

Examining the use of the pressure modulated knee rehabilitation machine (PMKR) in addition to traditional physical therapy versus traditional physical therapy alone following total knee arthroplasty: a randomized control study

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Disclosure

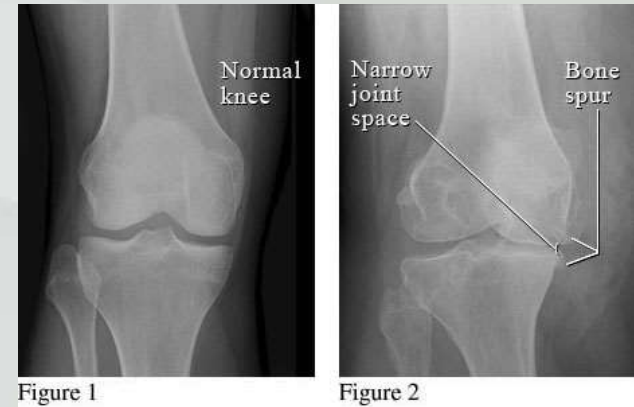
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Introduction

- Total Knee Arthroplasty (TKA)
 - Beneficial for disabling arthritis
 - Growing demand → 3.48 million by 2030
- Post-Operative Rehabilitation
 - Regain full mobility
 - Stiffness → scar tissue formation
 - Impedes Flexibility
 - Continuous Passive Motion (CPM) Machines



ROM Studies

- Contractures (5*) → Altered biomechanics and pain
 - Produce a noticeable limp during ambulation
 - Strain the quadriceps muscle
 - Contribute to patellofemoral pain
- Terminal Flexion → Activities of Daily Living

<u>ADL Activity</u>	<u>Knee Flexion Requirement</u>
Level Walking	60°
Sitting	93°
Get up from a chair	93°
Walk Up Stairs	105°
Tie Shoes	106°
Walk Down Stairs	107°
Ride Bicycle	110°
Squat	111°
Sit Cross-legged	111°
Squat and Pick Up Object	117°
Gardening	117°



CPM – Cochrane Review

- Active Knee Flexion ROM (Moderate Quality)
 - 78* vs. 80*
- Post-op Pain (Low Quality)
 - 3 vs 2.6
- Function (Moderate Quality)
 - 56 vs 54.4
- Quality of Life (Moderate Quality)
 - 40 vs 41
- Reduce risk of MUA (Low Quality)
 - 7.2% vs 1.6%
- Risk of adverse events (Low Quality)
 - 16.3% vs 17.9%
- **Summary: CPM does NOT have clinically important effects on ROM, pain, function or quality of life.**



X10 – Pressure Modulated Knee Rehabilitation Machine (PMKR)

- Utilizes variable pressure technology
 - Customizable programs for:
 - ROM (active & passive)
 - Isotonic, Isometric, & Eccentric Strengthening exercises
 - Quadriceps & Hamstring stretching
 - Neuromuscular re-education
- Biofeedback
 - Active response
 - Precisely regulates pressure to empower rehab

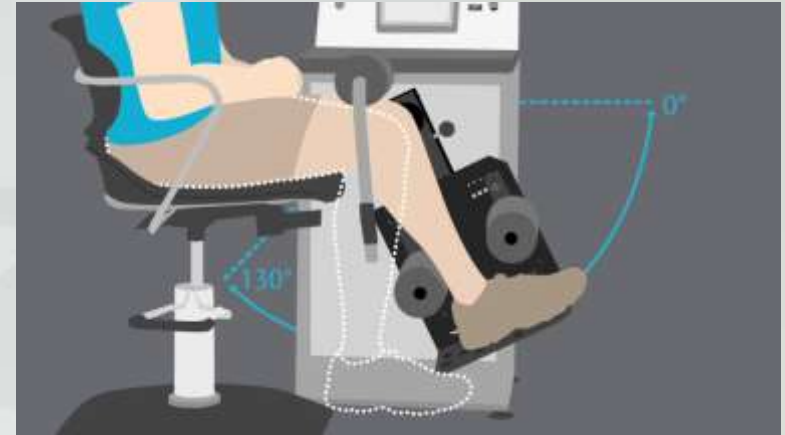


Purpose / Hypothesis



- **Purpose – To evaluate:**
 - The impact of PMKR machine therapy on ROM in patients undergoing primary TKA
- **Hypothesis:** Patients who utilize the PMKR machine will demonstrate improved ROM and clinical scores at two and four weeks post-operatively compared with individuals utilizing standard therapies

Power Analysis



- Prior ROM Study (Dr. Cochran)
 - 130 patients @ ~30 days post-op
 - Mean flexion → 110.75 degrees +/- 11.44 SD
- X10 Flexion Values:
 - 118.3 degrees @ 4-weeks post-op
- (G*Power) with an alpha = 0.05, beta = 0.80, effect size = 0.65
 - **Sample Size of 36 per group**
 - **Additional 14 patients per group (40% drop-out rate)**
 - **50 Patients per group**

Materials & Methods

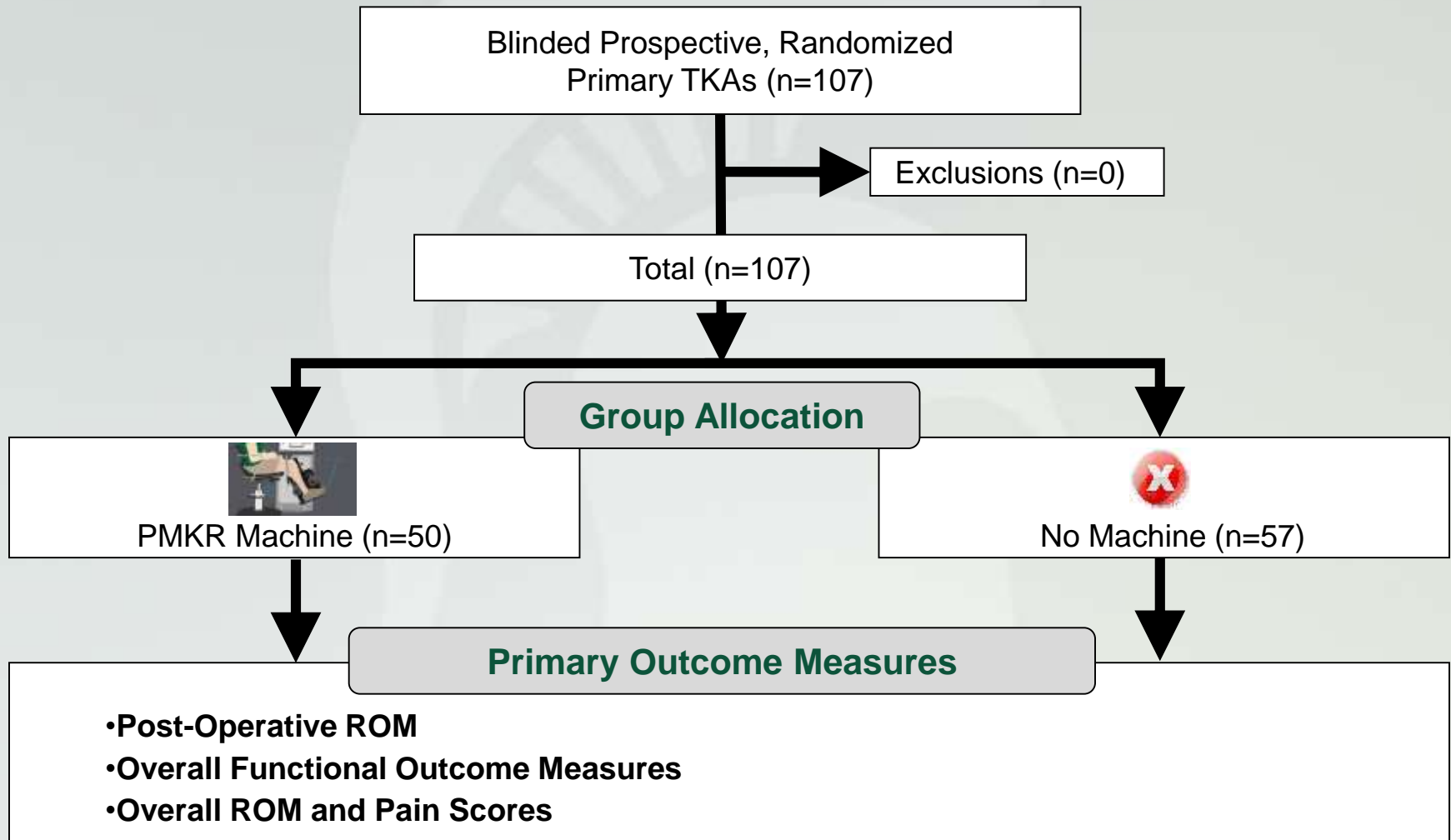


Figure 1. Flow diagram of the chart review process.

Materials & Methods

Patient Population:

Primary TKA, Single surgeon (JMC)

Study Design:

Blinded Prospective, Randomized

Range of Motion Assessment:

Goniometer

Function Outcome Measures:

Western Ontario and McMaster
Universities Arthritis Index (WOMAC)
-score range: 0-96 (worst function)
UCLA Activity Score
-score range: 1-11 (best function)
SF-36
-score range: 12-60 (best function)
Sit to Stand
-score range: unlimited (best function)

Exclusions:

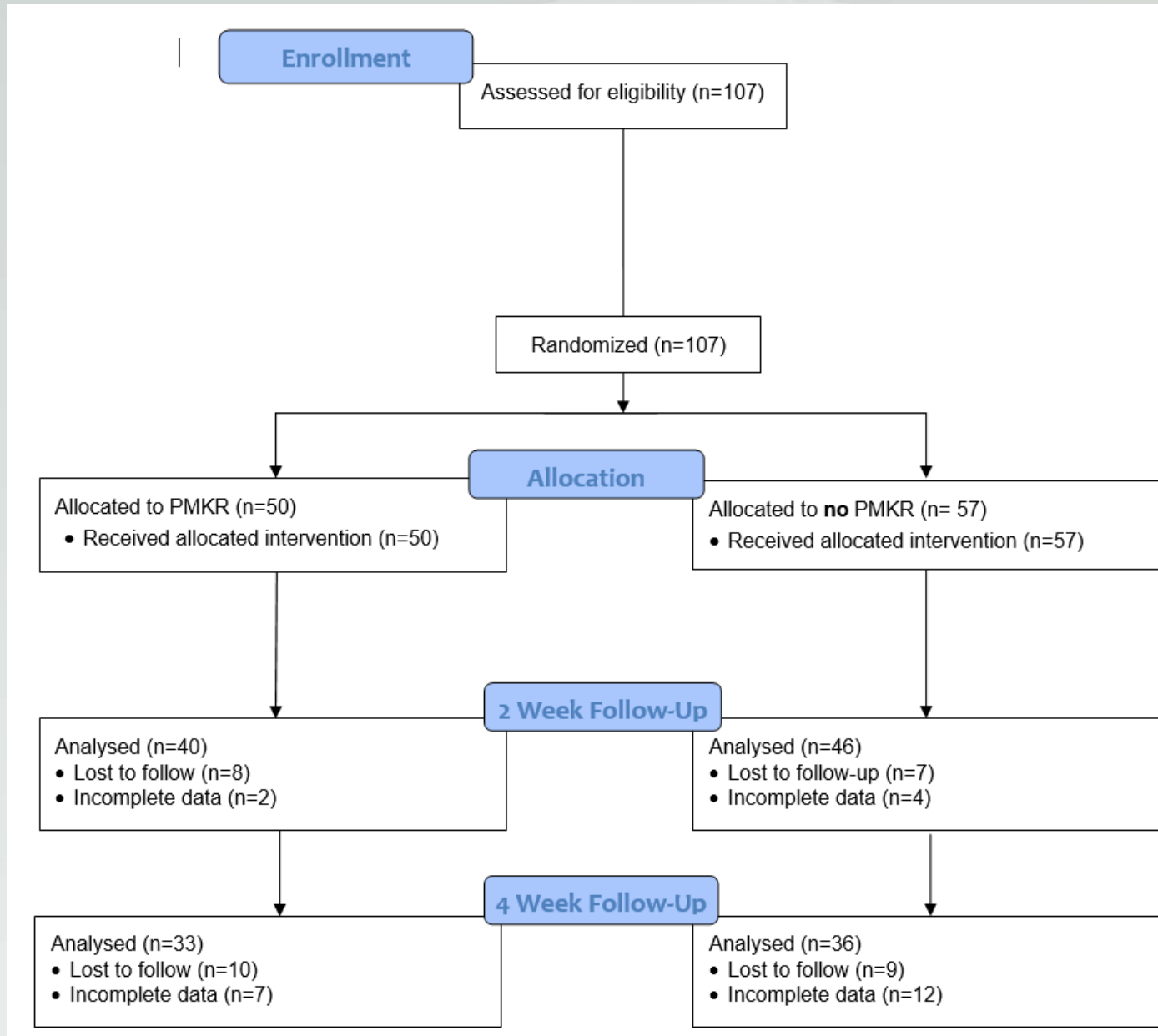
Bilateral TKAs within 8 weeks
Acute surgical intervention

Primary Analyses

Dependent Samples t-test
Pre-Op vs. Post-Op
Comparisons
Independent Samples t-test
Group Comparisons

Secondary Analyses

Two-way Analysis of Variance
(ANOVA)



Baseline Clinical & Demographic Information

	No PMKR	PMKR	<i>P</i> -value
Sex (Women)	29	28	0.50
Age	63.4 (10.6)	63.9 (8.3)	0.76
BMI	35.7 (8.1)	35.3 (8.6)	0.80
Knee Pain	7.3 (1.6)	6.3 (1.9)	0.007*
Extension ROM	7.6 (4.6)	5.6 (3.7)	0.018*
Flexion ROM	110.8 (13.5)	112.6 (14.1)	0.50
UCLA	4.2 (1.8)	3.8 (1.3)	0.20
WOMAC	52.5 (16.6)	55.0 (16.4)	0.47
SF-36 PCS	40.8 (16.6)	44.4 (16.8)	0.30
SF-36 MCS	61.7 (18.1)	98.8 (15.7)	0.05*

Outcome Change Scores (2 & 4 Weeks)

	No PMKR		PMKR		P-value
	2 week	4 week	2 week	4 week	
Knee Pain	3.5 (2.4)	4.9 (2.1)	3.4 (2.5)	4.5 (2.5)	< 0.001
Extension ROM	2.1 (5.5)	4.2 (4.3)	1.9 (3.0)	3.5 (2.6)	< 0.001
Flexion ROM	-8.9 (12.6)	-0.2 (10.6)	-5.2 (13.6)	2.5 (14.1)	< 0.001
UCLA	-0.85 (1.9)	0.19 (2.1)	-0.73 (1.7)	0.12 (1.66)	< 0.001
WOMAC	10.0 (22.8)	26.0 (22.0)	20.2 (21.3)	34.8 (17.9)	< 0.001
SF-36 PCS	2.2 (15.8)	12.1 (23.0)	-0.3 (15.7)	11.7 (17.1)	< 0.001
SF-36 MCS	1.3 (19.3)	4.8 (20.0)	-1.6 (16.8)	2.8 (18.5)	< 0.001
Sit to Stand	-1.3 (4.5)	1.9 (4.9)	-1.2 (4.2)	0.9 (4.3)	< 0.001

***P-value indicates the overall significance value for the Time main effect calculated from the ANOVA.**

Outcome Change Scores (4 Months)

	No PMKR	PMKR	<i>P</i> -value
Knee Pain	6.1 (1.8)	5.1 (2.0)	0.08
Extension ROM	7.3 (5.2)	5.9 (3.5)	0.24
Flexion ROM	10.9 (11.7)	9.8 (13.0)	0.73
UCLA	1.1 (2.5)	1.5 (1.8)	0.55
WOMAC	28.2 (15.8)	32.3 (17.7)	0.44
SF-36 PCS	25.7 (21.1)	22.2 (20.5)	0.58
SF-36 MCS	13.8 (15.6)	7.8 (17.2)	0.26
Sit to Stand	3.2 (5.5)	2.2 (5.7)	0.55

Table 3. Outcome change scores for both PMKR and No PMKR groups at 4 months post-TKA.

Patient Satisfaction Score with TKA

- 92% of patients

Discussion

- Contracture
 - Impair normal biomechanics
- Conservative management
 - Physical Therapy
- Operative management
 - Manipulation Under Anesthesia
 - Isolated Arthrolysis
 - Revision TKA



Discussion & Conclusion

- 600,000 TKA procedures (2010)
 - Growth to 3.48 million by 2030
- 1.4%-17% Contracture Complication
 - **Estimated Costs MUA: ~\$2,000**
 - Savings: ~\$97 million - \$1.18 billion
 - **Estimated Revision TKA: ~\$75,000**
 - Savings: ~\$3.65 billion - \$44.4 billion



Summary

- PMKR Machine
 - Does affect the initial post-operative ROM
- Proactive discussions with patients
- Potential post-operative cost differential



Overall Impact

- Higher Patient Satisfaction
- No minimally clinically important difference in ROM at 4 month time period

Thank You - The End

- Questions?