ATTUNE™ Knee System

An Early Outcome Study of the ATTUNE™ Knee System vs. the SIGMA™ CR150 Knee System

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Introduction

The ATTUNE™ Knee System has been designed to improve motion, function and stability. Anecdotally, surgeons are seeing patients experience decreased pain, better function, and greater, faster return of motion. The goal of this study was to evaluate these factors by comparing the ATTUNE Knee System with the SIGMA™ CR150 Knee System. The surgeon author for this study was not involved in the design or development of the ATTUNE Knee and the physical therapists in charge of recording in-hospital study outcomes were blinded to the brand of implant utilized to mitigate bias. Patients were not blinded to the implant received.

Method

Clinical outcomes were collected prospectively for all primary knee patients in an Institutional Review Board (IRB) approved study. Forty patients received the SIGMA CR150 RP Total Knee implant and upon product availability, 40 patients received the ATTUNE Cruciate Retaining Rotating Platform (CR RP) Knee. Patient demographics were similar in both groups (Table 1).

Table 1: Subject demographics

	ATTUNE CR RP Knee N= 40	SIGMA CR150 RP Knee N= 40	Significance
Age [yrs]	65.9 ± 7.4	67.7 ± 7	p>0.05, Not Significant (N.S.)
BMI	28.2 ± 4.9	29.3 ± 7.8	p>0.05, N.S.
Diagnosis	100% OA	100% OA	

The surgical technique was identical for both implants. The surgeries were performed by one surgeon. All in-hospital outcome measures were recorded by physiotherapists who were blinded to the brand of implant used. Patients were not blinded to the implant received.

The blinded data collection by physiotherapists included all measures except for two-week and six-week flexion. Post-operative flexion was not blinded, and was collected by the operative surgeon at the two and six week post-operative visits.

Motion related factors collected were flexion pre-operatively, at discharge and at two and six weeks post-op, as well as extension at discharge, ability to achieve 90° of knee flexion and ability to do a revolution on an exercise bike at discharge.

Functional factors collected were days to functional independence, days to straight leg raise (SLR), inability to SLR at discharge, days to lap the ward, days to crutch use, days to mastering the stairs and a Visual Analogue Scale (VAS) functional score (SF 1 - whereby 0 is a functionless knee and 10 is a normal functioning knee). VAS pain at rest and with exercise was collected at discharge. Days to reach the criteria for discharge and days to discharge were collected. The criteria for discharge was having the pain controlled, independent crutch use, stairs and toileting and ability to lap the ward. Exercise bike use and 90° of knee flexion were ideal but not mandatory.

Results

Table 2: Comparison of early clinical outcomes of the ATTUNE Knee CR RP and SIGMA CR150 RP Knee. Data is reported as mean.

	ATTUNE CR RP Knee N=40 knees	SIGMA CR150 RP Knee N=40 knees	Significance
Pre-Op flexion (°)	114.0° (10.3)	111.8° (12.7)	p>0.05, Not Significant (N.S.)
Discharge flexion (°)	101.4° (8.2)	98.6° (11.0)	p>0.05, N.S.
Discharge Range of Motion (ROM) (flexion minus extension) (°)	100.5° (8.3)	96.4° (11.8)	p>0.05, N.S.
2 week flexion (°)	113.0° (8.6)	106.1° (9.5)	p<0.001
6 week flexion (°)	121.1° (6.0)	115.0° (9.6)	p=0.002.
Days to 90° flexion	2.1 (1.0)	1.9 (1.1)	p>0.05, N.S.
Percent unable to get 90° flexion @ discharge	0/40 knees (0%)	6/40 knees (15%)	p=0.026, trending
Days to functional independence	2.4 (0.6)	2.4 (0.6)	p>0.05, N.S.
Days to straight leg raise (SLR)	1.8 (1.2)	2.0 (1.2)	p>0.05, N.S.
Percent unable to straight leg raise (SLR) @ discharge	2/40 knees (5%)	3/40 knees (7.5%)	p>0.05, N.S.
Days to exercise bike	3.3 (0.6)	3.1 (0.6)	p>0.05, N.S.
Percent unable to exercise bike @ discharge	2/40 knees (5%)	6/40 knees (15%)	p>0.05, N.S.
Days to lap ward	2.4 (0.5)	2.5 (0.7)	p>0.05, N.S.
Days to do stairs	2.9 (0.4)	3.0 (0.8)	p>0.05, N.S.
Days to crutches	2.3 (0.5)	2.6 (0.6)	p=0.018, trending
Discharge pain at rest	0.4 (0.6)	0.8 (1.1)	p= 0.048, trending
Discharge pain with exercise	3.9 (1.8)	4.5 (2.0)	p>0.05, N.S.
Functional score SF 1	6.6 (1.5)	5.3 (1.5)	p<0.001
Discharge days	4.3 (0.7)	4.5 (0.6)	p>0.05, N.S.
Days to reach criteria for discharge	3.3 (0.5)	3.6 (0.8)	p=0.048, trending

Numbers in parentheses denote the standard deviations.
N.S. denotes Not Significant.

A p value between 0.01 and <0.05 is noted as trending;
a p value <0.01 is statistically significant.

Pain

The patients who received ATTUNE Knees had better pain at rest upon discharge (trending). Pain with exercise was better but not statistically significant.

Flexion

ATTUNE Knee patients had statistically significant better 2 week and 6 week flexion and patient's improvement compared to the pre-operative flexion was also statistically significant. The ATTUNE Knee patients had better extension and flexion at discharge, but this was not statistically significant. Time to get to 90° was slightly longer with the ATTUNE Knee, however, 10% of SIGMA CR150 Knee patients did not get to 90° at discharge while all ATTUNE Knee patients did. Similarly, the ATTUNE Knee patients took slightly longer to ride an exercise bike, however 15% of SIGMA Knee patients could not do a revolution on an exercise bike at discharge vs. 5% of ATTUNE Knee patients.

Function

ATTUNE Knee patients had a statistically significantly better VAS function score at discharge and less days progress to crutch use. The ATTUNE Knee patients also achieved less time to lap the ward, days to straight leg raise and days to stairs, but this was not statistically significant.

Discharge

Patients with the ATTUNE Knee took a shorter time to reach the criteria required to permit for discharge. They were discharged earlier, but this was not statistically significant.

Discussion

Limitations of the present study include short-term follow up and a relatively small sample size. This study included data from 80 TKA patients, 40 with the ATTUNE Knee System and 40 with the SIGMA Knee System. If a larger sample size were studied, differences in results may occur. The operative surgeon was not blinded to the specific implant used. The days to reach discharge criteria, and all other in-hospital measures, were collected by physiotherapists who were blinded to the specific implant used.

Conclusion

With increasing focus on improved patient satisfaction after TKA by clinicians, patients, and health care providers worldwide, it is imperative that new implant systems provide the opportunity to advance outcomes. This is an early outcome study of a series of 40 ATTUNE Knee patients and 40 SIGMA Knee patients. Limitations of the present study include short-term follow up and a relatively small sample size. In this short-term study, patients who received the ATTUNE Knee System had less pain, better motion and function in the early post-operative phase when compared with the surgeon's previous knee of choice (SIGMA CR150 Knee). The operative surgeon was not blinded to the implant used. The days to reach discharge criteria, and all other in-hospital measures, were collected by physiotherapists who were blinded to the brand of implant used.

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