Richard Nguyen Addendum

1. Desired Needs

- Screw has increased osteointegration, improved tendon regeneration, Increased screw stability/less risk of tendon slippage

2. Constraints

a) Safety/Regulatory Affairs
   i) FDA 510k demonstrating substantial equivalence to existing interference screws
   ii) ISO 10993 governs cytotoxicity, sensitization, and implant-tissue interaction

b) Risks
   i) Mechanical risks including: screw fracture under cyclic loading, pull-out failure
   ii) Biological Risks: Aseptic loosening, Potential for bacterial colonization

c) Global Impact
   i) Reliance on specialized 3D metal printing infrastructure limits accessibility
   ii) Patient-specific manufacturing could reduce revision surgery rate globally

d) Manufacturability
   i) Ti-6Al-4V powder bed fusion printing, surface roughness, residual thermal stress

e) Quality Control/Marketability
   i) Each screw must undergo: Dimensional verification, porosity characterization

3. Engineering Standards

a) ASTM F136, ASTM F3001, ISO 10993-1, ASTM F543, ISO 14801, ASTM F1717

4. Ethical, Environmental, or Societal Concerns

- Patient specific titanium 3D printed implants raise concerns around equitable access, and environmental impact from metal powder waste

5. Active Teamwork and Leadership

- Diverse backgrounds in mechanical design, biomechanics, and materials science
- Subprojects delegated by expertise with dedicated leads assigned to CAD modeling, FEA, on top of iterative design milestones being established early to plan team progress

6. Most significant Motivating Factors that Led you

- Exposure to biomaterials, as well as CAD and 3D printing via laser metal deposition
- Challenges included failed plastic prototypes, troubleshooting the tapered thread, and pull out performance

7. Innovative/entrepreneurial ideas

- Voronoi lattice-integrated fixation screw is a commercially protectable design
- 3D printable + titanium increases osseointegration and patient specificity