Gravity-Assisted Passive Flexion in Total Knee Arthroplasty Recovery

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abstract

This study examined the use of gravity-assisted passive flexion (GAP-FLEX) for perioperative total knee arthroplasty (TKA) recovery. The main questions associated with this technique were: (1) Can GAP-FLEX improve patient recovery of range of motion after TKA? (2) Does GAP-FLEX reduce patient time and effort associated with therapy compared with continuous passive motion (CPM)? (3) Does GAP-FLEX reduce overall episodic care cost? A prospective, randomized multicenter study was conducted. Two senior surgeons used identical surgical approach, prosthesis, and postoperative management protocols. Patients consenting to the study were randomly assigned to either standard of care (CPM) or GAP-FLEX groups. Active flexion range of motion (ROM) was measured via goniometer with a primary endpoint established at 4 weeks after surgery. Secondary endpoints included pain and functional mobility. A total of 27 patients completed the study. Average ROM in the GAP-FLEX sample was 8.4° greater than the CPM sample (*P*=.009) at study endpoint. The GAP-FLEX patients achieved greater postoperative ROM within 2 days and maintained an improvement over CPM to study endpoint. Eighty-five percent (11 of 13) of GAP-FLEX patients achieved or surpassed their baseline ROM by study endpoint, compared with 50% (7 of 14) of CPM patients. These improvements occurred while requiring 90% less therapy time on device compared with the CPM patients. Patients did not report any statistically different pain levels but did exhibit higher functional mobility at endpoint (*P*=.026). [*Orthopedics*. 2020;43(5):e431-e437.]

More than 1 million total knee arthroplasties (TKAs) are performed every year.[1-4] The procedure has grown in use in the aging population and also increased in patients younger than 65 years.[5-8] The number of procedures performed annually is expected to double or triple in the next decade as TKAs and revisions have experienced high single- and double-digit growth rates even in bad economic times.[8-10]

The standard of care after surgery varies depending on patient, physician, and hospital. Traditional TKA recovery regimens have included hospital stays, inpatient facilities (rehabilitation facility or skilled nursing facility), rehabilitation services in the home, and outpatient physical therapy.[11] Others have moved away from inpatient rehabilitation facilities in favor of in-home physical therapy.[12] Some have even begun promoting outpatient TKA for qualifying patients followed by rigorous physical therapy.[13] Amidst the myriad recovery protocols and procedures adopted around the world, the use of continuous passive motion (CPM) machines in recovery remains a point of discussion and debate among top surgeons worldwide.[14-16]

The concept of CPM began with work by Salter,[17-20] Salter and Field,[21] and Salter et al[22] in the 1960s. Some CPM articles identified positive outcomes, including reduction of postoperative pain, swelling, and adhesions, while improving local blood circulation and return to motion.[11,23-31] However, most recent stud-

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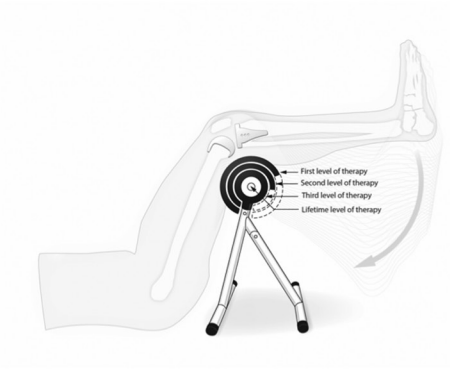
Therapy Part 1

a) Lie flat on the bed with the bed in a flat position.
b) Flex the hip on the same leg as the surgically replaced knee to 90 degrees.
c) Place the Gap-Flex under the knee with the Gap-Flex logo facing away from the patient. The Gap-Flex should be flush against the back of the thigh, and the padded T-Bar should be directly under the back of the knee, allowing the knee to bend over the padded T-Bar.
d) Allow the knee to rest comfortably over the bar for 6 minutes up to 6 times per day.

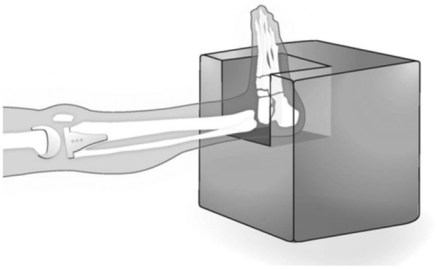


Therapy Part 2

Stand and walk as able for approximately 2 minutes.

Therapy Part 3

a) Lie flat on the bed with the bed in a flat position.
b) Place the foam Extender at the end of the bed and place the heel in the cutout area. Make sure that the leg is completely extended and straight.
c) Allow the leg to rest comfortably in the Extender for 10 minutes following each treatment with Gap-Flex.



Notes:

1) Stop treatment if patient experiences any significant pain or increased numbness in the knee, calf or foot.
2) Record therapy times on the Gap-Flex Patient Therapy Log. Bring the log to each physician office visit.

Figure 1: Gravity-assisted passive flexion (GAP-FLEX) therapy guidelines for flexion and extension.

ies and meta-analyses show little or no long-term benefit of CPM, as measured 3 months after surgery.[11,14,16,32-37] By 2002, it was estimated that CPM devices were in use in more than 77 countries at more than 17,000 hospitals and continue to be widely used today.[16]

In the United States, approximately half of all TKAs are performed on Medicare-eligible patients. The changing regulatory environment has shifted toward bundled payment systems.[38,39] Although this approach to health care payments is in its infancy in the United States, it has shed light on the process of selecting TKA recovery techniques that prove efficacious for patient outcomes and efficient for overall systemic cost.[40,41] Given these economic trends decreasing reimbursement in bundled payment systems,[38-41] the emergence of gravity-assisted passive flexion (GAP-FLEX) represents a potential opportunity to improve patient outcomes. A randomized comparative-outcomes study was designed to quantify the effectiveness of GAP-FLEX as compared with CPM, the current standard of care at the investigating hospitals. The objective was to determine whether there was a difference in recovery between the 2 techniques, leading to the following questions: (1) Can GAP-FLEX improve patient recovery of range of motion (ROM) after TKA? (2) Does GAP-FLEX reduce the patient time and effort (eg, set-up, device use, supervision) associated with therapy compared with CPM? (3) Does GAP-FLEX reduce overall episodic care cost? This article describes the methodology of the study, provides detailed results, and discusses the practical implications.

Materials and Methods

The prospective, randomized, 2-center study received institutional review board approval and was Health Insurance Portability and Accountability Act compliant. The primary endpoint was the degree of active flexion ROM, as measured by goniometer at the week 4 follow-up visit. This primary endpoint is the focus of this study, with a null hypothesis of H_0: $ROM_{GAP\text{-}FLEX} > ROM_{CPM}$. A power analysis was conducted using retrospective patient physical therapy ROM data. With an anticipated difference of 10° between 2 samples, a sample standard deviation of 10°, a desired alpha of 0.05, and a power of 0.8, the minimum sample size was calculated to be 13 patients in each of the 2 randomized arms of the study. The study was set up to enroll up to twice as many patients, with a midpoint analysis used to decide whether the data were sufficient to assess the primary endpoint. Multiple secondary endpoints were tracked, along with in-process patient physical therapy compliance. For surgeries, a medial parapatellar arthrotomy approach with a cruciate-retaining implant was used. A Vanguard knee joint replacement (Zimmer Biomet, Warsaw, Indiana) and a drain were used on all patients. Patients were closed at 90° of flexion, and post-acute pain management was done with a periarticular injection, an adductor canal block, and standard pain management medications.

The target audience for inclusion in the study was patients 50 years and older, undergoing TKA (not a revision), agreeing to the proposed physical therapy regimen, and signing an approved informed consent to participate in the randomized study. The postoperative physical therapy regimen was in-home therapy only, and no inpatient rehabilitation facility was used. Exclusion criteria were intended to eliminate other

Figure 2: Postoperative recovery using gravity-assisted passive flexion (GAP-FLEX) in the hospital setting.

sources of variation in the study. Major exclusion criteria included flexure contracture greater than 10°, flexion less than 60° before or immediately after the procedure (as measured on the operating table), severe deformities, body mass index greater than 40 kg/m^2, and a history of deep venous thrombosis (DVT) or pulmonary embolisms. Intraoperative and postoperative exclusion criteria included identification of a fracture, need for additional fixation devices, additional procedures other than TKA, newly identified conditions, admittance to the intensive care unit, and hospital stay longer than 4 days.

GAP-FLEX

Gravity-assisted passive flexion uses gravity to provide a completely passive flexion of the tibiofemoral joint and surrounding tissue followed by an extension. The decompressing effect minimizes pressure on the knee, which reduces irritation, swelling, and pain in the tibiofemoral joint during therapy. The therapy regimen begins postoperatively in the hospital and continues during inpatient rehabilitation in the home. **Figure 1** and **Figure 2** show GAP-FLEX therapy instructions and an example of the device in use postoperatively, respectively.

Study Protocol

The study included standard-of-care physical therapy for all patients and use of CPM or GAP-FLEX per standard operating instructions. The standard-of-care protocol for CPM both in hospital and at home was 3 times per day for 2 hours each, followed by use of an extension box for 20 minutes each time. The CPM protocol required an initial setting of -10° to 60°, increasing to 120° as tolerated. The GAP-FLEX protocol was 6 times per day for up to 6 minutes each (depending on comfort level), followed by 10 minutes on an extension block. Data were collected per the schedule of assessments presented in **Figure 3**. Patients were expected to go from hospital therapy to in-home therapy until the primary endpoint of the study (week 4). The same in-home physical therapists were used for all study patients. Outpatient physical therapy was optional post primary endpoint based on patient recovery and physician assessment of recovery. Active flexion was measured using a goniometer, pain was measured using Wong-Baker FACES Pain Rating Scale, and functional mobility was measured using the Tinetti Balance Assessment Tool.

Schedule of Assessments*

	Visit Schedule						
	Preop	Inpatient	Physician Office Visits			Outpatient	
	Screening	Surgery Day 0	V1	V2	V3	Home Care Treatment Phase	PT Clinic Optional
Visit Days	-60	0-4	14 (± 3)	28 (± 3)	60 (± 3)	DC – 28 (± 3)	29-60
Assessments / Visit Weeks	-8	0	2	4	8	0-4	5-8
Demographics and Medical History	◆						
Physical Assessment	◆						
Collect Pain Medications**	◆	◆	◆	◆	◆		
Assess ROM (XRAY)		◆					
Assess ROM (Goniometer)	◆	◆	◆	◆	◆	◆	
Assess Functional Mobility	◆	◆	◆	◆	◆	◆	
Assess Pain (specify method)	◆	◆	◆	◆	◆	◆	
Physical Therapy (PT) Treatment Plan		◆				◆	◆
Assess Adverse Events (per protocol)		◆	◆	◆	◆	◆	◆

*Refer to the treatment section (section #) for visit details

** Only collect medication prescribed for disease state (TKR)

Figure 3: Schedule of assessments for the study, with primary endpoint at visit (V) 2. Abbreviations: DC, discharge; PT, physical therapy; ROM, range of motion; TKR, total knee replacement.

RESULTS

Patients were prospectively randomized to either GAP-FLEX (treatment group) or CPM (control group) in a 1:1 format at each of the 2 clinical sites. A total of 27 patients completed the study to primary endpoint, with 14 assigned to the CPM group and 13 to the GAP-FLEX

Table 1

Demographic Data

Characteristic	CPM (n=14)	GAP-FLEX (n=13)	Total (N=27)
Age, y			
Mean±SD	65.6±8.6	66.3±7.0	65.9±7.7
Median (range)	66.5 (53-77)	66.0 (50-77)	66 (50-77)
Sex, No.			
Female	7 (50%)	6 (46.2%)	13 (48.1%)
Male	7 (50%)	7 (53.8%)	14 (51.9%)
Race, No.			
White	13 (92.9%)	13 (100%)	26 (96.3%)
Black	1 (7.1%)	0 (0%)	1 (3.7%)
Asian	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Other	0	0	0
Ethnicity, No.			
Hispanic or Latino	3 (21.4%)	2 (15.4%)	5 (18.5%)
Not Hispanic or Latino	11 (78.6%)	11 (84.6%)	22 (81.5%)
Unknown	0	0	0
Smoking history, No.			
Current smoker, less than 1 pack per day	1 (7.1%)	1 (7.7%)	2 (7.4%)
Never smoked or has not smoked within the past 10 years	13 (92.9%)	12 (92.3%)	25 (92.6%)
Preoperative baseline active flexion ROM, mean±SD	108.7°±17.8°	110.5°±9.8°	109.6°±14.3°
Postoperative baseline maximum passive flexion on operating table (ROM), mean±SD	131.4°±6.0°	132.7°±4.8°	132.0°±5.4°

Abbreviations: CPM, continuous passive motion; GAP-FLEX, gravity-assisted passive flexion; ROM, range of motion.

group. A summary of patient demographic data is presented in **Table 1**.

Therapy device use began within 24 hours after surgery, and first measurement occurred 48 hours after surgery in hospital (ROM day 2). GAP-FLEX patients achieved greater postoperative ROM within 2 days and sustained an improvement to the endpoint of the study. Eighty-five percent (11 of 13) GAP-FLEX patients achieved or surpassed their baseline ROM by study endpoint (week 4), compared with 50% (7 of 14) of CPM patients (**Table 2**).

A positive difference of 10.7° ROM day 2 was seen between the GAP-FLEX and CPM patients, with a one-tailed *t* test significance of *P*=.003. This difference decreased slightly at the midpoint of the study (ROM day 14) to 5.6° (*P*=.065). The endpoint results at day 28 showed a positive difference of 8.5° between the groups, with a significance level of *P*=.009. This result allows rejecting the null hypothesis H_0: $ROM_{GAP\text{-}FLEX} \leq ROM_{CPM}$ and accepting the alternate hypothesis H_a: $ROM_{GAP\text{-}FLEX} > ROM_{CPM}$. Note that 1 data point for the CPM group was imputed from 2 measurements that bounded the missing time point.

Patients in the GAP-FLEX group on average achieved a postoperative ROM day 2 that patients in the CPM group achieved a week later (**Figure 4**). At day 14, GAP-FLEX patients achieved an average ROM equal to that of the CPM patients at the study's primary endpoint. Ninety-two percent (12 of 13) of GAP-FLEX patients achieved 110° ROM or more at endpoint, compared with 50% (7 of 14) in the CPM group. The ROM trend indicates that CPM patients on average have a lower improvement rate than GAP-FLEX patients. From a patient burden perspective, the absolute time savings between therapy techniques was 151.2 hours with GAP-FLEX. This represents a 90% reduction in scheduled device therapy time. Therapy time for the extension box was equivalent for both groups at 28 hours (a total of 1 hour per day for 28 days). Pain scales showed no statistical difference between groups, whereas functional mobility showed a significant difference of 1.93 (*P*=.026) at study endpoint (**Figure 4**).

Discussion

Studies continue to be published arguing for or against the value of CPM machines in TKA recovery therapy. There have been some data collected concerning manipulation under anesthesia, yet there has been little discussion about the amount, intensity, and cost of physical therapy required for patients not using CPM.[14,16] This study introduces a new type of TKA recovery method using GAP-FLEX and attempted to answer 3 main research questions. Patients using GAP-FLEX were able to achieve a greater active ROM at endpoint. This result is both statistically significant and clearly answers the first question. Furthermore, the GAP-FLEX results at endpoint are significantly higher than those reported

in many other meta-analyses regardless of whether they used CPM or physical therapy and manipulation only.[24,42,43] As for the second question, the prescribed standard of care using GAP-FLEX requires 90% less patient time than the CPM standard of care (36 minutes vs 360 minutes per day), with equivalent extension box time for both groups (1 hour per day).

Finally, in answer to the third question, the ability of patients to handle the device may reduce the need for admission to a rehabilitation facility or skilled nursing facility. The earlier recovery precludes the need for prolonged outpatient physical therapy, and the faster recovery returns patients to normal life sooner. The number of patients electing optional outpatient physical therapy was greater in the CPM group (12 of 14) compared with the GAP-FLEX group (10 of 13). Patient compliance is a critical success factor in any prescribed therapeutic regimen.[44,45] The faster recovery and lowered time burden for patients using GAP-FLEX can improve patient compliance because it is easier to use and requires much less time than CPM. Anecdotal comments from in-hospital staff and in-home physical therapists about the general level of happiness with the device also support this thesis. From a systemic cost perspective, GAP-FLEX eliminates the cost of CPM, including the burden associated with maintaining, cleaning, and renting devices, and the potential for hospital-borne infection as a result of device contamination through reuse. By contrast, the GAP-FLEX is a single-patient system that the patient takes home and keeps. Older patients using CPM have much more difficulty getting on and off the machine and require assistance. The ease of use of the GAP-FLEX device compared with CPM has enabled patients, especially individuals who live alone, to forego a rehabilitation facility and elect for in-home physical therapy. This does not fully answer the third question but leads the authors to believe that further study may prove useful in quantifying potential economic benefits.

Table 2

Study Data

Outcome	CPM (n=14)	GAP-FLEX (n=13)	Difference	*P*
ROM, mean±SD				
Baseline active ROM	108.7°±17.8°	110.5°±9.8°	+1.8°	.374
Day 2	82.9°±8.8°	93.6°±9.0°	+10.7°	.003
Day 14	103.4°±10.0°	109.0°±8.4°	+5.6°	.065
Day 28 (endpoint)	109.8°±7.8°	118.3°±9.5°	+8.5°	.009
Pain, mean±SD				
Baseline	5.6±3.2	5.7±2.0	+0.1	.453
Day 28 (endpoint)	1.21±2.01	1.15±1.96	-0.06	.459
Functional mobility, mean±SD				
Baseline	23.3±2.8	23.2±6.2	-0.1	.471
Day 28 (endpoint)	24.1±3.1	26.1±1.5	+1.9	.026
Optional therapy, No.				
Yes	12 (85.7%)	10 (76.9%)	22 (81.5%)	
No	2 (14.3%)	3 (23.1%)	5 (18.5%)	

Abbreviations: CPM, continuous passive motion; GAP-FLEX, gravity-assisted passive flexion; ROM, range of motion.

This study had the limitations of any study with a small sample. However, using a prospective, randomized approach to patient enrollment, the level of statistical significance observed in the primary endpoint provides some comfort. Where possible, adverse events were categorized as device related and/or procedure related. There were 4 adverse events reported during the study, including 3 patients using the CPM device and 1 patient using the GAP-FLEX device. During use of the CPM device, patient 01-020 reported nausea (not related to device use) and patients 01-018 and 02-008 both reported sciatic nerve pain related to device use. During the use of GAP-FLEX, patient 02-011 reported pain and discomfort (not related to device use) and was discovered to have May-Thurner syndrome after TKA. This patient was removed from the study. No device-related adverse events have been reported from the broader population of

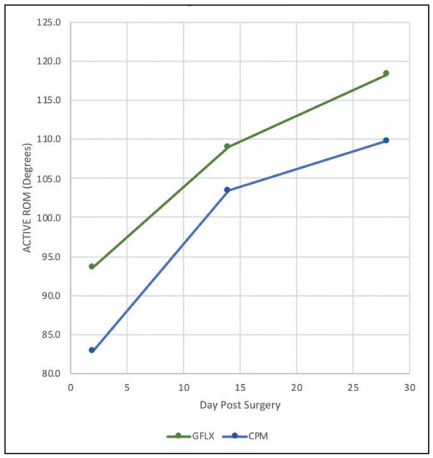


Figure 4: Active range of motion (ROM) recovery over time. Abbreviations: CPM, continuous passive motion; GFLX, gravity-assisted passive flexion.

greater than 500 patients who have been treated with GAP-FLEX at hospitals currently prescribing the therapy. To date, no contraindications have been reported; however, there may exist preexisting conditions or comorbidities that prevent a patient from using GAP-FLEX. In rare

and unusual cases where the patient has a preexisting condition that prevents standard mobilization treatment or use of GAP-FLEX, then CPM or intense physical therapy and manipulation may be useful. Further investigation may include the use of GAP-FLEX for recovery from revisions, fractures, anterior cruciate ligament surgery, and meniscus repairs.

Conclusion

For patients undergoing TKA, GAP-FLEX therapy is highly effective, achieving greater ROM and faster recovery than CPM. Ease of use makes implementation in hospital and home health care easy. A single-patient system reduces chances of hospital-borne infections from device reuse. Further evaluation of GAP-FLEX can address the ability of patients to elect home recovery as opposed to an inpatient rehabilitation facility and track potential reductions in need for outpatient physical therapy. A follow-up study is being launched with a larger sample size evaluating total episodic cost using physical therapy only as the control. Together, these studies could represent a potential change to the standard of care that returns patients to normal life faster while potentially reducing total episodic care cost.

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