Andrew Calvillo
Project 03

1) Design Needs

- The screw must achieve a maximum pullout resistance exceeding 180 N.
- The screw must effectively capture and secure the tendon.

2) Design Constraints a) The device must pursue FDA 510(k) clearance under the Safety and Performance-Based Pathway for orthopedic non-spinal metallic bone screws. b) Thread stripping may occur in low-density bone (15 PCF) if pitch and minor diameter are not properly optimized. c) Titanium additive offers the potential to reduce cost and lead time for patient-specific fixation devices, particularly in lower-resource settings. d) Fabrication requires powder bed fusion (PBF) with post-processing (HIP, machining, polishing) to meet ASTM F3001. e) Surgeon adoption remains a barrier, requiring clear justification for 3D-printed screws over conventional CNC-machined alternatives.

3) Applicable Standards a) *Material and manufacturing:* ASTM F3001 specifies requirements for additively manufactured Ti-6Al-4V ELI via PBF, governing chemistry, microstructure, and mechanical properties. ASTM E8 (tensile testing of metallic materials) is used to verify that printed coupons meet minimum strength requirements; the sponsor's material and process ensure compliance. b) *Mechanical performance:* ASTM F543, the core bone screw testing standard, addresses torsional strength, insertion torque, pullout strength, and self-tapping performance, directly constraining required mechanical performance. ISO 5835 defines bone screw thread geometry and dimensional tolerances, constraining thread design. c) *Surface characterization:* Guidelines for Voronoi lattice characterization (pore size, interconnectivity, and surface area) relevant to tendon-to-bone healing.

4) Environmental Considerations Titanium additive manufacturing generates unsintered metal powder waste, which must be handled as hazardous material and recycled through controlled processes.

5) Team Collaboration The team held weekly meetings supplemented by a group chat, enabling continuous collaboration and idea exchange. The project was divided into three subprojects — self-drilling buttress screw, self-tapping screw, and cylindrical screw — each led by an individual team member. Goals and deadlines were established at each meeting and documented in a shared Google Doc, and constructive feedback was exchanged organically as new ideas were proposed.

6) Initiative and Adaptation The unfamiliar nature of the project required significant independent initiative, as the sponsor had no prior experience with this class of device. When the sponsor's mechanical testing capacity was limited to a single pullout test on a 15 PCF foam block, I developed a more comprehensive testing framework to address gaps in their evaluation capability. The screw also underwent multiple design iterations, with each version informed by shortcomings identified in the previous one.

7) Innovation The most innovative contribution of this project was the development of novel screw geometries through CAD-based design. Using SOLIDWORKS, I designed custom buttress threads and applied helical geometries across a range of screw variants. These designs were subsequently fabricated via 3D plastic printing to (A) assess their suitability for titanium printing and (B) conduct preliminary testing to identify the optimal geometry.