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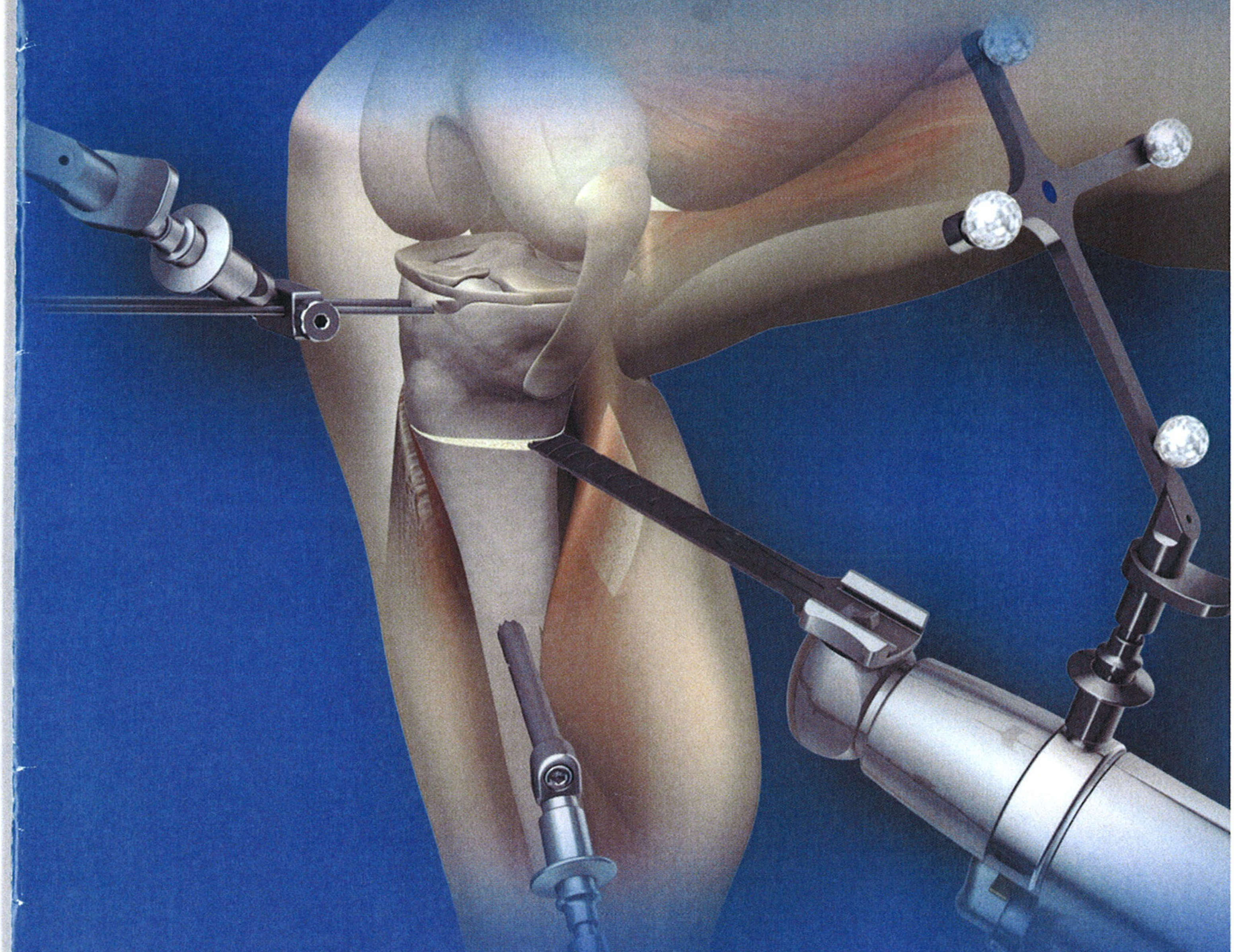

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Columbus Primary Total Knee Replacement: A 2- to 4-Year Follow-up of the Use of Intraoperative Navigation-derived Data to Predict Pre- and Postoperative Function

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abstract

The purpose of this study was to examine the clinical outcomes associated with the Columbus primary total knee replacement (B. Braun Aesculap, Tuttlingen, Germany), correlate these outcomes with variables measured intraoperatively with the OrthoPilot navigation system (B. Braun Aesculap), and explore the full potential of automating the process of intraoperative data collection. Clinical and functional outcomes at 2.5 years were similar to results reported in previous studies. Correlations were seen between initial mechanical axis deformity and postoperative range of motion as well as between final mechanical axis alignment and the presence of flexion contractures at later follow-up. It is now possible to potentially stratify particular segments of patients and develop specific intraoperative alignment targets that are most likely to yield positive clinical and functional outcomes.

Computer-assisted total knee replacement (TKR) has been shown to increase the precision and accuracy of implant alignment.[1-8] It is unclear, however, whether the potential improvements in implant alignment translate to improvements in implant durability or long-term clinical and functional outcomes. An intraoperative navigation system offers the potential to relate intraoperative variables, such as alignment, laxity, and soft tissue balance immediately before and after implant placement to long-term clinical and functional outcomes such as pain, range of motion (ROM), patient mobility, and movement independence. To our knowledge, there has not been a definitive examination of this relationship to date. Through the process of automation, it is possible to seamlessly translate the intraoperative data produced by the navigation system into a format that can be easily examined in relation to pre- and postoperative outcome measures. The purpose of this study was to examine the clinical and functional outcomes associated with the Columbus primary TKR (B. Braun Aesculap, Tuttlingen, Germany), correlate these with variables measured intraoperatively by the navigation system, and explore the full potential of automating the transfer of intraoperative limb and implant alignment data as measured with a computer-assisted navigation system.

MATERIALS AND METHODS

We performed 58 consecutive computer-assisted TKAs on 51 patients. Aesculap primary, posterior cruciate retaining Columbus implants were inserted using the OrthoPilot (B. Braun Aesculap) image-free navigation instrumentation. Of these patients, 30 underwent unilateral computer-assisted surgery (CAS), 7 underwent bilateral CAS, and 14 underwent bilateral TKA with one side performed using CAS. Basic

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Dr. Stulberg is a consultant for Aesculap. Drs Yaffe and Shah, Michael A. Granieri, and Philip H. Schmidt have no relevant financial relationships to disclose. ORTHOPEDICS *was unable to determine whether Susan E. Gall-Sims, or Nicholas Palmese have any relevant financial relationships to disclose or whether they are paid consultants for any companies.*

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Table 1

Demographics

Patients		51	
Unilateral TKA (%)		51%	
Age (y)	Age (range)	65.7	(48.0-86.1)
Sex (% male)		31%	
Dx (% OA)		100%	
BMI Avg	BMI (range)	32.0	(22-52)

demographic information was obtained for each patient (Table 1). For each TKA, we obtained weight-bearing, full-length anteroposterior (AP) and short film lateral radiographs. The AP mechanical axis and sagittal femoral and tibial axis measurements were recorded, both intraoperatively using the navigation system and with standard 4-week (short-term) and 2-year (long-term) postoperative radiographs. Investigational review board permission was obtained for this study.

We obtained intraoperative navigation measurements preoperatively before any cuts were made and again postoperatively after cuts were made and implants placed. The target intraoperative alignment was 0° for the mechanical, femoral, and tibial axes. Through an automated process, the alignment results generated by the navigation system were compared with postoperative outcomes. Pre- and postoperative clinical examinations at 4 weeks, 6 months, 1 year, and 2 to 4 years were performed by a physician blinded to intraoperative measurements. Average follow-up was 2.5 years. The Knee Society Knee score, which is a composite from measures of ROM, pain, and knee stability, and the Knee Society Functional score, which is an assessment of patient mobility and movement independence, were evaluated according to the Knee Society scoring system. Six patients (all with unilateral TKA) were lost to follow-up due to relocation, unwillingness to continue participation in the study, or lack of intraoperative measurements. These patients were excluded from the final analysis of the data.

Table 2

Clinical and Functional Findings: Preoperative, 1-month Postoperative, and 2-year Postoperative

	CAS Group
Mechanical Axis[a]	
Preoperative	5.62° ± 5.2 (-12°-16°)
Postoperative	0.56° ± 1.0 (-1°-3°)
Flexion Contracture	
Preoperative	5.36° ± 4.95 (0°-15°)
1 mo postoperative	1.59° ± 2.71 (0°-13°)
2-y postoperative	0.31° ± 1.07 (0°-5°)
ROM	
Preoperative	114.2° ± 17.0 (60°-145°)
1-mo postoperative	101.8° ± 20.9 (0°-135°)
2-y postoperative	120.7° ± 13.1 (50°-140°)
Total Laxity[a]	
Preoperative	8.7° ± 3.0 (3°-16°)
Postoperative	2.7° ± 1.1 (0° to 6°)
Pain Score[b]	
Preoperative	13.3 ± 11.7 (0-50)
1-mo postoperative	27.4 ± 13.6 (0-50)
2-y postoperative	43.1 ± 12.5 (0-50)
Function Score	
Preoperative	47.5 ± 15.0 (5-80)
1-mo postoperative	46.8 ± 16.9 (5-85)
2-y postoperative	76.7 ± 23.9 (30-100)
Knee Score	
Preoperative	43.5 ± 19.2 (0-100)
1 mo postoperative	68.9 ± 18.0 (27-100)
2-y postoperative	88.5 ± 18.1 (21-100)

(30 Unilateral, 7 Bilateral, 14 Bilateral with One-side CAS)

[a] *Navigation-generated intraoperative measurement.*

[b] *Pain score: 50 = no pain; 0 = maximum pain.*

Table 3

Change in Clinical and Functional Outcome Measures (Preoperative to 2 y)

	Minimum	Maximum	Mean	SD
Knee Score	-26	97	48.37	25.96
Function Score	-10	95	29.66	24.05
Pain Score[a]	-20	50	31.25	15.69
ROM (in degrees)	-72	55	7.05	18.11

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[a] *Pain score, 50 = no pain; 0 = maximum pain*

We used the Aesculap OrthoPilot navigation system for computer-assisted

Table 4

An Analysis of Radiographic and Navigation Measurement of Limb and Implant Alignment

Axis of Measurement	Measurement of Interest	Mean	Minimum	Maximum	SD
Mechanical Axis (Antero-posterior) (Varus +)	Preop **Radiograph**	8.76	-12	22	8.24
	Preop **Navigation**	5.62	-12	16	5.20
	Postop (1 mo) **Radiograph**	1.91	-4	8	2.89
	Postop (2 y) **Radiograph**	1.43	-2	4	1.91
	Postop **Navigation**	.56	-1	3	1.00
Femoral Axis (Sagittal) (Flexion, +)	Postop (1 mo) **Radiograph**	2.05	-4	7	2.46
	Postop (2 y) **Radiograph**	1.73	0	4	.961
	Postop **Navigation**	-.24	-2	2	.847
Tibial Axis (Sagittal) (Posterior Slope, -)	Postop (1 mo) **Radiograph**	-2.10	-7	2	1.80
	Postop (2 y) **Radiograph**	-2.93	-8	0	2.219
	Postop **Navigation**	-.76	-6	1	1.33

TKA and to generate navigation alignment measurements.

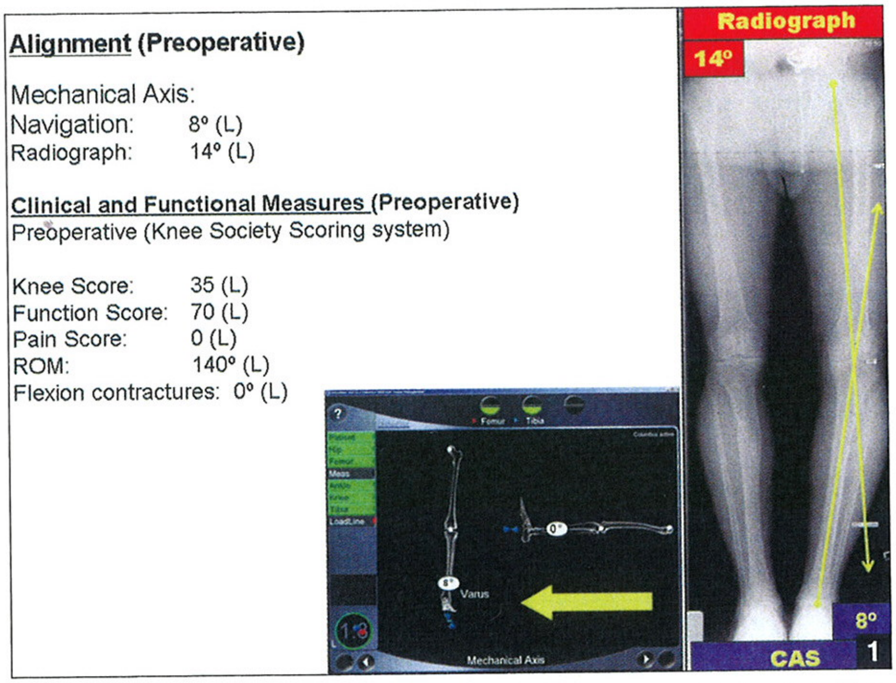
We used the ORUpload software system (EcomGlobalMedical Research and Development Inc, San Antonio, Texas) to automate the transfer and integration of intraoperative data collected by the navigation system to the postoperative data collection program.

A two-tailed bivariate Pearson correlation was used to evaluate the strength of the association between pre- and postoperative radiographic and navigation alignment measurements as well as the association of interobserver measurements. An analysis was performed on pre and postoperative navigation-generated alignment measurements as well as clinical and functional outcomes. Significance was considered *P* < .05. All statistical analyses were performed using SPSS version 14.0 statistical software (SPSS Inc, Chicago, Illinois).

RESULTS

At a mean follow-up of 2.5 years, patients exhibited mean Knee Society Knee scores (composite of pain, ROM, and knee stability) of 88.5 ± 18.1 (21 to 100), Knee Society Functional scores (composite of patient mobility and movement independence) of 76.7 ± 23.9 (30 to 100), Knee Society Pain scores of 43.1 ± 12.5 (0 to 50), ROM of 120.7° ± 13.1 (50° to 140°), and flexion contractures of 0.31° ± 1.0 (0° to 5°) (Table 2). Compared with preoperative values, patients exhibited mean increases in Knee Society Knee scores of 47.3 ± 25.9 (-26 to 97), Functional scores of 29.6 ± 24.0 (-10 to 95), Pain scores of 31.2 ± 15.6 (-20 to 50), and ROM of 7.0° ± 18.1 (-72° to 55°) (Table 3).

Mean preoperative mechanical axis measurements were 9.28° as measured on standard long-standing weight-bearing radiographs and 5.62° as measured by the navigation system while the patient was non-weight bearing and lying supine in the operating room. Mean postoperative mechanical axis measurements were 1.43° as measured by 2-year postoperative radiographs and 0.56° as measured by the navigation system once bone cuts were made and implants placed. Postoperative sagittal femoral flexion was 1.73° and posterior tibial slope was 2.93° as measured by 2-year radiographs and -0.24° and 0.76°, respectively, as measured by the navigation system (Table 4). The pre- and postoperative alignment and clinical and functional outcome measures of our study patient with the most no-



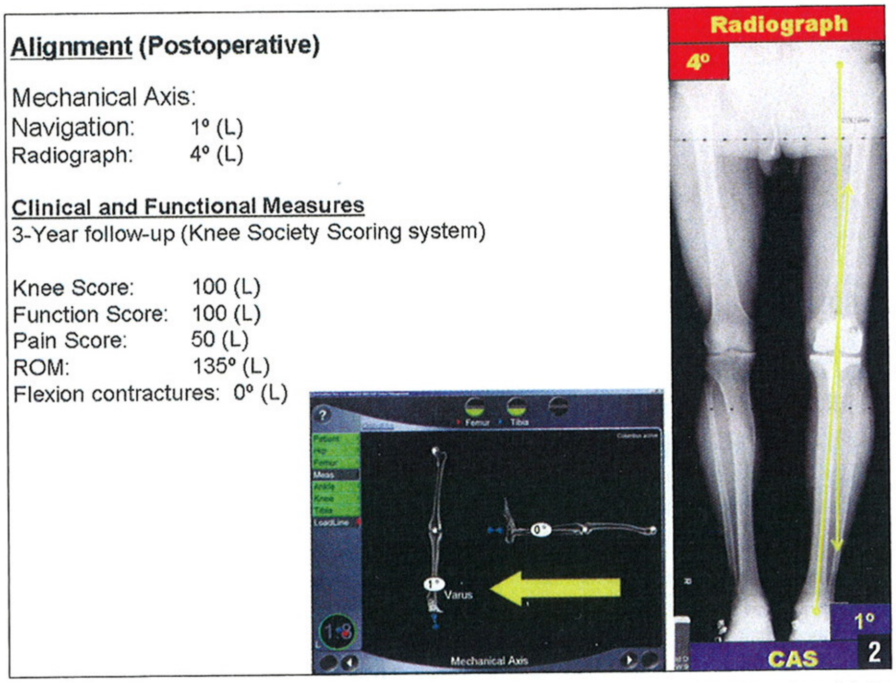
Alignment (Preoperative)

Mechanical Axis:
Navigation: 8° (L)
Radiograph: 14° (L)

Clinical and Functional Measures (Preoperative)
Preoperative (Knee Society Scoring system)

Knee Score: 35 (L)
Function Score: 70 (L)
Pain Score: 0 (L)
ROM: 140° (L)
Flexion contractures: 0° (L)

Figure 1: Preoperative alignment and clinical and functional outcome measures of study patient with the most notable preoperative limb deformities.



Alignment (Postoperative)

Mechanical Axis:
Navigation: 1° (L)
Radiograph: 4° (L)

Clinical and Functional Measures
3-Year follow-up (Knee Society Scoring system)

Knee Score: 100 (L)
Function Score: 100 (L)
Pain Score: 50 (L)
ROM: 135° (L)
Flexion contractures: 0° (L)

Figure 2: Postoperative alignment and clinical and functional outcome measures of study patient with the most notable preoperative limb deformities.

table preoperative limb deformities are presented in Figures 1 and 2.

An analysis of correlations between intraoperative navigation-generated variables and pre and postoperative (2 to 4 years) outcome measures were notable for (1) a statistically significant association between increased preoperative mechanical axis deviation and both a decreased absolute ROM (r = -0.438, P = .017), and increased ROM improvement (r = 0.482, P = .008) at 2 to 4 years; (2) a statistically significant association of increased preoperative flexion contracture with the presence and magnitude of a flexion contracture (r = 0.343, P = .035) at 2 to 4 years; (3) a statistically significant association of increased postoperative mechanical axis deviation and the presence and magnitude of flexion contractures (r = 0.653, $P < .01$) at 2 to 4 years, and (4) a statistically significant association between increased posterior tibial slope cut and increased postoperative laxity (r = 0.317, P = .032). An examination of additional correlations between intraoperative variables (laxity, mechanical axis, femoral and tibial cut axes) and postoperative outcomes (Knee Society Knee score, Function score, Pain score, ROM, and pre to postoperative changes in these variables) did not yield any statistically significant findings.

DISCUSSION

The majority of studies that have assessed outcomes of CAS TKA have focused on alignment as the primary outcome measure rather than clinical and functional outcomes.[1-8] The alignment results reported in this study using the Columbus Knee System and the OrthoPilot navigation system are consistent with the results reported in these previous studies. Moreover, it appears that the Columbus CAS TKA generates clinical and functional outcomes that are comparable with previous studies that have evaluated these outcome measures in TKA performed using manual instrumentation.

Analysis of Outcomes

In our study, we found Knee Society Knee, Functional, and Pain scores of 88.5 ± 18.1 (21 to 100), 76.7 ± 23.9 (30 to

100), and 43.1 ± 12.5 (0 to 50), respectively. These results were similar to results seen by Kane et al., who found mean Knee scores of 80.0 to 82.4 in 57 published studies with average follow-up between 6 and 189 months.[9]

Similar results were reported by Spencer et al., who used a Duracon knee prosthesis (Stryker Orthopaedics, St. Leonards, Australia) and noted an average Knee Society composite score (combined Knee and Functional scores) of 156.4 ± 33.1.[10] Molfetta et al., used a Search-evolution prosthesis (B. Braun Aesculap) and found Knee and Functional scores of 84 ± 5.4 and 90 ± 5.3 at an average follow-up of 5.4 years, which were slightly greater in value and exhibited smaller standard deviations than the results of our current study.[11] Clayton et al. used the PFC Sigma prosthesis (Depuy, Johnson & Johnson, New Brunswick, NJ) and evaluated Knee, Functional, and Pain scores at 5-year follow-up.[12] He found postoperative Knee scores of 89.3 ± 12.1 (mean improvement, 58.4), Functional scores of 79.9 ± 19.2 (mean improvement, 31.6), and Pain scores of 46.2 ± 10.4. The Pain scores in particular are notably similar in magnitude to those in our study. Matsumoto et al. used the Vector Vision (Depuy-BrainLab, Heimstetten, Germany) and the PFC Sigma (Depuy, Warsaw, Ind) and found 2-year postoperative Knee scores of 84.5, Functional scores of 94.3, and ROM of 113.0 at follow-up of 27 months.[13] These results demonstrate superior functional scores but slightly lower knee scores and ROM compared to the present study. Average ROM in our study was 120.7° ± 13.1° (50° to 140°). These results were similar to those from Laskin et al., who found mean ROM of 118° in a 5-year follow-up of patients who were implanted with the Genesis II (Smith and Nephew, Memphis, Tenn).[14] Kim et al. used the PFC Sigma prosthesis (Depuy) and found Pain scores of 44 and ROM of 127° at an average follow-up of 2.6 years.[15]

Several investigators have reported the tendency for Knee and Function scores to decline over time.[9,11,16] Benjamin et al. found that improvements in Knee Society scores are not permanent.[16] Rather, declines were seen in clinical and functional measures after 3 years of follow-up, most notably in patients with pre-existing, symptomatic arthritis in the contralateral knee or other joints. Declines over time in Knee Society and Hospital for Special Surgery Scores were also noted by Kane et al.[9] Given this trend, some investigators have suggested that the optimal or most appropriate time to evaluate Knee scores is 5 years postoperatively.[11] Our average follow-up was 2.5 years, thus there may be a potential for patients to continue to achieve improvements in ROM, reductions in pain, and advances in mobility in continued follow-up.

Relation of Intraoperative Variables to Postoperative Function

Intraoperative navigation allows the surgeon to correlate intraoperative limb and implant measurements to pre and postoperative outcome measures. To our knowledge, there are no studies that have examined this type of relationship. There are, however, several studies that have investigated the impact of demographic and baseline functional data on postoperative outcomes. Stickles et al. found a trend toward improved WOMAC scores, compared with preoperative baseline scores, in patients with a higher body mass index (BMI).[17] Jones et al. found no significant relationship between preoperative pain status and age, sex, or BMI.18 They did report however, that significant preoperative pain was a positive predictor of postoperative pain. Konig et al. found a positive correlation between BMI and functional outcomes but no correlation between age, gender, or BMI to pain or overall Knee Society scores.[19]

In our study, we discovered a statistically significant relationship between several key intraoperative and postoperative variables. We discovered that patients with the most significant preoperative mechanical axis deformities achieved less absolute postoperative ROM at 2 to 4 years but experienced greater overall ROM improvements than did patients with less significant initial deformities. We also found a significant association between postoperative mechanical axis deviation and the magnitude of flexion contractures at 2 to 4 years. In addition, the presence of a preoperative flexion contracture was strongly associated with the continued presence of a flexion contracture postoperatively. Increased posterior tibial slope was also associated with greater total mediolateral laxity at the end of the procedure. These types of relationships may help to identify the factors that will affect clinical outcomes most significantly and may further help to identify the patients who would benefit most from the use of CAS during TKA. These types of relationships may help establish optimal alignment goals for patients with varying preoperative deformities and instabilities who undergo TKA.

Automation Process

Automation tools allow the surgeon to analyze patient data both intraoperatively and postoperatively in real time and may help to predict postoperative outcomes. The use of an intraoperative navigation system and the automated management of the information that this system provides is proving beneficial in helping us understand the relationship between intraoperative variables, cuts, and alignment and pre and postoperative outcome measures. The automation process begins with a software interface that electronically captures data generated by the navigation system with minimal effort by the surgeon. Information on alignment, laxity, ROM, and bone cuts is stored and available for analysis. This information is then transferred as automated file algorithms to directories and datasets specific to the field of research. The information can then be stratified among a set of variable searching tools that macromanage the collected data. Physicians and staff use electronic data capturing (EDC) forms to enter clinical follow-up data directly into the patient record. Once entered, the data can be updated easily throughout the patient study timeline. The data is then available for immediate viewing, searching, and analysis. The system also has the ability to store and incorporate radiographic studies and measurements into the data evaluation, allowing real time evaluation of associations between specific alignment measures and clinical and functional outcomes. For example, a need to compare the correlation of preoperative mechanical axis measurements to postoperative Knee scores at 1 month and 2 years in patients with preoperative mechanical axis deviations ≤3° versus patients with deviations ≥5° can be accomplished in seconds. Given the considerable time to market acceptance of new medical technologies and devices, software automation tools have the potential to close the gap between physician-led studies and surgical innovations by streamlining and simplifying the process of data collection and analysis.

CONCLUSION

At an average of 2.5 years of follow-up, navigated TKA with the Columbus implant produced clinical and functional outcomes similar to those reported in previous studies.[9-12,14,15] The collection of intraoperative data through use of a navigation system allows for the establishment of a long-term database where one can easily analyze the relationship between intraoperative variables and pre and postoperative clinical and functional outcomes. Automation streamlines the data analysis process by electronically capturing intraoperative navigation-generated data and transforming it into a format that can be easily analyzed in relation to patient demographic variables, alignment measurements, and clinical and functional outcome measures. We are now able to stratify groups of patients, such as those with large initial deformities or flexion contractures, and develop intraoperative alignment targets most likely to yield positive clinical and patient-perceived functional outcomes.

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