SECURE TRACKS DEVICE IMPROVES FUNCTIONAL RECOVERY AND PAIN AFTER TOTAL KNEE ARTHROPLASTY: A PROSPECTIVE, RANDOMIZED, PILOT STUDY

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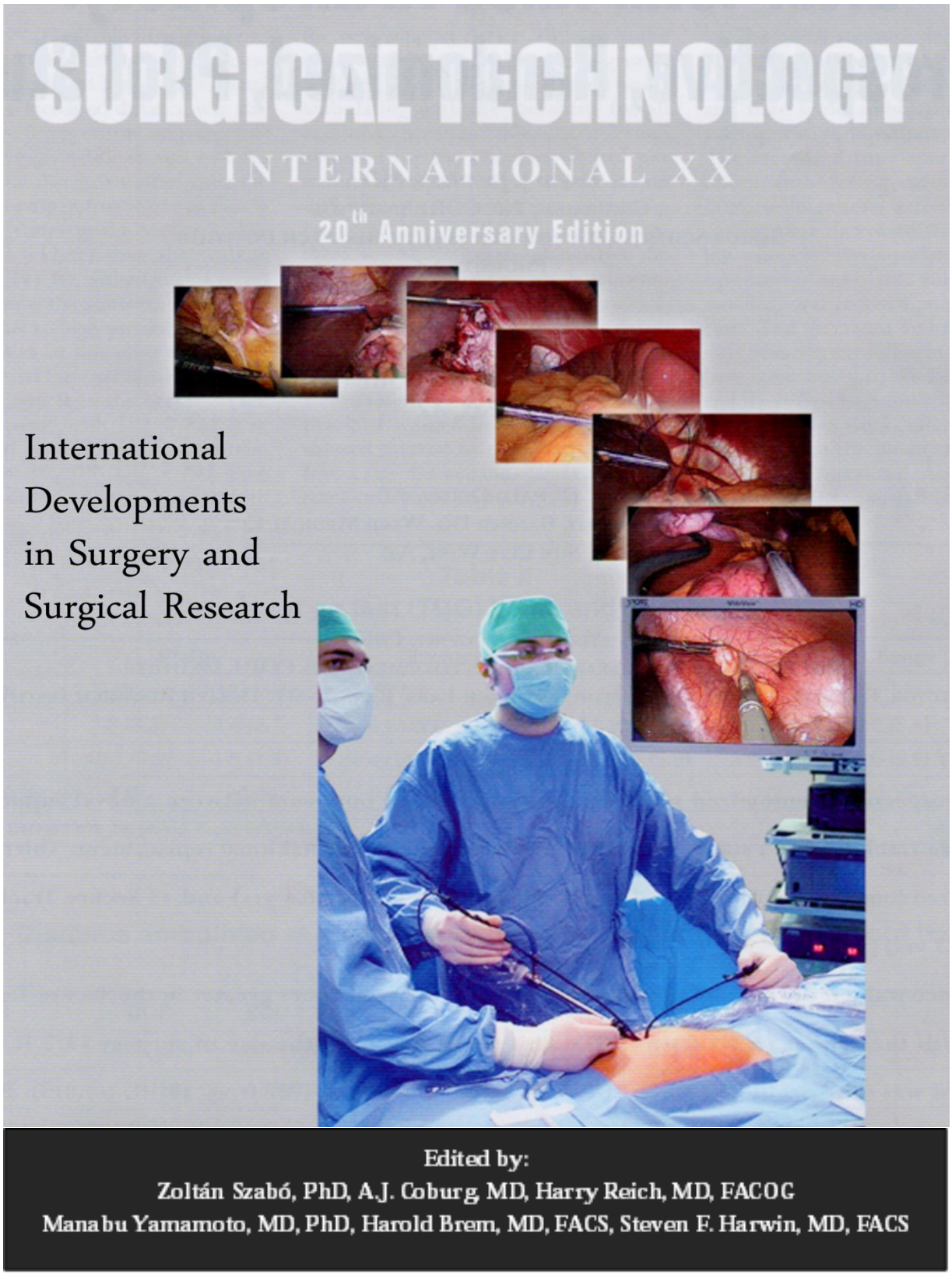

Secure Tracks Device Improves Functional Recovery and Pain after Total Knee Arthroplasty, A Prospective, Randomized, Pilot Study

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ABSTRACT

This prospective, randomized study compares functional outcomes between a novel support device (Secure Tracks) and a standard walker following unilateral total knee replacement. Thirty patients were randomized for the study; 15 walker patients (70.7 +/- 6.4 yrs) and 15 Secure Tracks patients (68.2 +/- 6.7 yrs) (p=0.31).

Total distance walked during all therapy sessions was nearly two times greater in the Secure Tracks (2,332 ft) than with the walker (1,241 ft)(p = .053). This trend began on the day of surgery (275 ft vs. 176 ft, p<.069) and was statistically significant by the following morning (287 ft vs. 151 ft, p=.019). Patients in the Secure Tracks spent a greater amount of time up and ambulating with the therapists in all sessions (.006< p >.30). At the first clinical follow-up, patients that had walked in the Secure Tracks completed the timed up and go test (TUG), a predictor of fall risk, 3 seconds faster than the standard rehabilitation group (9.6 vs. 12.9 seconds, p<.091). The novel therapy patients demonstrated significantly greater pain

relief following the TUG test (p=.005). This study demonstrates that the choice of support device can increase patient ambulation following surgery, which will in turn improve functional outcomes and pain relief.

INTRODUCTION

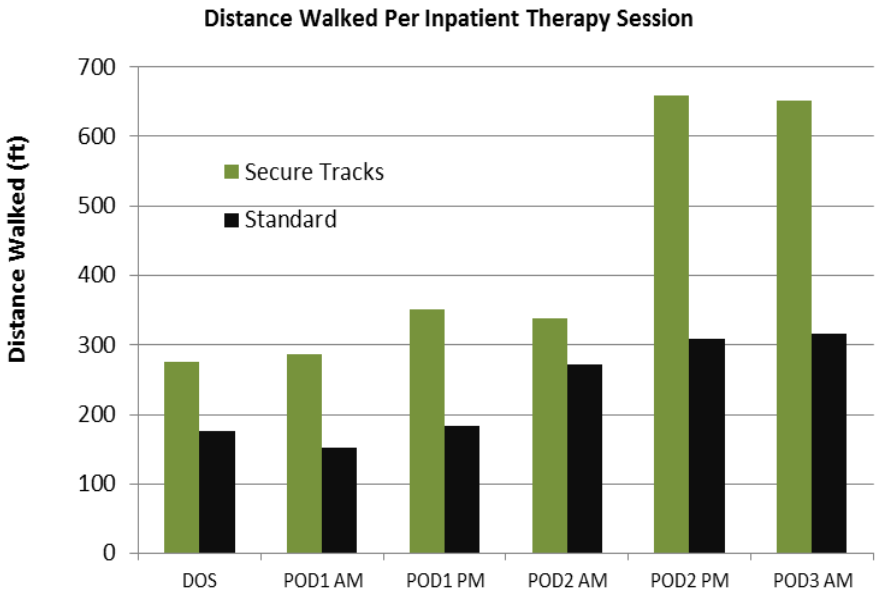
The standard four-legged walker is not often thought of in the context of surgical technology. However, when considering the utilization of support devices following surgery, injury, or the onset of a debilitating disease, this family of patient support devices is a very important technology.[1,2,3,4] The walker is perhaps the most common support device, particularly following lower extremity surgery and stroke, but its design has remained little changed for several decades. Along with the gait belt, the walker is the standard of care device for postoperative ambulation. The recent addition of wheels to the walker (e.g., Rollators) has shown no functional difference in rehabilitation by some measures,[4] and limited improvement over non-wheeled walkers and crutches in others.[5]

Few alternatives for safe, independent patient support have been proposed or studied in the clinical setting even though these devices are used across multiple surgical and non-operative disciplines.[6] The benefits of immediate postoperative ambulation are well known and include reduced comorbities such as deep vein thrombosis (DVT), swelling, and pulmonary compromise. The optimum distances or time that a patient ambulates following different surgical procedures are not well studied, but it stands to reason that increasing the distance walked and time spent ambulating, up to the point of pain as tolerated, should confer increasing benefit following many surgical procedures. It has been suggested that the bio-mechanics of the standard walker, such as stooped posture, support of partial body mass with the forelimb, and an inability to swing the leg through, limit patient ambulation following surgery to a greater extent than may be realized[7,8]. The inefficient nature of the walker gait may lead to earlier fatigue of the upper and lower, extremities, as well as the core muscles, compared with normal walking kinetics and kinematics. This could cause patients to return to rest sooner and decrease the maximum walking distance, all other things being equal. Additionally, the walker in and of itself does not prevent a fall from occurring. Altered posture and associated upper extremity fatigue can allow the patient to fall and injure themselves or the therapist assisting them. The gait belt used in conjunction with the walker allows the therapist to prevent or control an impending fall, but this strategy places the therapist at risk of suffering a work-related injury. Recent studies have shown that accelerated rehabilitation can confer immediate benefits to the functional recovery of patients recovering from total knee arthroplasty.[9] This prospective randomized pilot study evaluated the distance patients walked, as well as functional and pain assessments, following total knee replacement recovery with a walker versus a novel device that supports the patient in the periaxillary region while suspended from a track in the ceiling (Secure Tracks, Safe Independence,

Figure 1a

Figure 1b

Phoenix, AZ) (Figs.1a & 1b). The device encourages full weight bearing and is not designed to offload the lower extremities or assist with balance. Rather, it encourages the patient to maintain dynamic balance while ambulating, provides a high degree of fall prevention, and removes the therapist from an active support role thus allowing better assessment of a patient's gait deficiencies while limiting the risk of injury to the therapist.



METHODS

This pilot study was a prospective, randomized trial of postoperative ambulation following unilateral total knee replacement. A total of 30 patients between the ages of 50 and 90 years old undergoing unilateral total knee replacement were recruited and consented to participate under IRB approval. All patients had their surgery performed by the same fellowship trained adult reconstruction surgeon (DJJ) using the same implant (Stryker Triathlon, Stryker Corporation, Mahwah, NJ) under computer navigation to standardize implant alignment (Stryker Corporation, Mahwah, NJ). As a precaution, patients were excluded if they had any gait disturbance not related to their unilateral osteoarthritis of the knee, had diabetic neuropathy in the feet, or had surgery involving the shoulder or spine within the previous 12 months.

After signing the consent form, each patient was randomized to either the standard rehabilitation group, consisting of a gait belt and walker, or the Secure Tracks group, using no secondary assistive device during ambulation. A standardized rehabilitation program was implemented for both groups, which involved mobilization and ambulation the evening of surgery and once per 12-hour period (morning and afternoon) until discharge on the third postoperative day. Patients were permitted to weight-bear as tolerated starting the evening of their surgical procedure. A physical therapist or certified physical therapy assistant was at the patient's side during all ambulation trials. Patients were instructed to walk until they felt fatigued or unsafe and were not encouraged or discouraged to walk a specific distance. The device was only used for the duration of the inpatient hospital stay and all patients were trained for safe walker use and discharged with a standard walker as a gait aide.

The therapists were provided with a binder for each patient that included all of the study data collection sheets. The therapists tracked the distance each patient walked during each of their ambulation sessions and also recorded any incidence of falls or other adverse events. In addition to the distance walked, the time required for each therapy session was tracked. A timed up and go test (TUG), which is a known predictor of fall risk, was administered preoperatively, at discharge, and at two weeks postoperatively. Patients were permitted their assistive device of choice for the TUG preoperatively, used a standard walker for the test at discharge, and used no assistive device at the two week assessment. The TUG was repeated three times at each assessment point so an average could be calculated. A visual analogue scale (VAS) for pain with activity was administered immediately following the final TUG trial at each time point. The Lower Extremity Activity Survey (LEAS) was also administered at the time of consent, at discharge from the hospital, and at the 2 week clinical follow-up appointment. The Knee Society Score (KSS) was calculated at the time of consent at and the 2 week follow-up appointment.

All data were compiled in SPSS v 16 for data analysis. The distance walked in each ambulation session, the average time required for the TUG, the VAS score following the TUG, and the results of the clinical assessments were compared using an unpaired t-test, alpha = to 0.05. In addition, the total distance walked while in the hospital facility was calculated and compared between rehabilitation groups using an unpaired t-test. To examine hospital staff utilization, the time taken for each session relative to the distance walked by the patient in that session was calculated and compared between rehabilitation groups, again utilizing the unpaired t-test. An F-test for equal variance was run on each parameter prior to analysis due to the small sample size in the pilot study. If the F-test detected unequal variance, the t-test calculation was adjusted to account for the unequal variance.

Table 1
Pre and Postoperative Knee Society Scores

	PreOp		2 Week Post Op	
Treatment	KSS Pain	KSS Func	KSS Pain	KSS Func
Secure Tracks	16.0 (8.3)	62.0 (16.7)	36.6 (14.1)	55.0 (18.9)
Standard	25.7 (6.5)	52.5 (14.8)	39.6 (10.8)	47.9 (20.4)
t-test p value	0.00	0.12	0.53	0.34
*Standard Deviations provided in parentheses				

RESULTS

An equal number of patients (n=15) were randomized to the walker group and Secure Tracks group. The average age of the walker group was 70.7 (+/- 6.4 yrs) (4M/11 F), and the average age of the novel support device group was 68.2 (+/- 6.7 yrs) (9M/6F). There was no statistical difference in the average age of patients in the two groups (p=0.31).

Preoperatively, there were no significant differences in lower extremity function as determined by the KSS function score (p=.12) (Table 1) or the timed up and go test (p=.67) with only a half second separating the groups (Table II). The Secure Tracks group started the study with higher pain levels reported in both the KSS (p<.0l) and VAS with activity (p<.O5) (Tables I and II). Starting on the evening of surgery, there was a trend for patients to walk a greater distance in the Secure Tracks group than in the walker group (275 ft vs.176 ft, p<.07) (Table III). This trend for increased ambulation with the new device was consistent for all time points (Fig. 2), The increased distance was statistically significant on the morning following surgery (287 ft vs. 151 ft, p=.02). The total distance walked over the three-day postoperative stay was nearly two times greater in the Secure Tracks patients (2,332 ft) than the walker patients (1,241 ft), although this trend was just above the statistical threshold (p=.053) due to high variability relative to sample size in this pilot study. The range observed for total distance walked was 488 - 7,946 ft in the Secure Tracks group compared with 192 - 2,331 ft in the standard group. The minimum distance was therefore 2.5x greater and the maximum distance 3.4x greater with the new support device. Patients in the novel support group also spent a greater amount of time out of their rooms ambulating with the therapists for all sessions (p range .006-.30). When adjusted for the distance walked per minute of therapy time, there was no difference between therapy groups (p range .27 - .99). At the time of discharge there was no statistical difference in the timed up and go or pain levels reported by patients. No fall events were reported by the therapy staff for either group throughout the study.

At the time of staple removal, two weeks following discharge, the patients that had walked in the Secure Tracks showed a trend to complete the TUG test a full 3.3 seconds faster than the standard rehabilitation group (p<.09) (Table II). Furthermore, the Secure Tracks patients demonstrated significantly greater pain relief from before surgery to after surgery as measured by the VAS after activity, with the standard therapy patients showing an increase in pain of 0.7 points and Secure Tracks patients showing a decrease of 2.2 points (p<.01)

DISCUSSION

The novel support device provided the needed support and fall prevention while increasing ambulation distance and time spent ambulating during the post-operative inpatient care period. The increased time spent out of the room ambulating, along with the increase in general activity level, may confer some decreased risk of developing comorbidities associated with post-operative sessility such as DVT, swelling, and reduced pulmonary function. The increased ambulation in the days immediately following surgery may have contributed to the increased speed and decreased pain observed during the TUG test two weeks after hospital discharge. Since the timed up and go test is a general functional assessment and a known predictor of fall risk[10], this difference implies a reduced fall risk and general functional improvement a full two weeks following the use of the device. Given that the only difference in patient care was the random assignment of the support device during ambulation, these differences are dramatic and encouraging for improved post-operative rehabilitation.

The use of the device did not increase the time the therapist spent ambulating the patient when accounting for the increased distances traveled. Since the therapist can stand well behind or to the side of the patient without having to hold on to the gait belt, they are better able to assess the gait of the patient and provide instruction and tailored rehabilitation plans. The potential for a decrease in workman's compensation claims due to on-the-job therapist injury from patient falls requires further investigation, but may present an avenue for cost savings to the hospital. If multiple Secure Tracks carriages were used on a single track, a single therapist could ambulate multiple patients simultaneously while providing adequate fall prevention and gait coaching, thus increasing therapist efficiency.

This study was limited by the number of subjects enrolled; how-ever, the prospective randomized design and careful choice of statistical analysis mitigates the risk that this pilot study will not reflect the results of larger ensuing studies. The choice of unilateral total knee arthroplasty as the study population provided a consistent cohort with similar preoperative function. The device may have further

Table II
Timed up and go test (TUG) times and pain levels (VAS)

	PreOp		Discharge		2 Week PostOp		Change (2 Wk-Pre)	
Treatment	TUG (s)	TUG VAS	TUG (s)	TUG VAS	TUG (s)	TUG VAS	TUG (s)	TUG VAS
Secure Tracks	9.6 (3.3)	3.4 (2.7)	37.4 (20.7)	2.9 (2.3)	9.6 (4.3)	1.2 (1.2)	0.0 (5.4)	-2.2 (3.1)
Standard	10.1 (3.2)	1.5 (1.8)	36.4 (16.3)	2.9 (2.2)	12.9 (5.9)	2.0 (1.4)	4.0 (8.9)	0.7 (2.1)
t-test p value	0.67	<0.05	0.89	0.98	0.09	0.09	0.15	<0.01

**Standard Deviations provided in parentheses*

Table III
Distance ambulated at each therapy session and in total throughout the Hospital stay

Treatment	DOS	POD 1.1	POD 1.2	POD 2.1	POD 2.2	POD 3	Total
Secure Tracks	275 (125)	287 (185)	351 (298)	339 (250)	659 (614)	651 (763)	2332 (1999)
Standard	176 (96)	152 (78)	184 (103)	271 (186)	308 (269)	316 (137)	1241 (608)
t-test p value	0.07	0.02	0.07	0.41	0.06	0.15	0.05

** Standard Deviations provided in parentheses*

utility in non-orthopedic applications such as stroke, hemiplegia, or disorders with spasticity for which traditional walker that requires consistent upper body support is not feasible. However, these studies are more difficult to design and implement in a controlled and randomized manner due to the unique nature of each individual patients' disorder. Further studies are needed to determine if there is a rehabilitation benefit for patients with these or other disabilities.

CONCLUSION

The Secure Tracks device proved to be a safe and effective patient support device that significantly increased the distance that patients walked during the postoperative period when compared with a standard walker and gait belt. Furthermore, these patients showed an increase in speed and decrease in pain during the timed up and go test two weeks following discharge. With the increasing push for early ambulation following total knee replacement, new support aides such as Secure Tracks may be instrumental in improving postoperative ambulation and should not be overlooked as an important component of an accelerated postoperative rehabilitation program.

AUTHOR'S DISCLOSURES

David J. Jacofsky is a consultant for Stryker Orthopedics, Bacterin International, Cold Plasma Medical Technologies, and Safe Independence. He receives royalties from Stryker Orthopedics and Smith and Nephew. He owns stock in Bacterin International and Safe Independence. And he receives laboratory research support from Arthrex, Biomet, Depuy-Mitek, Exactech, Stryker, Smith and Nephew, and the Foundation for Orthopedic Trauma.

Marc C. Jacofsky receives laboratory research support from Arthrex, Biomet, Depuy-.Mitek, Exactech, Stryker, Smith and Nephew, and the Foundation for Orthopedic Trauma. He has an immediate family member who receives consulting fees from Stryker Orthopedics, Bacterin International, Cold Plasma Medical Technologies, Safe Independence, and owns stock in Bacterin International and Safe Independence, and receives royalties from Stryker Orthopedics and Smith and Nephew.

Sarah Kocisky and Donald Dixon have no financial relationships to disclose.

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