Analysis of 5.5mm PunchTac™ Threaded Anchor PEEK System Implantation for rotator cuff repairs: An Observational Study

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Objective:

The purpose of this study was to analyze the safety and effectiveness of Dunamis Medical's 5.5mm PunchTac™ Threaded Anchor PEEK Preloaded with two 2mm DFX Tensile Tape, 5.5mm PunchTac™ Threaded Anchor PEEK Preloaded with two #2 DFX Force Suture and One 1.5mm Fiber Connect Tape, and 5.5mm PunchTac™ Threaded Anchor PEEK Preloaded with two 2mm Fiber Connect Tape for arthroscopic rotator cuff repair.

Materials and Methods:

The Study was performed using 5.5mm PunchTac™ Threaded Anchor PEEK Preloaded with two 2mm DFX Tensile Tape (35A), 5.5mm PunchTac™ Threaded Anchor PEEK Preloaded with two #2 DFX Force Suture and One 1.5mm Fiber Connect Tape (36A), and 5.5mm PunchTac™ Threaded Anchor PEEK Preloaded with two 2mm Fiber Connect Tape (40A) (Dunamis Medical, Greenville, AL). The 35A, 36A and 40A were used by 3 orthopedic surgeons at independent sites over a period of 5 months (June – October). All the surgeons reported their usage of these anchor systems per month. The suture breakage, anchor pull out and anchor fracture for each type of anchor systems per month if any were recorded by the surgeons along with reason for failure and the need to implant a second anchor.

All the anchors were implanted using manufacturers instructions for use for 5.5 threaded anchors. The age group was recorded to understand the effect of increasing age on the strength of fixation and stability of repair. The type of 5.5 anchor used was surgeon preference with factors as described but not limited to type of tear, soft tissue consistency and location of tear.

Results:

150 consecutive implantations were performed for rotator cuff repair by 3 independent orthopedic surgeons at 3 different medical centers. The surgeons observed no failures in the form

of suture breakage, anchor pull out and anchor fracture for any of the 3 types of 5.5 Punchac™ threaded anchor systems (Table 1).The patients age group ranged from 20 years to 88 years old (Table 2) with majority of the repairs being performed in patients over 50 years old .One incidence of suture mismanagement and dislodging of the suture from the implant was noted.. However, the same anchor was reinserted into the same pilot hole after removing the anchor and rethreading the sutures. In one case the surgeon augmented the fixation of the 5.5mm PunchTac Threaded Anchor, with secondary screw in an osteoporotic patient. Most surgeons also preferred the 5.5 anchors with tapes due to the low knot profile or even as a knotless construct.

Conclusion:

In conclusion, Dunamis Medical's PunchTac™ Threaded Anchor PEEK System showed no suture breakage, anchor pull out or anchor fracture in a wide range of age groups of patient population. The security of fixation along with the stability of the repair construct at time 0, suggests that the anchor can be used effectively to perform soft tissue to bone repairs. The anchors presented for the study were approved for shoulder, knee, ankle and elbow.

Table 1: 5.5mm PunchTac™ Threaded Anchor – Implantations

Month, 2018	Anchor Type	Surgeon # 1	Failures	Surgeon # 2	Failures	Surgeon # 3	Failures
June	35A	2	0	2	0	0	0
	36A	10	0	0	0	0	0
	40A	0	0	4	0	0	0
July	35A	0	0	0	0	0	0
	36A	8	0	0	0	0	0
	40A	0	0	3	0	0	0
August	35A	0	0	0	0	0	0
	36A	8	0	0	0	2	0
	40A	0	0	4	0	1	0
September	35A	0	0	5	0	0	0
	36A	7	0	0	0	0	0
	40A	0	0	0	0	0	0
October	35A	4	0	8	0	3	0
		70		**36**		**44**	

Total implantations for 5.5 PunchTac™ Threaded anchor system - 150 anchors

Table 2: 5.5mm PunchTac™ Threaded Anchor - Patient Age Group

	20	20-35	35-50	50-65	65-88
Surgeon 1	0	2	8	31	23
Surgeon 2	2	0	8	9	14
Surgeon 3	0	1	5	20	7