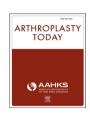


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Patient-Reported Outcomes in Robotic-Assisted vs Manual Cementless Total Knee Arthroplasty

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ABSTRACT

Background: Robotic-assisted total knee arthroplasty (RA-TKA) was introduced to provide surgeons with virtual preoperative planning and intraoperative information to achieve the desired surgical goals in an effort to improve patient outcomes. The purpose of this study was to compare clinical outcomes and patient-reported outcome measures following primary TKA using RA-TKA vs manual instrumentation. Methods: This was a retrospective cohort review study comparing 393 primary RA-TKAs vs 312 manual TKAs at a minimum 2-year follow-up. The same cementless implant design was utilized in all cases at a single institution. There were no significant differences in age or gender between groups. Outcome measures included range-of-motion, Knee Society (KSS), Western Ontario and McMaster Universities Osteoarthritis Index, Forgotten Joint Score-12, Knee Injury and Osteoarthritis Outcome Score for Joint Replacement, and overall patient satisfaction scores along with complications and survivorship. Results: Compared to manual TKA, the RA-TKA group had significant higher postoperative KSS Function and Knee scores, Western Ontario and McMaster Universities Osteoarthritis Index, and Knee Injury and Osteoarthritis Outcome Score for Joint Replacement scores (P < .001). A total percentage of 95.0% of RA-TKA vs 87.4% of manual TKAs were very satisfied or satisfied (P = .001). Survivorship with all-cause failure as the endpoint at 3 years was 96.9% in the RA-TKA group compared to 95.8% in the manual group (*P*= .54).

Conclusions: RA-TKA demonstrated significant improvement over manual jig-based instruments in KSS Function, KSS Knee, Western Ontario and McMaster Universities Osteoarthritis Index, Knee Injury and Osteoarthritis Outcome Score for Joint Replacement, and patient satisfaction scores following primary TKA with no differences in complications and revision incidence. RA-TKA provided a virtual 3-dimensional preoperative plan along with intraoperative information for adjustments to approximate the patients' native joint line and achieve a well-balanced soft-tissue sleeve about the knee for primary TKA.

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Introduction

Total knee arthroplasty (TKA) is widely regarded as the most effective treatment for end-stage knee osteoarthritis due to its ability to alleviate pain and improve function [1]. TKA is one of the most performed surgical procedures and continues to increase in volume in North America [2]. Between 2000 and 2019, the annual volume of estimated TKAs increased by an average of 156%, and the projected number of TKAs by 2040 is expected to rise to 1,222,988 in the Medicare population [3]. Several advancements in TKA have been made in recent decades, including improvements in surgical technique, implant design, a better understanding of knee kinematics, and a greater focus on patient-reported outcomes [4].

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Despite these advances and excellent survivorship following modern design primary TKA, about 20% of patients are dissatisfied following TKA [5–7]. The underlying reasons are believed to be multifactorial, including suboptimal implant positioning, malalignment, and inadequately balanced gaps leading to pain and instability [8–11]. While traditional manual techniques have been the mainstay of TKA, the introduction of robotic-assisted total knee arthroplasty (RA-TKA) incorporates technology to help the surgeon obtain accurate bone cuts, achieve the target limb alignment, and implant position along with intraoperative data to achieve well balanced gaps [12–17].

Few publications in the literature investigate the difference in patient-reported outcome measures (PROMs) and survivorship between traditional manual jig-based TKA and RA-TKA [18–21]. The purpose of this study was to compare clinical outcomes, PROMs, and complications in patients who underwent RA-TKA to those who underwent traditional manual TKA using the same cementless implant design.

Material and methods

This was an Institutional Review Board—approved retrospective study from our institution's total joint registry evaluating 500 consecutive primary cementless manual TKAs and 500 consecutive robotic-assisted cementless TKAs between October 2016 and September 2019.

Both cohorts received the same cementless TKA implant design (Tritanium Triathlon, Mahwah, NI) with over 90% of patellae being resurfaced. In the RA-TKA cohort, 316 patients received a posteriorstabilized implant and 78 received a cruciate ligament-retaining implant. In the manual cohort, 303 patients received a posteriorstabilized implant and 17 received a cruciate ligament-retaining implant. All cases were performed by a single surgeon at a single institution. All RA-TKA knees had a preoperative computed tomography scan, which was used to create a virtual 3-dimensional (3D) preoperative plan. There was a learning curve in the RA-TKA group. The initial learning curve was the placement of the trackers into the femur and tibia along with registration. The more important learning curve included analyzing the preoperative 3D data and making the intraoperative adjustments in implant position to achieve the desired results which in our experience took approximately 25 surgical cases to become efficient. The overall surgical goal in the RA-TKA group was to achieve functional knee positioning through approximating the native joint line, use the bony cuts to develop the medial and lateral gap spaces, avoid releasing intact, normal, native soft-tissue structures, and achieve well-balanced gaps within 1 to 2 millimeters through manipulation of the implant position in all 3 planes. With manual TKA, jig-based instruments were utilized with the goal of neutral mechanical alignment and achieving balanced flexion and extension gaps using a manual tensioning device to obtain a rectangular gap space in flexion adjusted to match the extension gap.

Inclusion criteria included patients who underwent either RA-TKA or manual TKA with the same cementless implant design, a minimum postoperative follow-up of 2 years, and body mass index (BMI) <40. After excluding patients who did not meet the inclusion criteria along with those lost to follow-up, there were 393 available for review in the RA-TKA group and 312 patients in the manual jigbased group. There was one robotic-assisted device shared among surgeons at the institution and RA-TKA was performed during the week when the technology was available and with manual instrumentation TKA when it was not available. The patient's surgical date was scheduled a few weeks prior to the procedure based on the next available operative time slot. Due to the learning curve and concern for possible pin tract complications, obese patients were excluded from RA-TKA initially until we had gained further experience.

The RA-TKA cohort included 178 males (44.8%) and 215 females (54.7%) with a mean age of 65.62 \pm 9.42 (range 26.55-85.86), a mean BMI of 30.4 kg/m 2 \pm 4.62 (18.19-39.93), and a mean follow-up of 34.7 months \pm 13.6 (24-72 months). The manual TKA cohort included 145 males (46.5%) and 167 females (52.5%) with a mean age of 65.4 \pm 9.70 (34.00-91.52), a mean BMI of 31.97 kg/m 2 \pm 4.82 (19.37-38.87), and a mean follow-up of 51.6 months \pm 19.0 (24-89 months). There was no statistically significant difference in gender or age between the 2 cohorts but there was a difference in BMI and mean follow-up, (<0.001 and <0.001, respectively). The average length of stay for the RA-TKA cohort was 1.80 days compared to 2.66 days for the manual TKA cohort (<0.001). The average ASA for the RA-TKA cohort was 2.41 compared to 2.36 also for the manual TKA cohort (<0.001) (see Table 1).

The preoperative knee range of motion (ROM) of flexion and extension in the RA-TKA group was 114.04 and 1.15 degrees, respectively, vs the manual TKA group with a preoperative ROM of 110.66 and 1.60 degrees (P=.068 for degrees of extension and P<.001 for degrees of flexion). There was a significant difference between the pre-operative KS Function scores, KS Knee scores, and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores between the RA-TKA and manual TKA cohorts (48.8 vs 46.6, P=.045, 44.8 vs 40.9, P<.001, and 48.0 vs 42.6, P=.013, respectively) (see Table 2).

Primary outcome measures included PROMs, patient satisfaction, and post-operative complications. All PROMs and patient satisfaction data were collected from patients through a paper

Table 1Demographic data stratified by cohort.

Demographic	Manual TKA	RA-TKA	T test/Fisher exact test (P)
Total number of patients	312 (97.5%, 312/320)	393 (99.7%, 393/394)	.0135
Sex			
Male (%)	145 (46.47%)	178 (44.79%)	.7614
Female (%)	167 (52.53%)	215 (54.71%)	
	Mean ± St. Dev (range)	Mean ± St. Dev (range)	
Age	$65.40 \pm 9.70 (34.00-91.52)$	$65.62 \pm 9.42 (26.55-85.86)$.75	
BMI (kg/m ²)	$31.97 \pm 4.82 (19.37 - 38.87)$	$30.38 \pm 4.62 (18.19-39.93)$	<.001
ASA	$2.36 \pm 0.51 (1-4)$	$2.41 \pm 0.56 (1-4)$.2611
Length of stay	$2.66 \pm 1.10 (1-9)$	$1.80 \pm 1.06 (0-12)$	<.001

ASA, American Society of Anesthesiologists physical status classification system; BMI, body mass index; RA-TKA, robotic-assisted-total knee arthroplasty; St. Dev., standard deviation; TKA, total knee arthroplasty.

Table 2 Preoperative patient metrics.

Metric	Manual TKA	RA-TKA	T test (P)
Degrees active extension	1.60	1.15	.068
	SD = 3.41	SD = 2.81	
	Range: 0-35	Range: 0-20	
Degrees active flexion	110.66	114.04	<.001
	SD = 10.98	SD = 9.98	
	Range: 70-130	Range: 85-135	
KS function score	46.57	48.85	.045
	SD = 14.99	SD = 12.41	
	Range: 0-100	Range: 0-100	
KS knee score	40.91	44.82	.0005
	SD = 13.30	SD = 13.18	
	Range: 11-85	Range: 18-95	
WOMAC	42.59	47.95	.013
	SD = 16.82	SD = 18.779	
	Range: 7-83	Range: 1-92	

RA-TKA, robotic-assisted-total knee arthroplasty; SD, standard deviation; TKA, total knee arthroplasty; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index

survey in the clinic or by telephone if the patient was unable to follow-up in person. The total joint registry staff at our institution were responsible for contacting patients for their follow-up which was usually the 1st, 2nd, 5th, and 10th year following the index procedure. PROMs consisted of the Knee Society Knee and Function Scores (KSS Knee, KSS Function) [22], Forgotten Joint Score-12 (FJS-12) [23,24], Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS-JR) [25], and WOMAC [26]. The minimal clinically important differences were determined based on previously published studies: KSS Knee (5.3-5.9), KSS Function (6.1-6.4), FJS-12 (10.8), KOOS-JR (14), and WOMAC (7.2) [27-29]. Patient satisfaction was measured by a 5-point Likert scale and included: 1, "Very Dissatisfied;" 2, "Dissatisfied;" 3, "Neutral;" 4, "Satisfied;" and 5, "Very Satisfied." Postoperative complications were grouped into categories such as requiring revision TKA, requiring a nonsurgical intervention, and other complications that did not fall within the above groupings. Patients underwent manipulation under anesthesia postoperatively for stiffness defined as failure to achieve 105 degrees of knee flexion at approximately 6 weeks following the index TKA in both groups.

Statistical analysis was conducted using Microsoft Excel and IBM SPSS Statistics (version 29). Student's *t*-tests were used to compare group means and Chi-squared analysis for categorical data. Univariate analysis was used to compare the preoperative and post-operative PROM delta between the groups after the data were tested for normality and normalized if needed. All tests were considered significant at 0.05.

Results

Both the RA-TKA and manual TKA cohorts demonstrated statistically and clinically significant improvement in the KSS Function, KSS Knee, and WOMAC scores postoperatively compared to preoperative scores. When the postoperative PROMs were compared using a Student's t-test, the RA-TKA had clinically significant higher postoperative KSS Function and KSS Knee scores compared to the manual group according to the minimal clinically important differences referenced previously (86.9 vs 80.6 and 93.0 vs 85.8, P < .001 respectively). The RA-TKA group had significantly higher postoperative KOOS JR and WOMAC scores compared to the manual TKA group (86.4 vs 81.5 and 90.6 vs 84.6 P < .001 respectively). We did not identify a difference in postoperative FJS-12 scores between the RA-TKA and manual TKA cohorts, 70.8 vs 69.6 respectively (P = .62) (see Table 3).

Table 3 Postoperative patient metrics.

Metric	Manual TKA	RA-TKA	T test/Fisher exact test (P)
Degrees active extension	0.22	0.23	.903
_	SD = 1.09	SD = 1.33	
	Range: 0-10	Range: 0-15	
Degrees active	117.51	120.36	<.001
flexion	SD = 8.80	SD = 6.96	
	Range: 40-130	Range: 85-140	
KS function score	80.60	86.87	<.001
	SD = 19.35	SD = 15.60	
	Range: 5-100	Range: 30-100	
KS knee score	85.77	92.96	<.001
	SD = 13.75	SD = 8.88	
	Range: 32-100	-	
FJS	69.57	70.78	.624
	SD = 29.93	SD = 28.01	
	Range: 0-100	Range: 0-100	
KOOS JR	81.53	86.42	<.001
	SD = 18.25	SD = 14.48	
	Range: 28-100		
WOMAC	84.63	90.63	<.001
	SD = 17.7	SD = 13.82	
	Range: 13-100	-	
Satisfaction	4.55	4.70	.01
(Likert 1-5)	SD = 0.86	SD = 0.69	
	Range: 1-5	Range: 1-5	
% of patients either satisfied		95.01%	.001
or very satisfied at most recent follow-up	(248/281)	(362/381)	

RA-TKA, robotic-assisted-total knee arthroplasty; SD, standard deviation; TKA, total knee arthroplasty; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

We conducted a comparison of the delta values derived from the preoperative and postoperative scores across the cohorts. The RA-TKA group demonstrated statistically significant improvement in the delta between preoperative and postoperative improvement in KSS Function (P = .008) and KSS Knee scores (P = .001) compared to the manual group. The RA-TKA cohort had a 38.05, 48.14, and 42.73 point increase in KSS Function, KSS Knee scores, and WOMAC, respectively. The manual jig-based TKA group had a 34.1, 44.86, and 42.03 point increase in KSS Function, KSS Knee scores, and WOMAC, respectively. Despite the RA-TKA group having higher preoperative PROMs compared to the manual group, the RA-TKA had a significant delta in 2 of the 3 PROM scores.

With overall patient satisfaction, 95% of the RA-TKA cohort and 87.4.% of the manual TKA cohort reported a Likert Patient Satisfaction Score of either 4 (satisfied) or 5 (very satisfied) (P=.001). The mean Likert scores were 4.70 and 4.55 for the RA-TKA and manual TKA, respectively (P=.012). The RA-TKA group had

Table 4 Complications requiring revision TKA.

Revision diagnosis	Manual TKA	RA- TKA	Fisher exact test (P)
Total	13	12	.5394
Prosthetic joint infection	4	1	.1763
Extensor mechanism rupture with open	-	2	.5059
arthrotomy \pm contamination			
Periprosthetic fracture	2	2	1.00
Aseptic loosening	2	1	.5867
Broken polyethylene post	1	-	.4426
Instability	2	3	1.00
Wound dehiscence	1	-	.4426
Arthrofibrosis	-	1	1.00
Surgery performed elsewhere for pain	1	2	1.00

RA-TKA, robotic-assisted-total knee arthroplasty; TKA, total knee arthroplasty.

postoperative knee range of motion with extension and flexion of 0.23 and 120.36 degrees vs the manual TKA group with 0.22 and 117.51 degrees of knee extension and flexion. There was no statistically significant difference in postoperative knee extension (P = .90), but there was a significant but not clinically relevant difference in knee flexion (P < .001).

There were 25 total revisions in this study, 12 in the RA-TKA and 13 in the manual TKA cohort. There was not a significant difference between the 2 cohorts in total revisions (P = .074). Table 4 outlines the complications requiring revisions of each cohort. Survivorship with all-cause failure as the endpoint at 3 years was 96.9% in the RA-TKA group compared to 95.8% in the manual group (P = .54).

There was no significant difference in incidence or types of complications requiring a nonrevision procedure between the 2 cohorts (P=.45) (see Table 5). There were a total of 16 arthroscopic synovectomies/lysis of adhesions (6 manual TKA, 10 RA-TKA, P=.62). A total of 52 manipulations under anesthesia were performed due to contracture/knee stiffness (28 manual TKA, 24 RA-TKA, P=.15). The strict criteria for manipulations under anesthesia in both groups was failure to achieve 105 degrees of knee flexion at 6 weeks postoperative from the index TKA. There was no significant difference in overall incidence or types of other complications recorded between the groups (P=1.00) (see Table 6).

Discussion

The RA-TKA group had significantly higher postoperative KSS Function and Knee Scores along with significantly higher WOMAC and KOOS JR scores at 2 years postoperatively compared to the conventional TKA group. These data are consistent with prior literature demonstrating significant improvements in PROMs in RA-TKA [30]. In a multicenter study of 861 primary RA-TKA patients with minimum 2-year postoperative follow-up, Joo et al. [31] showed clinically important improvements in mean FJS, KOOS JR, and mean pain scores. They reported that minimally important clinical differences for FJS, KOOS JR, and pain scores were met for 91%, 96%, and 90% of their patients, respectively. Others have found similar improvements in KSS and WOMAC scores in smaller cohorts of RA-TKA and manual TKA patients [32].

In this study of RA-TKAs (393) compared to manual jig-based TKA (312), we found that 95% of RA-TKA patients vs 87.4% of manual TKA patients were very satisfied or satisfied with their procedure, P=.001. This finding is also consistent with prior data reported by Smith et al. [33] who had similar outcomes in a sample of 150 patients. In their study, they showed 94% of patients were either very satisfied or satisfied with their RA-TKA compared to 82% in a manual cohort.

Many studies have shown that accuracy of ligamentous balancing of the flexion and extension gaps, along with satisfactory limb alignment and stable fixation are essential for patient function and durability of the prosthetic knee [34,35]. The use of advanced

Table 5Complications requiring nonrevision procedure.

Complication	Manual TKA	RA- TKA	Fisher exact test (P)
Total	34	36	.4499
Arthroscopic synovectomy/LOA (Patellar Clunk Syndrome, capsulitis, synovitis, arthrofibrosis)	6	10	.6218
Manipulation under anesthesia (contracture)	28	24	.1505
Excision of necrotic skin/wound dehiscence	-	1	1.00
Hematoma evacuation	-	1	1.00
Wound dehiscence + I&D	1	7	.0833

RA-TKA, robotic-assisted total knee arthroplasty; TKA, total knee arthroplasty.

Table 6 Other complications.

Complication	Traditional	Robotic assisted	Fisher exact test (P)
Total	15	18	1.00
Patellar clunk syndrome	1	1	1.00
(nonoperative)			
DVT/PE	1	-	.4426
Stroke (L MCA)	-	1	1.00
Patella fracture	1	2	1.00
Capsulitis w/ no LOA	1	3	.6338
Post-op ileus	1	-	.4426
Significant leg-length discrepancy	1	-	.4426
Pes anserine bursitis	1		.4426
CRPS	1	-	.4426
Neurogenic pain	-	3	.2588
Peroneal nerve palsy	2	-	.1955
Instability/pain	2	1	.5867
Tibial component loosening (nonoperative)	1	-	.4426

technology to develop a 3D preoperative plan, achieve the target limb alignment and implant position in all 3 planes along with well-balanced gaps within 1 to 2 mm, likely helped achieve the higher patient satisfaction score in the RA-TKA group. In a prospective randomized study of 100 patients who underwent primary TKA, Song et al. [34] showed that a cohort of robotic-assisted knees resulted in fewer mechanical axis outliers, which they defined as \pm 3 degrees from neutral, compared to 24% in a conventional group. In RA-TKA, intraoperative flexion-extension and mediallateral gap data within 1 mm are provided allowing for adjustments through implant position to accurately achieve the target gap balance. With conventional jig based TKA, gap balancing is in large part based on the use of laminar spreaders or other ligamentous tensioning tools which in large part still rely on the surgeon's experience in subjective intraoperative gap assessment. With RA-TKA, objective numbers are provided within 1 mm on the computer screen which can help surgeons make adjustments intraoperatively in achieving well balanced gaps. In addition, haptic boundaries of the saw blade in RA-TKA limit soft-tissue damage, promoting accurate bone cuts and decreased soft-tissue release. Kayani et al. [35] showed that there is decreased inadvertent macroscopic bone and periarticular soft-tissue injury in patients undergoing RA-TKA vs conventional TKA, a finding that leads to lower pain scores, deceased opioid usage, and earlier discharge from the hospital.

In this study, the tools provided with RA-TKA surgery including 3D preoperative planning, accurate bone cuts, precise gap balancing within 1 to 2 mm, and the ability to achieve and confirm the target limb and component alignment likely contributed to the increased patient satisfaction and improved PROMs. In the manual jig-based group, the target alignment was neutral mechanical alignment, whereas in the RA-TKA group, the overall goal was to approximate the patient's native oblique joint line and achieve well-balanced gaps in the coronal plane within 1 to 2 mm through manipulating implant position to restore the native soft-tissue sleeve and avoid release of healthy native soft-tissue structures when feasible. The avoidance of neutral mechanical axis as the target alignment for the RA-TKA may have also contributed to the improved PROMs in this study. We did not demonstrate any difference in the incidence of revision surgery between the RA-TKA group and manual jig-based TKA cohort.

There are limitations to this study given its retrospective nature which can introduce selection bias among the RA-TKA group vs the manual jig-based group. It is worth noting that the RA-TKA cohort had statistically significantly higher preoperative PROMs. To further reinforce our observation of improved PROMs in the RA-TKA cohort

relative to the manual cohort, despite the initial differences in preoperative PROMs, we conducted a comparison of the delta values derived from the preoperative and postoperative scores across the cohorts. This comparison showed the RA-TKA group had a statistically significant increase in the KSS Function and KSS Knee scores over the MA-TKA group. Both groups saw a similar improvement in the WOMAC scores, and the delta was not statistically significant between the 2 groups.

There was no difference in the groups between the preoperative ASA scores. All cases were performed at a single institution and by a single surgeon which may limit the external validity and generalizability of the findings. However, this approach also enhances the internal validity of the study. We also did not include radiographic data since we were primarily evaluating PROMs and patient satisfaction following TKA. Another limitation to our study is that we did not include comorbidities or social determinates of health in our analysis which could potentially have an impact on outcomes and patient satisfaction. Despite these limitations, given the significant increase in the use of RA-TKA, this study does add to the growing body of knowledge comparing the use of RA-TKA vs manual jig-based instruments due to the fairly large number of patients in the 2 groups using the same implant design along with the same preoperative and postoperative protocols.

The use of advanced technology for TKA continues to be controversial similar to other innovations in the evolution of TKA with most major orthopedic implant companies now providing technologic tools for the surgeon to perform a TKA. This study using RA-TKA resulted in significantly improved postoperative Knee Society scores, along with WOMAC, KOOS JR, and patient satisfaction scores when compared to manual jig-based TKA. Patient satisfaction was significantly higher in the RA-TKA group, with 94.0% reporting being either very satisfied or satisfied compared to 87.4% in the manual TKA group.

The improved satisfaction in patients undergoing RA-TKA in this study was likely multifactorial and included the use of 3D preoperative planning, the ability to approximate the patient's native 3D joint-line, achieve the target limb alignment, and obtain a wellbalanced soft-tissue sleeve within 1 to 2 mm in flexion and extension. The ability to virtually manipulate the implant position and bony cuts in order to obtain the soft-tissue gaps also led to avoidance of soft-tissue releases of native intact soft-tissue structures. Historically, patient satisfaction following TKA has been inferior compared to total hip arthroplasty [36]. This gap may be getting closer with the advent of technological tools available at present to the surgeon performing TKA. Additional work is needed to determine the individual patient's ideal limb alignment, the native 3D joint line and ideal soft-tissue tension and balance to restore the native knee kinematics for the best functional outcome following primary TKA.

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Conflicts of interest

Arthur Malkani reports receiving IP royalties from, being a paid consultant for, being a paid presenter or speaker, and receiving research support from Stryker Orthopedics. He also reports having stock or stock options in Parvizi Surgical Innovation.

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CRediT authorship contribution statement

Michael J. Stoltz: Writing — review & editing, Writing — original draft, Investigation. Nolan S. Smith: Investigation, Formal analysis. Sarag Abhari: Investigation, Formal analysis. John Whitaker: Writing — review & editing, Validation, Investigation, Formal analysis. James F. Baker: Writing — review & editing. Langan S. Smith: Writing — review & editing, Project administration, Investigation, Data curation. Rohat Bhimani: Formal analysis, Data curation. Madhusudhan R. Yakkanti: Writing — review & editing, Supervision. Arthur L. Malkani: Writing — review & editing, Writing — original draft, Supervision, Methodology, Funding acquisition, Conceptualization.

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