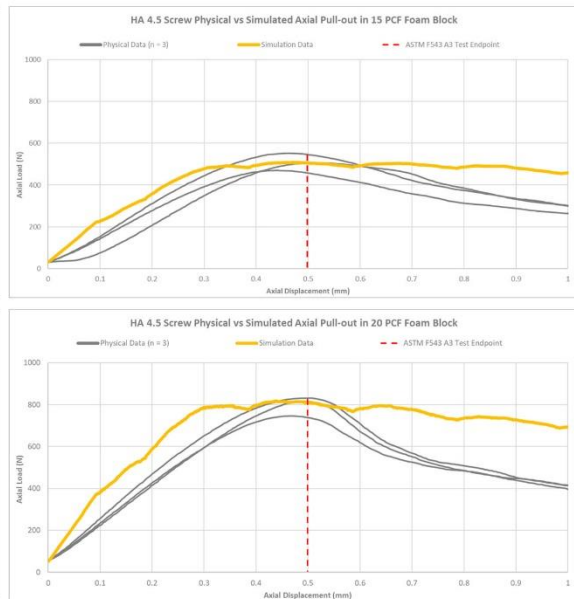


Figure 1B. Load-displacement curves from the physical experiment ( $n = 3$ ) and simulated axial pull-out tests of HA 4.5 screws in 15 PCF (top) and 20 PCF (bottom) polyurethane foam blocks up to 1 mm pull-out displacement