

# Robotic-assisted total knee arthroplasty reduces soft-tissue releases which improves functional outcomes: A retrospective study

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## ABSTRACT

**Background:** There is increasing use of Robotic-Assisted (RA) and personalized alignment techniques in total knee arthroplasty (TKA). The hypothesis of this study was that RA TKA would result in fewer soft-tissue releases, and that fewer soft-tissue releases would be associated with improved clinical outcomes.

**Methods:** A retrospective review of an internal company registry was conducted for all primary TKAs performed from Jan 1, 2014, through a database extract date of Nov 4, 2022. These were grouped by whether there was an intentional soft-tissue release performed (STR) during the surgery or not (NSTR) and whether RA was utilized. The incidence of STR was compared between RA-TKAs and those performed with manual instrumentation. Knee Society Score (KSS) and Knee Society Function Scores (KSFS) were collected at 6 months, 1 year and 2 years. Kaplan-Meier survivorship was performed.

**Results:** The incidence of STR was significantly lower for RA vs. Manual (43.81% Vs 86.62%,  $p < 0.0001$ ). The TKAs with NSTR had higher KSFS compared to those with STR at 6 months (84.73 Vs. 77.51,  $p < 0.0001$ ), 1 year (89.87 Vs. 83.54,  $p < 0.0001$ ) and 2 years (90.09 Vs. 82.65,  $p < 0.0001$ ). There was no difference in survivorship, or KSS at any time point. However, the NSTR group had improved KSS pain sub score at 2 years.

**Conclusion:** The results of this observational, retrospective analysis found that the incidence of soft-tissue release was lower with RA-TKA. Further, regardless of if RA was used, avoiding releases was associated with improved KSFS and KSS pain scores through 2 years post-operatively.

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**Abbreviations:** TKA, Total Knee Arthroplasty; HKA, Hip Knee Ankle Angle; MCL, Medial Collateral Ligament; LCL, Lateral Collateral Ligament; PCL, Posterior Cruciate Ligament; IT band, Iliotibial Tract; RA, Robotic-Assisted; MI, Manual Instrumentation; STR, Soft Tissue Release; NSTR, No Soft Tissue Release; KSS, Knee Society Score; KSFS, Knee Society Function Score; BMI, Body Mass Index; DOTS, DePuy Outcomes Tracking System; ANCOVA, Analysis of Covariance; PROMs, patient reported outcome measures.

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## 1. Introduction

Total Knee Arthroplasty (TKA) is a highly effective procedure, which reduces pain, improves mobility and function, and has durable long-term survivorship. However, there remain a subset of 10–20% of patients who are not fully satisfied [1] with their pain relief and functional outcomes. One of the primary operative goals of TKA is to achieve balance and stability throughout range of motion. This goal has traditionally been coupled with the goal to implant the knee perpendicular to the mechanical axis according to the principles of Insall [2] with some studies associating Hip Knee Ankle (HKA) alignment angles exceeding  $\pm 3$  degrees from neutral with an increased risk of revision [3,4]. However, as most patients' pre-operative alignment is not neutral [5,6], releases of soft-tissue structures are frequently required to achieve a balanced knee with a neutral mechanical axis [7]. For example, in a varus knee, it may be necessary to release structures on the medial side to balance the knee (e.g., posteromedial capsule, medial collateral ligament (MCL)) and in a valgus knee, it may be necessary to release structures on the lateral side to balance the knee (e.g., iliotibial tract (IT band), posterolateral capsule, popliteus, and lateral collateral ligament (LCL)).

More recently the influence of neutral mechanical alignment on long term survivorship has been challenged [8,9] and there is growing interest in patient specific techniques in TKA with the aim of improving patient outcomes [10–14]. Whilst there are many different techniques, all fundamentally aim to balance the knee via adjustments to the angles of the bone resections and joint line instead of adjustments to the soft-tissue envelope, ultimately resulting in reduced soft-tissue releases. This has been accelerated by the adoption of new technologies which improve accuracy and critically provide feedback on the size of the gaps during the planning phase of the procedure (Fig. 1) [14–17]. Improvements in patient outcomes have been recorded for these patient specific techniques [14,16,18–20], and it is hypothesised that one of the drivers for this is the reduction in the number of soft-tissue releases performed. However, there is currently limited information on the impact of soft-tissue releases on outcomes to support this hypothesis.

This study aimed to answer two questions:

1. How did the introduction of a new Robotic-assisted system impact the incidence of soft-tissue releases and
2. How do soft-tissue releases influence mid-term clinical performance?

Our hypothesis was that robotic-assisted (RA) TKA would result in fewer soft-tissue releases, and that fewer soft-tissue releases would be associated with improved outcomes following TKA.

## 2. Methods

A retrospective review of primary TKAs in a company sponsored registry known as the DePuy Outcomes Tracking System (DOTS) was conducted. Participating surgeons contributed prospectively collected standardized preoperative, surgical, and postoperative follow-up data at prescribed intervals postoperatively on each patient. To participate in the registry each site was required to receive either IRB approval or exemption to collect the data. All ATTUNE™ (DePuy Synthes, Warsaw IN)



**Fig. 1.** Screen shot of planning screen from Robotic-Assisted system, the impact of adjustments to the position and angle of implants on the resultant gaps between the femur and tibia through the range of motion are displayed.

primary TKAs implanted from Jan 1, 2014, through a database extract date of Nov 4, 2022, were examined. To be eligible for enrolment in this observational registry, patients needed to provide informed consent for participation and had procedures according to the devices' indications for use. The primary TKA operative details case report form of the registry included a question that asked the participating surgeons to indicate which soft-tissue releases (STR) were performed; if none were performed, this is also positively indicated (NSTR) (Fig. 2). Soft-tissue releases were defined as releases to structures executed with the intent to balance the knee. Any releases of the posterior cruciate ligament (PCL) were excluded from the analysis as it was not possible to determine if these releases were part of the planned technique or based on a decision made intra-operatively to balance the knee. Similarly, any documented synovectomies were ignored. These are not performed to balance the knee, and previous studies have found that they do not influence outcomes [21].

Robotically-Assisted (VELYS™ Robotically-Assisted Solution (DePuy Synthes, Warsaw IN)) procedures began with the ATTUNE implant in 2021 and were prospectively differentiated in the registry. Each knee was categorized according to whether a STR had been intentionally performed during the operation or not (NSTR), and whether the TKA was performed using RA or manual instrumentation (MI).

The procedures were conducted at 10 contributing centres in the US. Most procedures were conducted via either a medial parapatellar approach (62.7%) or trivector approach (21.5%). But further specific information on individual surgical techniques employed were not prospectively captured, and due to the number of contributing sites and surgeons there is certain to be variation in surgical technique. For example, there is variation in the methodology of determining femoral rotation. Some favour 3 degrees relative to the posterior condylar axis (measured resection technique) and others use a gap balancing

#### SOFT TISSUE RELEASES:

(Mark **NONE** or **ALL** that apply.)

☐ None

General

☐ Synovectomy \*

Medial

☐ Deep MCL

☐ Pes Anserinus

☐ Posteromedial Capsule

☐ Superficial MCL

Lateral

☐ Biceps Femoris

☐ Iliotibial Tract

☐ LCL

☐ P/L Capsule

☐ Popliteus Tendon

Posterior

☐ PCL \*

☐ PCL (Medial) \*

☐ Posterior Capsule

☐ Medial Femoral

☐ Lateral Femoral

☐ Medial Tibial

☐ Lateral Tibial

☐ Femoral Resection

☐ Tibial Resection

☐ Medial Stabilizers

Extensor Mechanism

☐ Lateral Patellar /

Lateral Retinacular Release

☐ Full

☐ Partial

☐ Quad Release

☐ Rectus Snip

☐ Tibial Tuberplasty/

Tibial Tubercle Osteotomy

☐ Other – specify:

**Fig. 2.** Section of Registry Intra operative case reports where the performed soft tissue releases were recorded. \*Synovectomies and PCL releases were not considered soft-tissue releases in the analysis.

technique, setting rotation based on the tibial cut with tensioners placed in flexion to achieve a rectangular flexion space. Further, the sequence and choice of STRs performed was determined by each individual surgeon. In the MI group, it is assumed that neutral mechanical alignment was targeted in most cases. Whilst in the RA group, it is likely that there was an evolution to a more patient specific alignment philosophy. Surgical time defined as incision to close was captured for all procedures.

Subjects were followed clinically according to each individual site's standard of care with the visits between 1 and 303 days classified as 6 months, between 304 and 668 days classified as 1 year and from 669 and 1034 days classified as 2-year visits. At each visit, including preoperatively, original Knee Society Score (KSS) and Knee Society Function Scores (KSFS) [22] were collected.

Kaplan-Meier implant survivorship was compared between STR and NSTR using all available data. The time variable for each subject was either the time to revision or the time from primary surgery to the time of database extract for those who were not revised.

The incidence of STR was compared between RA and MI using a Fishers' Exact test. To control for changing surgical techniques over time, an additional analysis of the incidence of STR was completed, restricting the MI to the same time period the RA system was available. KSS and KSFS were compared between STR and NSTR at 6 months, 1 year and 2 years among subjects with 2-year follow-up using an independent sample *t*-test. When a strong trend was identified in a *T*-test an analysis of covariance (ANCOVA) statistical analysis was used to compare mean differences accounting for any pre-op differences including age, body mass index (BMI), gender, pre-op KSFS, and pre-op anatomic alignment category.

### 3. Results

A total of  $N = 5982$  primary ATTUNE TKAs were identified with information on soft-tissue releases prospectively documented in the registry. Of these, RA TKA was performed on 331 knees, whereas 5651 TKAs were performed using MI. The RA and MI groups were of a similar mean age (69 Vs. 65.6), BMI (29.8 Vs. 30.2) and gender (56.7% female Vs. 50.9% female). There was a significant decrease in the incidence of soft-tissue releases in the RA group compared to MI (145/331 (43.8%) Vs. 4895/5651 (86.6%),  $p < 0.0001$ ) (Table 1). When the MI cohort was restricted to procedures performed within the same time-frame as the RA procedures the difference in rates of STRs reduced but remained significant (43.8% Vs. 69.4%,  $p < 0.0001$ ). The most common type of STR in the RA group was to the deep MCL (38.7% of RA procedures) (Table 2). There was no difference in the mean surgical time between the RA and MI (77.0 min (Standard Deviation 28.2) Vs. 76.9 min (Standard Deviation 20.1)  $p = 0.95$ ).

Of the 5982 total subjects there were 5040 in the STR group, and 942 in the NSTR group. There was no statistically significant difference in survivorship between STR and NSTR at 2 years (99.2% Vs. 99.9%) or at any other time points (Table 3, Fig. 3). The revisions (4/942, 0.4%) in the NSTR group were for infection ( $n = 2$ ) and stiffness ( $n = 2$ ). Of the revisions in the STR group (56/5040, 1.1%), 13 were for infection, 14 for loosening, 14 for instability, 5 for pain/stiffness, 3 for dislocation/spin out, and 1 for periprosthetic fracture. In addition to the revisions, the NSTR group had one reported superficial hematoma and one dislocation reported that did not result in a revision procedure. The STR group had 33 local serious adverse events reported that did not result in revision (33/5040, 0.7%) including 19 cases of arthrofibrosis, seven cases of superficial skin complications and four cases of patella femoral complications (Table 4). All the reported revisions and adverse events were in the MI group, with none reported in the RA group.

Of the 5982 total subjects, 948 were identified who had preoperative and 2-year KSFS scores, of which 684 were in the STR group. The most common STRs were deep MCL (49.7%), posteromedial capsule (24.6%) and lateral patella release (13.5%) (Table 2). Pre-operatively, the NSTR group were younger, had a higher BMI, a lower pre-op KSS and KSFS (Table 5). The NSTR and STR groups had similar distributions of neutral, varus and valgus knees (Table 5). In the NSTR group, a greater proportion of the implanted knees were cruciate retaining (CR) compared to the STR group, where the most common type of knee performed was posterior stabilized (PS) (Table 5). Age ( $Pr < 0.0001$ ), BMI ( $Pr < 0.0001$ ), KSFS pre op score ( $Pr < 0.0001$ ), the timing of the assessment within window ( $Pr < 0.0001$ ) and the pre-operative alignment ( $Pr = 0.023$ ) were all found to have a significant effect on KSFS and therefore included in the ANCOVA model. The choice of implant between PS and CR was not found to influence KSFS ( $Pr = 0.83$ ).

There was no significant difference between the NSTR and STR groups in KSS at 6 months (90.14 Vs. 88.39,  $p = 0.09$ ), 1 year (92.55 Vs. 91.84,  $p = 0.39$ ) or 2 years (92.60 Vs. 91.49,  $p = 0.16$ ). The NSTR had higher unadjusted KSFS at 6 months (84.73 vs. 77.51,  $p < 0.0001$ ), 1 year (89.87 vs. 83.54,  $p < 0.0001$ ) and 2 years (90.09 vs. 82.65,  $p < 0.0001$ ) (Fig. 4). After ANCOVA adjust-

**Table 1**  
Incidence of soft-tissue release in robotic assisted (RA) and manual procedures.

	RA ( $N = 331$ )	Manual ( $N = 5651$ )	Manual since Jan 1st 2021 ( $N = 939$ )
NSTR	186 (56.2%)	756 (13.4%)	287 (30.6%)
STR	145 (43.8%)	4895 (86.6%)	652 (69.4%)
P-Value, RA Vs. Man	–	<0.0001	<0.0001

**Table 2**

Incidence of different types of soft-tissue releases for all procedures with 2 years KSS and the RA group.

Types	ATTUNE with 2 years KSS (n = 948) n (%)	Robotic Assisted (RA) (n = 331) n (%)
<b>Medial</b>		
Deep MCL	471 (49.7)	128 (38.7)
Pes Anserinus	4 (0.4)	0 (0)
Posteromedial Capsule	233 (24.6)	0 (0)
Superficial MCL	39 (4.1)	0 (0)
<b>Lateral</b>		
Biceps Femoris	1 (0.1)	0 (0)
Iliotibial Tract	114 (12.0)	4 (1.2)
LCL	6 (0.6)	0 (0)
<b>Posterior</b>		
Posterolateral Capsule	54 (5.7)	0 (0)
Popliteus Tendon	33 (3.5)	0 (0)
Posterior Capsule	38 (4.0)	0 (0)
Medial Femoral	1 (0.1)	0 (0)
Lateral Femoral	1 (0.1)	0 (0)
Medial Tibial	6 (0.6)	0 (0)
Lateral Tibial	7 (0.7)	0 (0)
Femoral Resection	12 (1.3)	1 (0.3)
Tibial Resection	28 (3.0)	1 (0.3)
Medial Stabilizers	1 (0.1)	0 (0)
<b>Extensor Mechanism</b>		
Lateral Pat./Lateral Retinacular	128 (13.5)	0 (0)
<b>Soft-tissue Other</b>	13 (1.4)	13 (3.9)

**Table 3**

Implant survivorship for NSTR and STR groups.

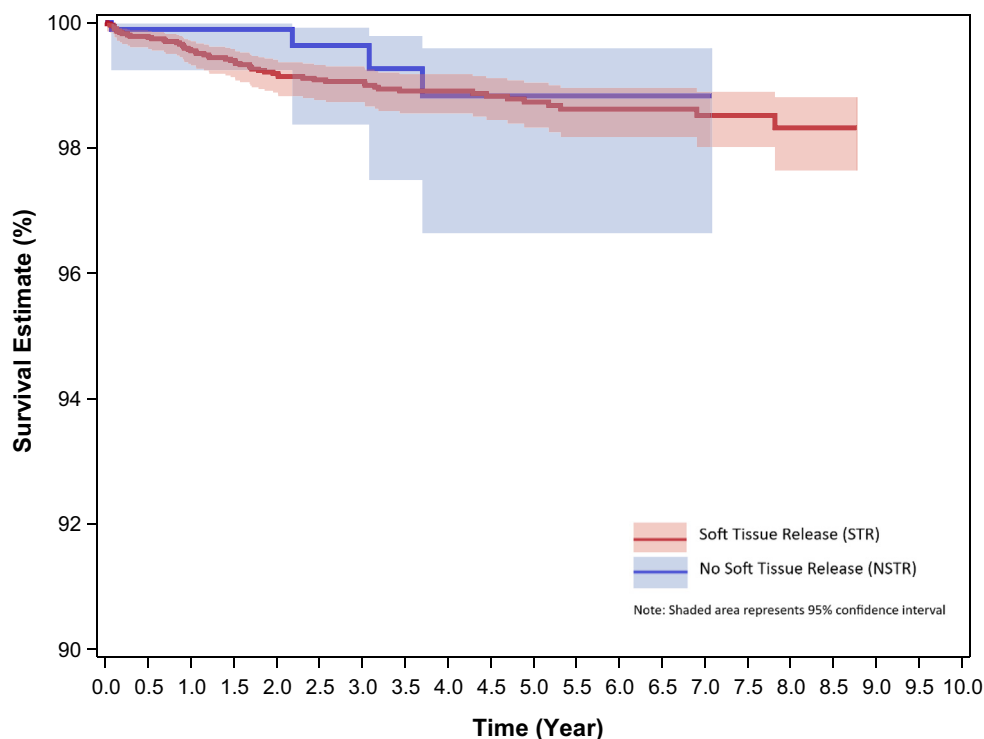
Statistic		Years from Surgery											
		0	0.5	1	1.5	2	3	4	5	6	7	8	9
NSTR	Survival Estimate	100	99.9	99.9	99.9	99.9	99.6	98.8	98.8	98.8	98.8		
	Lower 95% Confidence Limit	100	99.2	99.2	99.2	99.2	98.4	96.6	96.6	96.6	96.6		
	Upper 95% Confidence Limit	100	100	100	100	100	99.9	99.6	99.6	99.6	99.6		
	Knees Remaining	942	826	685	548	443	282	206	132	84	44		
	Cum. No. Revisions	0	1	1	1	1	2	4	4	4	4		
STR	Survival Estimate	100	99.8	99.5	99.4	99.2	99.1	98.9	98.7	98.6	98.5	98.3	
	Lower 95% Confidence Limit	100	99.6	99.3	99.1	98.9	98.7	98.6	98.3	98.2	98.0	97.6	
	Upper 95% Confidence Limit	100	99.9	99.7	99.6	99.4	99.3	99.2	99.0	99.0	98.9	98.8	
	Knees Remaining	5040	4891	4625	4417	4089	3408	2662	1908	1367	918	421	<40
	Cum. No. Revisions	0	12	22	29	38	43	48	52	54	55	56	56

ment to account for pre-operative differences in the groups, the differences remained statistically significant at 6 months (85.28 Vs. 77.41,  $p < 0.0001$ ), 1 year (90.09 Vs. 83.63,  $p < 0.0001$ ) and 2 years (90.71 Vs. 82.38,  $p < 0.0001$ ) (Fig. 4).

Breakdown of the 2-year KSS into its components revealed that the NSTR had lower pain scores than the STR group but the impact of this is offset by a larger deduction related to the alignment component (Table 6). Breakdown of the KSFS into the components revealed walking to be the biggest contributor to the difference between the NSTR and STR groups (Table 6).

#### 4. Discussion

The observed significant reduction in the rate of soft-tissue releases with RA is likely driven by a shift in the surgical technique employed. Many contributing surgeons utilize the additional information provided by the system during the planning phase to balance the knee via small adjustments to the positions of the implants (alignment, rotation, flexion, and resection levels of the femoral component, and alignment and slope of the tibial component). The rate of RA cases with at least one soft-tissue release found in this study (44%) is comparable to that reported by Plaskos et al. [23] who compared the rates of releases for two different robotic-assisted techniques, tibial-first gap-balancing (31%) and femur-first measured-resection (50%) and compared to published results from conventional (66%) [24]. In the current study, femur first and tibia first techniques were not differentiated. Further, the RA data captured in this study represents the learning curve of a recently introduced RA system and the rates of soft-tissue release may further decrease as proficiency with the technique improves. The rate of soft-tissue release reported for the manual group is higher than reported previously [24,25], however,



**Fig. 3.** Kaplan-Meier Survivorship plot comparing the rate of revision between the STR and NSTR groups.

**Table 4**

Reasons for revision and adverse events in STR and NSTR group. Note – none of the revisions or adverse events were reported in the RA group.

Events	STR (n = 5040) n (%)	NSTR (n = 942) n (%)	P-value
<b>Revisions</b>	56 (1.1)	4 (0.4)	0.0504
Infections	13 (0.26)	2 (0.21)	1
Loosening	14 (0.28)	0 (0)	0.146
Instability	14 (0.28)	0 (0)	0.146
Pain/Stiffness	5 (0.10)	2 (0.21)	0.304
Dislocation/Spin Out	3 (0.06)	0 (0)	1
Periprosthetic Fracture	1 (0.02)	0 (0)	1
<b>Adverse Events (not resulting in revision)</b>	33 (0.65)	2 (0.21)	0.157
Arthrofibrosis	19 (0.38)	0 (0)	0.059
Patella Femoral Complications	4 (0.08)	0 (0)	1
Superficial Skin Complications	7 (0.14)	1 (0.11)	1
Dislocation	0 (0)	1 (0.11)	0.158
Other	3 (0.06)	0 (0)	1

these studies did not include the releases to the deep MCL as soft-tissue releases with Unitt et al. grouping deep MCL and capsule releases with the none release group [25]. It is also interesting to note that the rate of releases with manual instrumentation reduces when the analysis is limited to procedures since 2021 suggesting that the recent literature may be having an impact on techniques.

The mean differences in the KSFS at 2 years between the STR and NSTR groups (7.44) is larger than the previously defined minimal clinically important difference for the KSFS (6.1–6.4) [26]. This suggests that the observed differences are not only statistically significant but also clinically meaningful. The use of the ANCOVA model did not materially impact the findings, with differences in the pre-op age and BMI having off-setting effects in the analysis with younger age associated with improved KSFS, but higher BMI associated with worse KSFS. The lack of influence of implant choice between CR and PS is consistent with prior studies [27].

Within the KSS there is an offsetting effect between improvements in pain scores for the NSTR group compared to STR and increased deductions for subjects with alignments that deviated away from neutral, resulting in similar total scores. The improved mean pain score for NSTR group correlates with the improved functional scores observed in the KSFS and together

**Table 5**

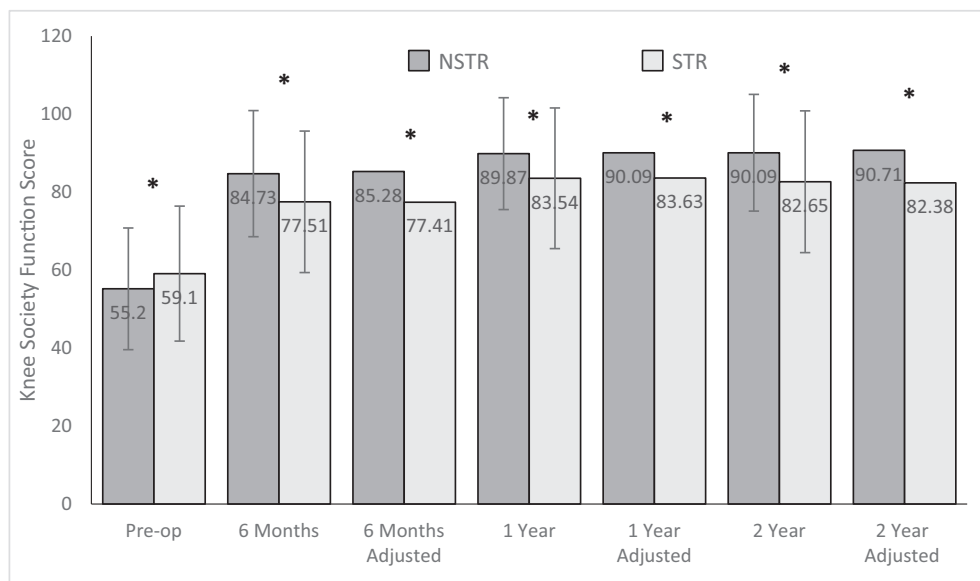
Preoperative demographics, alignment, KSS and KSFS of subjects with 2-year KSS and KSFS. Note alignment is anatomic as defined in the original KSS score.

	NSTR (N = 264)	STR (N = 684)	P-value
Age	Mean = 60.9 (SD 6.5)	Mean = 65.0 (SD 8.2)	<0.0001*
BMI	Mean = 32.9 (SD 7.6)	Mean = 29.9 (SD 6.0)	<0.0001*
Gender	120 (45.5%) Male, 144 (54.6%) Female	319 (46.8%) Male, 362 (53.2%) Female	0.717**
Indication			
Osteoarthritis	261 (98.9%)	660 (96.5%)	
Post traumatic	1 (0.4%)	17 (2.5%)	
Rheumatoid	2 (0.8%)	3 (0.4%)	
Avascular Necrosis	0 (0%)	1 (0.1%)	
Other	0 (0%)	3 (0.4%)	
Implant			
Cruciate Retaining	198 (75.9%)	243 (35.7%)	<0.0001**
Posterior Stabilized	63 (24.1%)	438 (64.3%)	
Pre-op KSS	Mean = 35.5 (SD 15.7)	Mean = 40.6 (SD 19.0)	<0.0001*
Pre-op KSFS	Mean = 55.2 (SD 15.6)	Mean = 59.1 (SD 17.3)	0.001*
<b>Anatomic alignment</b>			
Neutral (5–10 degrees valgus)	150 (56.8%)	364 (53.9%)	0.131***
Valgus (>10 degrees valgus)	30 (11.4%)	112 (16.6%)	
Varus (<5 degrees valgus)	84 (31.8%)	199 (29.5%)	

\*t-test

\*\*Fisher's exact test

\*\*\*Pearson Chi-square test

**Fig. 4.** Comparison of the effect of soft-tissue release on the Knee Society Function score at 6 months, 1 year and 2 years, Error bars +/- one standard deviation. Adjusted values are following an ANCOVA model whereby the pre-op KSFS, age, gender, BMI, alignment classification were included as influencing factors. \*  $p < 0.0001$ .

infers an improved patient reported outcome. The higher alignment deductions in the NSTR group is a logical observation as surgeons likely prioritized soft-tissue preservation over adjusting to neutral alignment. The alignment deductions incurred when deviating from mechanically neutral alignment in the KSS system may not be as relevant in the current context of RA TKA and surgeon preference for non-mechanically aligned TKA. This nuance of the KSS may confound interpretation of KSS total scores in all knee arthroplasty investigations.

KSS and KSFS have also been reported to have a High (33–53%) ceiling effect [28,29], which can make differentiating TKA techniques challenging. Further investigation with PROMS (patient reported outcome measures) with lower ceiling effects such as the Forgotten Joint Score may be warranted [30].



**Table 6**

Breakdown of KSS (Knee Society Score) and KSFS (Knee Society Function Score) at 2 years into subcomponents.

Score (possible range of score)	NSTR Mean (SD)	STR Mean (SD)	P-Value
KSS (0–100)	92.6(9.97)	91.49(12.16)	0.16
Pain (0–50)	47.27(8.54)	43.17(11.50)	<0.0001
Mediolateral Stability (0–15)	14.96(0.44)	14.88(0.85)	0.06
Anteroposterior stability (0–10)	9.98(0.31)	9.92(0.63)	0.045
Range of Motion (0–25)	23.4(1.81)	23.99(1.68)	<0.0001
Flexion contraction (deductions) (0–15)	0.02(0.21)	0.04(0.32)	0.28
Extensor lag (deductions) (0–15)	0(0)	0.03(0.47)	0.1
Alignment (deductions) (0–20)	3.34(4.79)	0.99(3.61)	<0.0001
KSFS (0–100)	90.09(14.97)	82.65(18.18)	<0.0001
Walking (0–50)	47.39(7.92)	42.25(10.98)	<0.0001
Stairs (0–50)	42.84(9.66)	40.86(9.0)	0.003
Walking support –deductions (0–20)	0.21(1.81)	0.53(2.55)	0.03

There was no significant difference in overall survivorship and incidence of complications between the two groups, indicating that any enhancements in functional outcomes for the NSTR group did not compromise safety measures. There may be an emerging trend toward reduced adverse events in favour of the NSTR group which will be important to monitor in future studies. The absence of arthrofibrosis in the NSTR group is of particular interest. It is logical to assume that minimizing soft tissue trauma would lead to a decrease in the fibroblast response and subsequently the incidence of arthrofibrosis. However, further research with greater power is required to confirm this hypothesis.

There are limited studies that directly assess the impact of soft-tissue releases on outcomes. Peters et al. conducted a comprehensive analysis of a single surgeon series and overall found very little influence of soft-tissue releases on outcomes with only valgus knees with NSTR showing improved KSS compared to valgus knees with one or two STRs [24]. Another study found that those knees requiring extensive soft-tissue release achieved similar KSS and KSFS at 1 year compared to those with none/minimal releases [25]. A more recent study found soft-tissue releases to be associated with worse KOOS scores at 6 months, 1 year and 2 year in robotic-assisted procedures [15]. However, the findings may have been heavily influenced by the STR group being subjects with more extreme preoperative deformities that were not possible to balance with changes to the bone resections alone.

There is continued debate about the relative importance of the Hip Knee Ankle angle (HKA) to long term survivorship. Personalized techniques which accept a restricted non-mechanical boundary for the HKA angle, in contrast to insisting on mechanical neutrality, reduce the need for soft-tissue releases. Preoperative HKA, especially in significant deformity, may determine whether even these more lenient boundaries may be sufficient to eliminate releases or whether there still may be need for releases, albeit fewer, in some knees. This study attempted to control for this by including the KSS classification of neutral, varus and valgus knees in the ANCOVA model; however, this classification is based on measurement of anatomical alignment on standard AP X-rays and are unlikely to correlate perfectly with assessment of alignment on full length, hip to ankle X-rays [31].

This study was exploratory and therefore subject to limitations. Surgical techniques and alignment philosophies may impact the need for soft-tissue releases, and the lack of that information may compromise our results. Further, there is some potential for variation between participating surgeons on the definition of a soft-tissue releases versus standard exposure particularly with the deep MCL. Nevertheless, it is our opinion that our results reflect an accurate reflection of the negative impact of STRs, and that as techniques evolve to minimize those releases, results of TKA will improve. In addition, only 948 of the total 5982 subjects in the study had KSS and KSFS scores at 2 years. The impact of increasing the sample size is difficult to predict but can be assessed in future studies. The strengths of this study are that it contains contributions from a large number of sites and surgeons collected as real-world standard of care making the results more generalizable. Further, the use of an ANCOVA model to control for pre-operative differences in the group to confirm the observed findings of the differences in the KSFS improve confidence in the findings.

## 5. Conclusion

The results of this retrospective, exploratory analysis found that the incidence of soft-tissue release was reduced with the use of Robotic-Assistance in TKA. When all TKAs were reviewed (regardless, if robotic-assistance was used or not) avoiding soft-tissue releases is associated with improved KSFS at 6 months, 1 year and 2 years post operatively, and KSS pain sub scores at 2 years without adversely impacting the survivorship.

## Disclosures

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## CRediT authorship contribution statement

**Andrew Spitzer:** Writing – review & editing, Methodology, Investigation, Data curation. **Robert Gorab:** Writing – review & editing, Supervision, Data curation, Conceptualization. **William Barrett:** Writing – review & editing, Resources, Methodology, Data curation. **Nader Nassif:** Writing – review & editing, Resources, Investigation, Data curation. **Michael Hunter:** Writing – review & editing, Investigation, Data curation. **Ian Leslie:** Formal analysis, Conceptualization. **James Lesko:** Writing – review & editing, Formal analysis, Conceptualization. **David Dalury:** Writing – review & editing, Methodology, Investigation, Data curation, Conceptualization.

## Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Andrew Spitzer reports financial support was provided by DePuy Synthes. Robert Gorab reports financial support was provided by DePuy Synthes. William Barrett reports financial support was provided by DePuy Synthes. Nader Nassif reports financial support was provided by DePuy Synthes. Michael Hunter reports financial support was provided by DePuy Synthes. David Dalury reports financial support was provided by DePuy Synthes. Andrew Spitzer reports a relationship with DePuy Synthes that includes: consulting or advisory, speaking and lecture fees, and travel reimbursement. Robert Gorab reports a relationship with DePuy Synthes that includes: consulting or advisory, speaking and lecture fees, and travel reimbursement. Nader Nassif reports a relationship with DePuy Synthes that includes: consulting or advisory, speaking and lecture fees, and travel reimbursement. David Dalury reports a relationship with DePuy Synthes that includes: consulting or advisory, speaking and lecture fees, and travel reimbursement. Ian Leslie and James Lesko are employees of DePuy Synthes.

## References

- [1] Gunaratne R, Pratt DN, Banda J, Fick DP, Khan RJK, Robertson BW. Patient dissatisfaction following total knee arthroplasty: a systematic review of the literature. *J Arthroplasty* 2017;32(12):3854–60. doi: <https://doi.org/10.1016/j.arth.2017.07.021>.
- [2] Insall JBR, Soudry M, Mestriner L. Total knee arthroplasty. *Clin Orthop Relat Res* 1985;192:13–22.
- [3] Ritter MA, Davis KE, Meding JB, Pierson JL, Berend ME, Malinzak RA. The effect of alignment and BMI on failure of total knee replacement. *J Bone Joint Surg Am* 2011;93(17):1588–96. doi: <https://doi.org/10.2106/JBJS.I.00772> [doi].
- [4] Ritter MA, Faris PM, Keating EM, Meding JB. Postoperative alignment of total knee replacement. Its effect on survival. *Clin Orthop Relat Res* 1994;299:153–6.
- [5] Bellemans J, Colyn W, Vandenuecker H, Victor J. The Chitranjan Ranawat award: is neutral mechanical alignment normal for all patients? The concept of constitutional varus. *Clin Orthop Relat Res* 2012;470:45–53.
- [6] Hirschmann MT, Hess S, Behrend H, Amsler F, Leclercq V, Moser LB. Phenotyping of hip-knee-ankle angle in young non-osteoarthritic knees provides better understanding of native alignment variability. *Knee Surg Sports Traumatol Arthrosc* 2019;27(5):1378–84. doi: <https://doi.org/10.1007/s00167-019-05507-1>.
- [7] Whiteside LA. Soft tissue balancing: the knee. *J Arthroplasty* 2002;17(4 Suppl 1):23–7. doi: <https://doi.org/10.1054/arth.2002.33264>.
- [8] Parratte S, Pagnano MW, Trousdale RT, Berry DJ. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. *J Bone Joint Surg Am* 2010;92(12):2143–9. doi: <https://doi.org/10.2106/JBJS.I.01398>.
- [9] Abdel MP, Ollivier M, Parratte S, Trousdale RT, Berry DJ, Pagnano MW. Effect of postoperative mechanical axis alignment on survival and functional outcomes of modern total knee arthroplasties with cement: a concise follow-up at 20 years. *J Bone Joint Surg Am* 2018;100(6):472–8. doi: <https://doi.org/10.2106/JBJS.16.01587>.
- [10] Murgier J, Clatworthy M. Variable rotation of the femur does not affect outcome with patient specific alignment navigated balanced TKA. *Knee Surg Sports Traumatol Arthrosc* 2020. doi: <https://doi.org/10.1007/s00167-020-06226-8>.
- [11] Clatworthy M. Patient-specific TKA with the VELYS robotic-assisted solution. *Surg Technol Int* 2022;40. doi: <https://doi.org/10.52198/22.STI.40.QS1561>.
- [12] MacDessi SJ, Griffiths-Jones W, Harris IA, Bellemans J, Chen DB. Coronal Plane Alignment of the Knee (CPAK) classification. *Bone Joint J* 2021;103-B(2):329–37. doi: <https://doi.org/10.1302/0301-620X.103B2.BJJ-2020-1050.R1>.
- [13] Shatrov J, Battelier C, Sappey-Mariniere E, Gunst S, Servien E, Lustig S. Functional Alignment Philosophy in Total Knee Arthroplasty - Rationale and technique for the varus morphotype using a CT based robotic platform and individualized planning. *Sicot-J* 2022;8:11. doi: <https://doi.org/10.1051/sicotj/2022010>.
- [14] Parratte S, Van Overschelde P, Bandi M, Ozturk BY, Batailler C. An anatomic-functional implant positioning technique with robotic assistance for primary TKA allows the restoration of the native knee alignment and a natural functional ligament pattern, with a faster recovery at 6 months compared to an adjusted mechanical technique. *Knee Surg Sports Traumatol Arthrosc* 2022. doi: <https://doi.org/10.1007/s00167-022-06995-4>.
- [15] Vigdorchik JM, Wakelin EA, Koenig JA, Ponder CE, Plaskos C, DeClaire JH, et al. Impact of component alignment and soft tissue release on 2-year outcomes in total knee arthroplasty. *J Arthroplasty* 2022. doi: <https://doi.org/10.1016/j.arth.2022.04.042>.
- [16] Winnock de Grave P, Kellens J, Tampere T, Vermue H, Luyckx T, Claeys K. Clinical outcomes in TKA are enhanced by both robotic assistance and patient specific alignment: a comparative trial in 120 patients. *Arch Orthop Trauma Surgery* 2022. doi: <https://doi.org/10.1007/s00402-022-04636-6>.
- [17] Doan GW, Courtis RP, Wyss JC, Green EW, Clary CW. Image-free robotic-assisted total knee arthroplasty improves implant alignment accuracy: a cadaveric study. *J Arthroplasty* 2022. doi: <https://doi.org/10.1016/j.arth.2021.12.035>.
- [18] Elbuluk AM, Jerabek S, Suhardi J, Sculco P, Ast M, Vigdorchik JM. Head-to-head comparison of kinematic alignment versus mechanical alignment for total knee arthroplasty. *J Arthroplasty* 2022. doi: <https://doi.org/10.1016/j.arth.2022.01.052>.
- [19] Dossett HG, Estrada NA, Swartz GJ, LeFevre GW, Kwasman BG. A randomised controlled trial of kinematically and mechanically aligned total knee replacements: two-year clinical results. *Bone Joint J* 2014;96-b(7):907–13. doi: <https://doi.org/10.1302/0301-620X.96b7.32812>.
- [20] Clatworthy M. Outcome & survival analysis of conventional measured resection, neutral alignment attune TKA vs CAS anatomic tibia, balanced femur, constitutional alignment attune TKA. *Orthop J Sports Med* 2017;5(5\_suppl5):. doi: <https://doi.org/10.1177/23259671175001562325967117S0015>.

- [21] Zhao Z-Q, Xu J, Wang R-L, Xu L-N. The efficacy of synovectomy for total knee arthroplasty: a meta-analysis. *J Orthop Surg Res* 2018;13(1). doi: <https://doi.org/10.1186/s13018-018-0752-y>.
- [22] Insall J, Dorr LD, Scott RD, Rationale SWN. of The knee society clinical rating system. *Clin Orthop Relat Res* 1989;Nov(248):13–4.
- [23] Plaskos C, Wakelin E, Shalhoub S, Lawrence J, Keggi JM, Koenig JA, et al. Soft-tissue release rates in robotic-assisted gap-balancing and measured-resection total knee arthroplasty. *International Society for Technology in Arthroplasty (ISTA) meeting, 32nd Annual Congress*. 102-B. Toronto, Canada; 2019.
- [24] Peters CL, Jimenez C, Erickson J, Anderson MB, Pelt CE. Lessons learned from selective soft-tissue release for gap balancing in primary total knee arthroplasty: an analysis of 1216 consecutive total knee arthroplasties: AAOS exhibit selection. *J Bone Joint Surg Am* 2013;95(20):e152. doi: <https://doi.org/10.2106/JBJS.L.01686>.
- [25] Unitt L, Sambatakakis A, Johnstone D, Briggs TWR. Short-term outcome in total knee replacement after soft-tissue release and balancing. *J Bone Joint Surg Brit* 2008;90-B(2):159–65. doi: <https://doi.org/10.1302/0301-620X.90b2.19327>.
- [26] Lee WC, Kwan YH, Chong HC, Yeo SJ. The minimal clinically important difference for Knee Society Clinical Rating System after total knee arthroplasty for primary osteoarthritis. *Knee Surg Sports Traumatol Arthrosc* 2017;25(11):3354–9. doi: <https://doi.org/10.1007/s00167-016-4208-9>.
- [27] Li N, Tan Y, Deng Y, Chen L. Posterior cruciate-retaining versus posterior stabilized total knee arthroplasty: a meta-analysis of randomized controlled trials. *Knee Surg Sports Traumatol Arthrosc* 2014;22(3):556–64. doi: <https://doi.org/10.1007/s00167-012-2275-0>.
- [28] Jenny JY, Louis P, Diesinger Y. High Activity Arthroplasty Score has a lower ceiling effect than standard scores after knee arthroplasty. *J Arthroplasty* 2014;29(4):719–21. doi: <https://doi.org/10.1016/j.arth.2013.07.015>.
- [29] Steinhoff AK, Bugbee WD. Knee Injury and Osteoarthritis Outcome Score has higher responsiveness and lower ceiling effect than Knee Society Function Score after total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc* 2016;24(8):2627–33. doi: <https://doi.org/10.1007/s00167-014-3433-3>.
- [30] Behrend H, Giesinger K, Giesinger JM, Kuster MS. The “forgotten joint” as the ultimate goal in joint arthroplasty: validation of a new patient-reported outcome measure. *J Arthroplasty* 2012;27(3):430–6 e1. doi: <https://doi.org/10.1016/j.arth.2011.06.035>.
- [31] Lee SA, Choi SH, Chang MJ. How accurate is anatomic limb alignment in predicting mechanical limb alignment after total knee arthroplasty? *BMC Musculoskelet Disord* 2015;16:323. doi: <https://doi.org/10.1186/s12891-015-0756-2>.