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Total knee arthroplasty patients using the in-home X10 machine fully recovered. No additional therapy required

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ABSTRACT

Following total knee arthroplasties patients using the X10 increased their quadriceps strength 120% at 30 days post-surgery compared to their pre-surgical baseline. This contrasts sharply with contrast studies outpatient physical therapy that show patients suffer a 50–60% quadriceps strength deficit at 30 days post-surgery. For X10 patients, the average range of motion at 30 days was 124° and at discharge it was 128° (mean 43 days). The trial involved a single surgeon and two groups. Group one (21 patients) used only the X10 for pre-habilitation and rehabilitation, while group two (20 patients) used X10 alone for pre-habilitation and then utilized the X10 plus home care plus outpatient physical therapy for rehabilitation. Adding home care and outpatient physical therapy did not improve outcomes compared to patients who utilized X10 alone. Our results show no significant difference between the two groups. Indicating that the X10 by itself is adequate to completely rehabilitation patients from total knee arthroplasties. Finally, we compared our results to those of Calatayud et al.[1] who monitored two groups of patients, one group had only physical therapy for rehabilitation while the other group used physical therapy for both prehabilitation and rehabilitation. Our results were superior to Calatayud et al.[1] for extension, flexion, and quadriceps strength; for each of these measures the X10 treatment groups improved over time, while the Calatayud et al.[1] groups showed losses.

1. Introduction

The debate about the nature of rehabilitation, following a total knee arthroplasty, has been ongoing for decades. Rajan et al.[2] believe that home-based exercises are as efficacious as outpatient physical therapy with its machines and modalities.[3] Pozzi et al.[4] vigorously disagree, arguing that patients using only home-based exercises are under treated. Wickline[5] argued that, "there is a worldwide belief that aggressive, formal, organized physiotherapy is a prerequisite for a satisfactory total knee arthroplasty (TKA) outcome." He suggests that this is not necessarily so.[3] NIH[5] argued that, "Despite the wide spread use of TKR, there is a notable lack of consensus regarding which medical and rehabilitative perioperative practices should be employed … the site of post-acute care (home versus acute rehabilitation unit versus skilled nursing facility) is currently determined by local practice patterns and insurance reimbursement policies and not by available data.".[5] The debate has not abated.

Home-based exercises offer safety (home is the safest play to protect patients from contagious diseases), flexibility, and convenience. Most TKA patients are home-bound during the first several weeks of therapy and need to either have home care or arrange rides to get to and from a physical therapy clinic. Standard physical therapy usually leaves patients with a 50–60% quadricep strength deficit at one-month post-surgery[1,12] and this deficit can persist over considerable time[6]).

Here, we introduce the X10, a computerized, in-home knee recovery system (Fig. 1) which includes the X10 machine, a telehealth therapist, and the physician who is provided with weekly reports on the patient progress and can adjust care as necessary. Patients are trained in the use of the machine, when it is delivered, and control the machine. The patient sets the amount of pressure the machine uses to work the leg, based upon the patient's tolerance to pain. If the machine senses that it is approaching the pressure set by the patient, it stops, pauses to allow the fluid to escape and then reverses, protecting the patient from pain.

The X10 uses pressure, applied to the ankle, to regain passive range

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of motion. This pressure can be set to 0, enabling patients to work on active range of motion. The machine has resistance capability and can perform isometric and isokinetic exercises, to strength both the quadriceps, and hamstring muscles, and isotonic exercise to strengthen the calf muscles. The latter is important to reduce swelling. Here, we report on quadriceps strength but not hamstring as there was no consistent pattern for hamstring strength.

The X10 measures the angles of extension and flexion with each stroke of the machine. These are displayed on the computer screen to help motivate the patients. All the data is texted to a HIPPA compliant server and made available weekly to the surgeon enabling them to monitor progress, correct deficiencies, and discharge patients based upon reaching benchmarks rather than the number of authorized visits.

X10 causes little therapeutic pain, consequently little recovery time is needed between sessions. Patients use the X10 three times a day, seven days a week for range of motion. Because the X10 is gentle, patients begin using the machine the day after they come home from the hospital, and can begin muscle strengthening within one week of surgery. This accelerated schedule shortens recovery time, improves patient outcomes, and hasten neuromuscular re-education.

2. Methods

Group one patients used only the X10 for both prehabilitation and rehabilitation; while group two patients used the X10 for prehabilitation and then X10 plus homecare plus outpatient physical therapy for rehabilitation. If home care and outpatient physical therapy enhance outcomes then group two patients should outperform group one. However, if group two patients do not outperform the group one, then we can conclude that X10 therapy is sufficient to rehabilitate patients.

We report results at baseline, pre-surgery, one-month post-surgery and 1.5 months post-surgery.

Forty-one patients (43 TKAs), were recruited from a single surgeon, (RJF). All participants consented and signed a release form to participate. Patient ages ranged from 44 to 88 years old (mean 64.71 years). Patients were placed into one of two groups based upon when they enrolled. Group one patients enrolled from February 6, 2019 to January 13, 2020; group two enrolled from August 27, 2019 to September 17, 2020. Participants had 7–21 days of use of the X10 prior to surgery (prehab) and 30–47 days of post-surgery use based on return of strength and range of motion. Potential participants were excluded if this was not their initial TKA on the involved joint.

Extension, and flexion were measured in degrees.

Strength measurements were measured, in pounds. All values were stored by the X10 computer. All measurements were done in the seated position. For quadriceps muscles force was applied downward and outward during quadriceps contraction repetitively, for 30 s.

The isokinetic calf strengthening was performed with force was applied outward during isokinetic ankle plantarflexion, performed for one to 3 s, repetitively, for 30 s. Isokinetic concentric strengthening of the quadriceps was performed for two to 3 min, based on how quickly patient fatigued, with active knee extension and flexion against the machine ankle rollers to move the joint each way, respectively. The machine maintained a constant speed as force varied, with a minimum two-pound threshold. Isokinetic eccentric strengthening of the quadriceps was performed for two to 3 min, based on patient fatigue, with resistive knee extension or flexion as the machine arm moved the joint the opposite direction. The machine maintained a constant speed as force varied, with a minimum two-pound threshold. Here we report only the isometric exercises for quadriceps strengthening.

Strengthening exercises were completed every other day with effort specific to participant ability. Participants performed three sets of isometric quadricep strengthening, isometric strengthening, and isokinetic calf strengthening, and one set of concentric and eccentric strengthening, every other day. The best daily exercise results were recorded each day. Here, we report only isometric values.

The X10 is new; we compared our results to standard physical therapy using Calatayud et al.[1] Like us, they measured extension, flexion and quadriceps strength at baseline, pre-surgery, one-month post-surgery. They also measured these parameters at three months post-surgery. Because of the additional time, we expect that Calatayud et al.'s. patients to perform better. We refer to the two treatments in the Calatayud et al.[1] study as physical therapy and physical therapy plus prehabilitation.

3. Data analysis

Age was analyzed using an Onaway ANOVA. Gender distribution data were analyzed using a Chi-square test. Extension, and flexion, were measured at the same time on the same subjects and were analyzed using a multivariate repeated measures ANOVA. We normalized quadriceps strength data by dividing each time point by the value we measured at baseline yielding the percentage of baseline. These data were analyzed using a repeated measures analyses variance.

We graphically analyzed data from Calatayud et al.[1]because they report only the means.

Fig. 1. Patient using the X10.

4. Results

The X10 groups did not differ significantly for age (group 1 mean = 65.3 years; group 2 = 64.1, P < 0.67). Nine males and 12 females were enrolled in group 1 while group 6 males and 14 females were enrolled in group 2. The distribution of genders did not differ between the two groups (Chi-square N.S.).

The two groups could differ in several temporal parameters (Table 1). Of these parameters only the number of days patients used the machine past 30 days post-surgery differed significantly between the groups ($F_{1,38} = 22.46$, P < 0.001) (Table 1). We are emphasizing the first 30 days because historically the company has kept the machine in patients' home for 30 days. Here we have gone beyond 30 days to see if longer is better and because the surgeon wanted to be certain that the patients were ready for discharge.

Group 1 patients used the machine for an average 47.3 days and group 2 patients used the machine for an average 38.5 days. Group 1 patients were the first group enrolled and the surgeon was unfamiliar with how long to keep the machine in the patients' home. As the study progressed the surgeon revised this parameter. This we believe is the major reason for the difference between the two groups.

Similar to the range of motion parameters, quadriceps strength could differ for a number of temporal parameters (Table 2). Patients who used only the X10 (group 1) used the machine significantly more in the first 30 days post-surgery than did patients in group 2 (Table 2). Group one patients used the machine significantly more in the post-30-day period than did group 2. With group 2 patients they used the machine for only 1–2 exercise days in the post-30-day period. Patients who had homecare and physical therapy used the X10 significantly less in the first 30 days post-surgery.

We have summarized the data on the measurements on extension, flexion, and quadriceps strength into three figures because Calatayud et al.[1] did not report data for 1.5 months, there is a break in the lines.

4.1. Extension

The overall pattern of the of the graph (Fig. 2) did differ significantly between the two groups (multivariate $F_{3,114} = 6.03$, P < 0.001); both groups reached full extension.

The two Calatayud et al.[1] groups (Fig. 2) lost ground and never reached full extension.

4.2. Flexion

There was no difference in the pattern of the outcomes (Fig. 3) (multivariate $F_{2,36} = 1.42$, P < 0.26). Both X10 groups approached full flexion. The two Calatayud et al.[1] groups (Fig. 3) showed substantial losses at one-month post-surgery, and showed lesser losses at three months.

Table 1
Temporal parameters that could differ between the groups.

Range of Motion Parameters	X10 Alone	X10 +HC + PT	Total	F	P
Prehab Days Used	10.9	12.35	11.63	0.69	0.41
Prehab Day of First Use	−12.75	−12.2	−12.48	0.1	0.76
Range of Motion Parameters Rehab Day of First Use	2.85	2.95	2.9	0.1	0.71
Range of Motion Parameters Rehab Days Used Within 30 Days Post Surgery	26.85	26.2	26.53	0.96	0.33
Range of Motion Parameters Rehab Days Used Post 30 Days	17.3	8.45	12.88	22.46	0.000

Table 2
Temporal pattern in strength parameters that could differ between the groups.

	X10 Alone	X10 + HC + PT	$F_{1,40}$	P
Prehab Day of 1st Use	9.38	12.05	1.09	0.30
Prehab Days Used	6.19	5.55	0.67	0.42
Post-Surgery Day of 1st Use	7.90	8.85	1.17	0.29
Days used within the 1st 30 Day Post Surgery	9.10	4.50	25.35	0.00
Days used Post 30 Days post-surgery	5.67	1.65	15.91	0.00

4.3. Quadriceps

The results did not differ between the two X10 groups ($F_{2,35} = 0.94$, P < 0.96. Both X10 groups (Fig. 4) increased their quadriceps strength from the baseline through 1.5 months post-surgery. Typically patients suffer a 50% quadriceps strength dificit at one month post-surgery and a 30% strength at one year post-surgery[1,6]

The two Calatayud et al.[1] groups (Fig. 4) demonstrate the importance of prehabilitation. Without prehabilitation patients suffer a 67% deficit and a 39% deficit at one-and-three-months post-surgery. With prehabilitation patients suffered a 62% deficit at one-month post-surgery but only a 3% deficit at three months post-surgery.

5. Discussion

Patient outcomes, when using the X10 alone, are not inferior to when X10 is used with home care and outpatient physical therapy. X10 is equal to or more effective than standard physical therapy at regaining range of motion and quadriceps strength.

The results of Calatayud et al.[1] are consistent with other published studies.[14] The patients in the Calatayud et al.[1] had deficiencies in both range of motion and strength by the end of the study. However, the literature makes clear, the major problem with the standard physical therapy is the protracted deficit in quadriceps strength.[6] This is a major advantage of the X10.

The most common TKA surgery causes quadricep deficits[8] as it involves an incision through the quadriceps.[9] Studies show that at one-month post-surgery, most patient's quadriceps produce less than half their pre-operative torque[22]. Strength rarely reaches the levels of age matched healthy individuals.[9]

Quadriceps weakness has been implicated in the development and progression of osteoarthritis (OA) of the knee.[10] As a result, strength deficits are common in patients with OA considering TKA and in those who have had TKAs.[6,9] Quadriceps muscle weakness, in patients with OA, is attributed to a failure of voluntary muscle activation known as arthrogenic muscle activation (AMI),[11] an ongoing, reflex response to joint injury or disease. The term refers to the inability to completely contract a muscle despite no structural damage to the muscle or innervating nerves. It is a reflex response, beyond voluntary control.[12] AMI is most likely a protective mechanism, but poses problems during rehabilitation and can limit the effectiveness physical therapy.

During the first few months after surgery, AMI may be severe and quadriceps strengthening protocols can be largely ineffective. Despite resistance training, quadriceps strength may remain unchanged or even decline as we saw with Calatayud et al..[1] As a result, quadriceps strength deficits may remain long after joint trauma. Persistent quadriceps weakness is clinically important as it may impair dynamic knee stability, physical function, and quality of life.[6,7,13]

AMI is believed to be caused by a change in the discharge of articular sensory receptors due to factors such as swelling, inflammation, joint laxity and damage to joint afferents.[13] Spinal reflex pathways that contribute to AMI include the group I nonreciprocal (Ib) inhibitory pathway, the flexion reflex, and the gamma loop. Preliminary evidence suggests that supraspinal pathways may also play an important role.[11,13]

Therapeutic interventions that counter AMI are divided into two

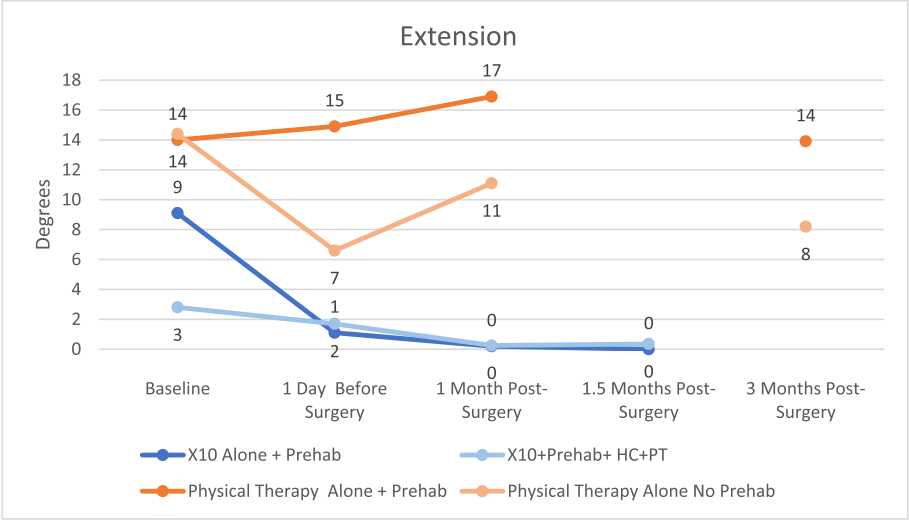

Fig. 2. Extension. The outpatient physical therapy data are from Calatayud et al..[1] Calatayud et al. did not measure data at 1.5 months hence the break in the lines. Both X10 groups performed better than the physical therapy groups. Calatayud et al. did not measure patients at 1.5 months hence the break in the lines.

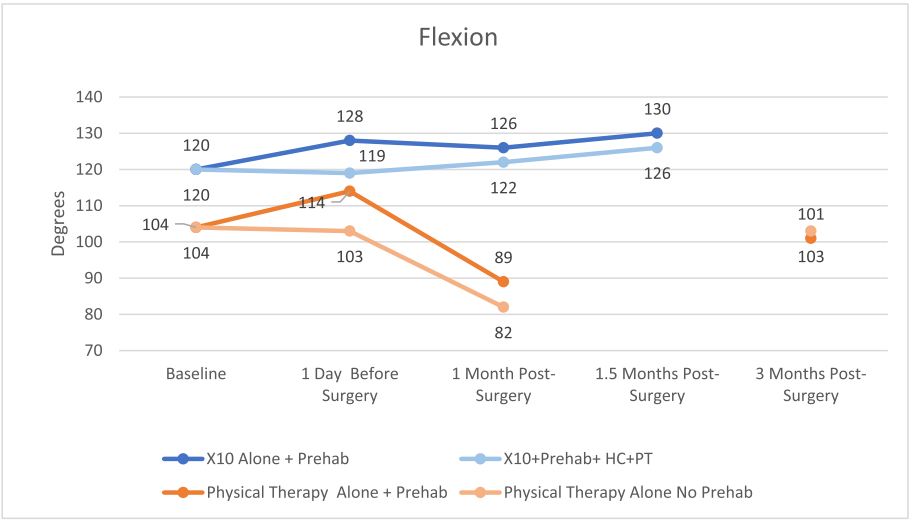

Fig. 3. Flexion. The outpatient physical therapy data are from Calatayud et al..[1] Calatayud et al. did not measure data at 1.5 months hence the break in the lines. Note that both X10 groups outperformed both of the outpatient physical therapy groups. Calatayud et al. did not measure patients at 1.5 months hence the break in the lines.

groups, those that modulate joint efferent discharge and those that stimulate the quadriceps directly. Therapies include cryotherapy, transcutaneous electrical nerve stimulation (TENS), and neuromuscular electrical stimulation (NMES). Intra-articular corticosteroids and NSAIDS may be effective when an inflammatory component is present.[14] Biofeedback and strength training to contraction failure also increases activation of the quadriceps following TKA surgery[15].

Significantly, the X-10 rehabilitation system incorporates several AMI ameliorating strategies. The X-10 system addresses swelling, contracts muscles to failure and incorporates biofeedback. This may explain, at least in part, the dramatic improvement in function experienced by both the X-10 groups.

The X-10's computerized range of motion program rapidly reduces swelling (which also reduces pain). Swelling in and around knee can shut down the nerves that cause the quadriceps muscle to contract. Experiments have shown that when liquid is infused into the knee, the nerves are shut down. Draining or removing the fluid resolves the problem.[13]

In the X-10's eccentric program, patients resist a descending arm, attempting to halt and reverse its direction—patient's do this for as long as they can until muscle failure occurs. This exercise is repeated several times. It has been postulated that as the quadriceps muscle nears failure other neurons are recruited. Consequently, repeated exercise to muscle failure activates new neurons improving AMI symptoms.

In addition, the X-10 system incorporates bio-feedback. Patients are able to see on screen the force they are exerting with every stroke of the machine. Training with biofeedback devices improves clinical outcomes in TKA patients[15].

The X10's incorporation of features known to reduce AMI may explain the dramatic difference between the results of Calatayud et al.[1] and those we report here. We believe that it is impossible for patients to achieve between 135% and 142% of the baseline quadriceps strength following surgery without address the deleterious effects of AMI.

6. Conclusion

We began by focusing on the debate over whether home exercises are as efficacious as outpatient physical therapy. To the extent that the

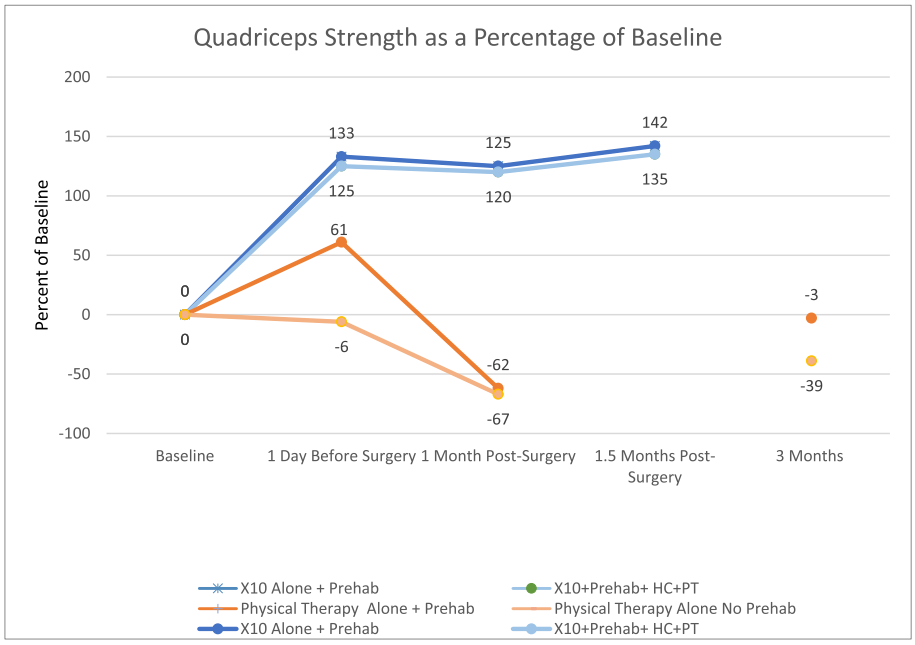

Fig. 4. Quadriceps strength. X10 patients more than regained their baseline quadriceps strength over the course of 1.5 months. The Calatayud et al. patients did not return to their baseline values even at three months post-surgery, though the prehabilitation group fared better than the non-prehabilitation group. Calatayud et al. did not measure patients at 1.5 months hence the break in the lines.

Calatayud et al.[1] study is representative of outpatient physical therapy, we can conclude that the X10 knee recovery system is at least as efficacious as outpatient physical therapy, if not superior, and that combining outpatient physical therapy with X10 therapy has no added benefits over X10 therapy alone.

Author contributions

Daisy Ference, Robert Ference and D. Carl Freeman were all involved in the conception of the project and the writing of the paper. D. Carl Freeman did the statistical analysis and produced the graphics. Erin Rempher conducted the coaching of patients, the collection of the data and contributed to the writing of the method section of the paper.

Declaration of competing interest

Erin Rempher is employed by Halley Orthopedics the manufacturer of the X10 the operator of X10 Therapy. She has no stock in the company or financial conflicts.

Daisy Ference, Robert Ference and D. Carl Freeman are not employed by Halley Orthopedics and have no financial interest in the company.

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