Radical™ Pedicle screw – Thread design information.

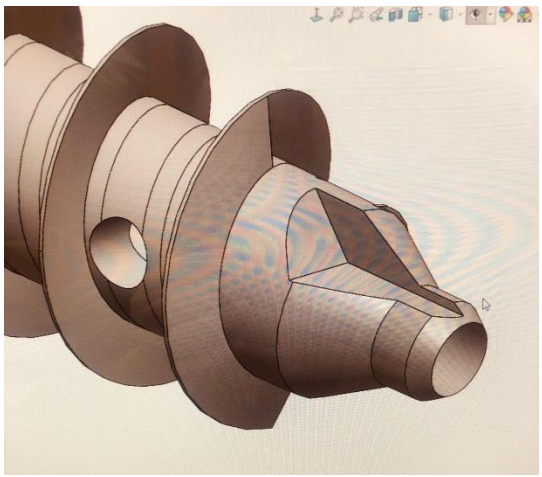
Design logic including reasons for excellent pullout results.

The RADICAL Pedicle screw is designed specifically to address the post-op pedicle screw loosening crisis which is a global phenomenon;

a) In an effort to address this crisis in Spinal fusion surgery, OCI has designed the Radical™ Pedicle screw system. The name “Radical” is used simply to highlight the huge radically difference between a coarse thread and routine pedicle screw designs.

b) A drastically modified cancellous type thread (*coarse thread) was considered during the design phase, mainly because of its deeper core thread ratio. At the risk of a coarse thread introducing potential for flank shearing, mechanical tests have proven this fear to be non-existent. The increased flank dimension results in a feature for improved bone penetration. Tests have shown zero deformation of the Radical thread (post test).





c) *Coarse threads are more resistant to stripping because of the greater flank engagement with the adjacent bone. Coarse threads install much faster as they require fewer turns per unit length, thereby reducing bone damage/interference and reducing potential bone stripping which could potentially lead to screw loosening.

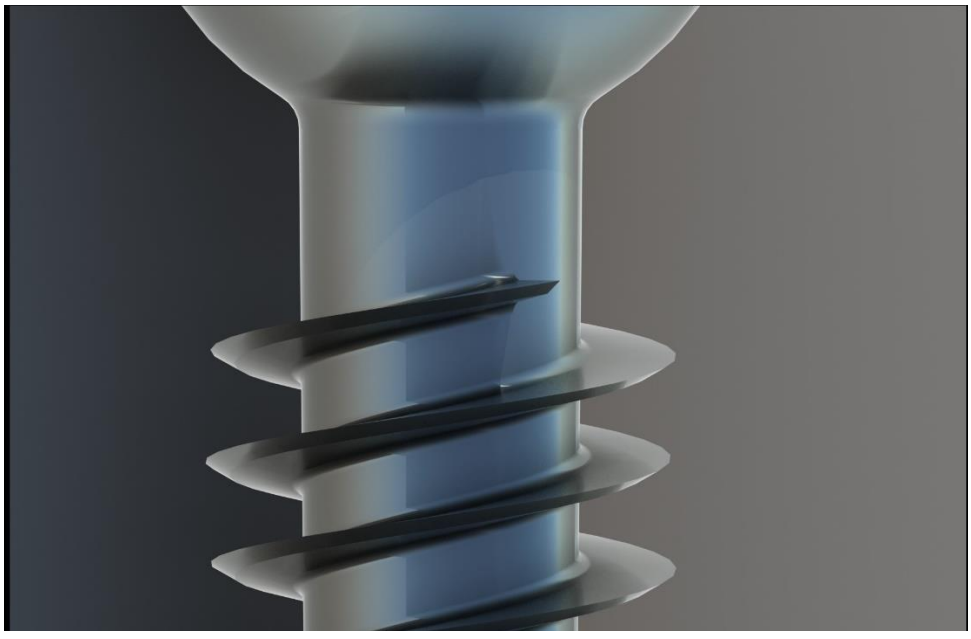
d) Since the inception of its radical design, samples of the Radical™ Pedicle screw have been manufactured specifically for “pull-out” testing. Cannulated Titanium 6Al4V raw material is provided by Forcreu, a reputable French company specializing in hollow bars for medical devices.

e) A general overview of Pedicle screws globally, has shown Pedicle screw designs to follow a cortical type or modified cortical type thread. It is the opinion of OCI, that this type of thread design is totally lacking in the struggle to eliminate pedicle screw loosening. We all understand that a closely spaced, shallow thread design and a reduced core-to-outer diameter ratio are typical of cortical screws.
Radical screw design is based upon a logic of widely spaced deep threads with an improved core to outer diameter ratio. At the proximal area the Radical screw has a double thread which is considered to improve cortical bone fixation at that extremity of the screw.

Test Results – ref ASTM -F 543-17

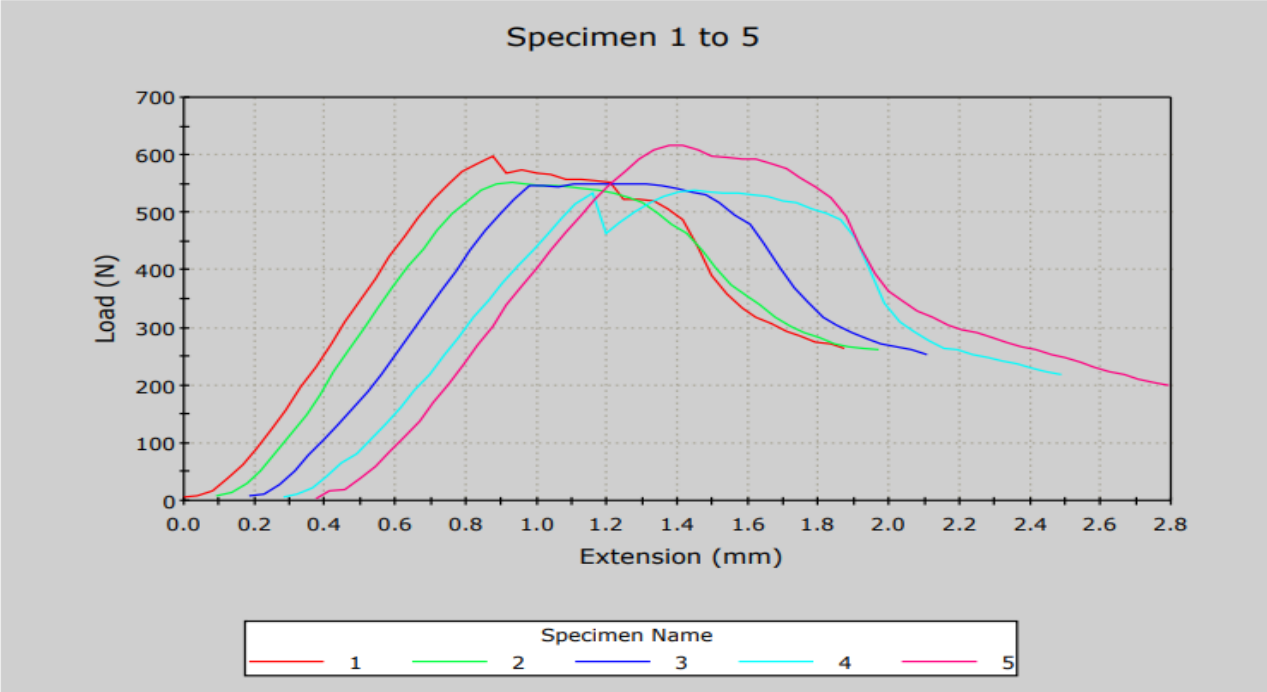
These tests are performed locally to prove the efficacy of the thread design. Pull out tests are performed in conformance with ASTM-F543-17 (Standard specifications and Test methods for Metallic Bone screws”.

Proximal view:



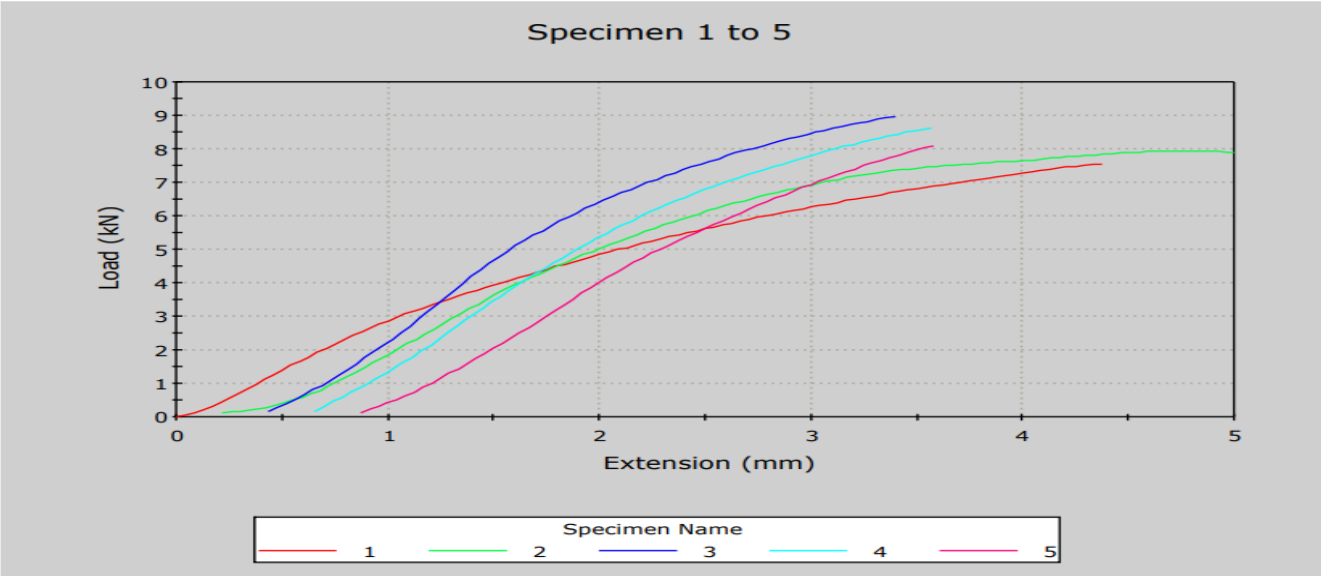
Axial pullout force: 7mm screw

	Specimen label	Maximum Load (N)	Maximum Load (kgf)	Tensile extension at Maximum Load (mm)
1	1	597.5	60.92	0.874
2	2	553.0	56.39	0.836
3	3	550.5	56.14	0.959
4	4	539.8	55.04	1.168
5	5	616.9	62.91	1.043
Mean		571.5	58.28	0.976
Standard Deviation		33.629	3.429	0.134
Coefficient of Variation		5.884	5.884	13.722
Range		77.1	7.86	0.333



Ultimate tensile strength: 7mm screw

	Specimen label	Maximum Load (N)	Maximum Load (kgf)	Tensile extension at Maximum Load (mm)
1	1	7552.5	770.14	4.375
2	2	7932.1	808.85	4.500
3	3	8965.0	914.18	2.958
4	4	8601.8	877.14	2.917
5	5	8074.3	823.35	2.706
Mean		8225.1	838.73	3.491
Standard Deviation		559.111	57.014	0.870
Coefficient of Variation		6.798	6.798	24.925
Range		1412.6	144.04	1.794



DISCUSSION:

This mini report shows only the tapered 7mm test results, as this is considered to be the highest risk (weakest link) when performing a risk analysis (full CSIR test report available if interested).

The test results show the average axial pullout force of the 7mm and 8mm sample screws was 572N and 699N respectively. Both the 7 mm and the 8mm screw samples pulled out of the polyurethane test blocks, stripping the polyurethane from the test block, see figure 3.

The ultimate tensile strength of the 7mm and 8mm sample screws was 8225N (839kg.f) and 9296N (948 kg.f) respectively. The *coarse screw thread of both the 7mm and 8mm samples screws showed no flank deformation after testing.