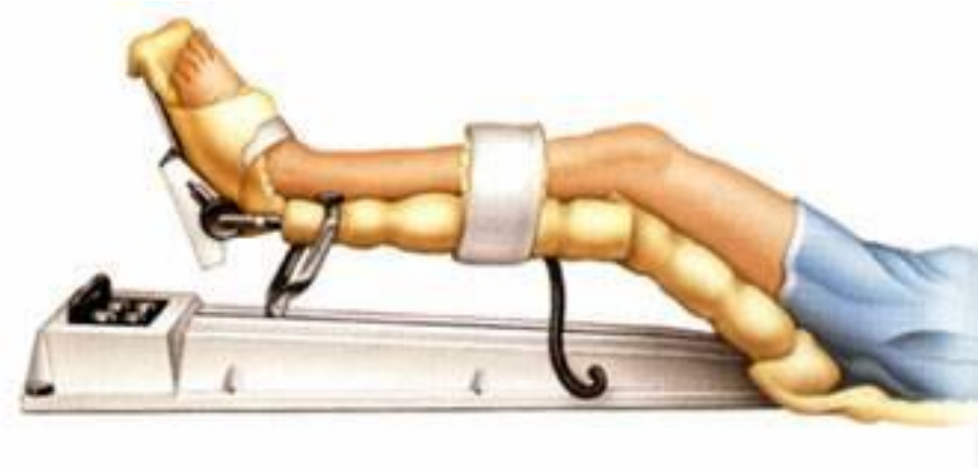
Randomized Controlled Trial of the Effectiveness of Continuous Passive Motion After Total Knee Replacement



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引言人: 韓善寰

Randomized Controlled Trial of the Effectiveness of Continuous Passive Motion After Total Knee Replacement

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Year	Impact Factor (IF)
2013/2014	2.44

評讀工具:RCT Appraisal sheets (RAMbo)

- RCT Appraisal sheets (RAMbo)
  - Validity
  - Impact
  - Applicability

步驟 I：研究探討的問題為何？

研究族群 / 問題 (Population/ Problem)	**Patients After a Total Knee Replacement**
介入措施 (Intervention)	**Continuous Passive Motion (CPM)+conventional PT**
比較 (Comparison)	**conventional PT**
結果 (Outcomes	Effectiveness (Active knee flexion, Active Range of Motion, Length of stay, FIM…)

步驟 2：研究的品質有多好(內在效度)？

- 2-1 招募(Recruitment) - 受試者是否具有代表性？

我們是否知道病人族群為何(收案場所、納入 / 排除條件)	• All patients transferred directly to the Inpatient rehabilitation facility (IRF) within 5 days after their surgery between November 2011 and November 2012 were assigned a primary therapist who assessed the patient’ s active knee flexion and extension ROM on the day of admission. • Patients were enrolled consecutively.

步驟 2：研究的品質有多好(內在效度)？

- 2-1 招募(Recruitment) - 受試者是否具有代表性？

病人族群為何(收案場所、納入 / 排除條件)	***Inclusion criteria*** **:** **(1) transferred to an IRF after a single knee replacement;** **(2) etiology of osteoarthritis;** **(3) aged 40 to 80 years;** **(4) initial maximal knee flexion ROM between 45 and 75 of flexion;** **(5) body mass index <40.** ***Exclusion criteria were as follows:*** **(1)revision to a previous TKR;** **(2) bilateral TKR;** **(3) comorbid medical conditions that could interfere or complicate recovery (eg, stroke, Parkinson’ s disease, significant cognitive impairment).**

步驟 2：研究的品質有多好(內在效度)？

- 2-1 招募(Recruitment) - 受試者是否具有代表性？

了解符合收案條件的對象且簽署同意書	The **institutional review board approved** the study, and written informed consent was obtained for each participant.

評讀結果：■是 □否 □不清楚

步驟 2：研究的品質有多好(內在效度)？

2-2分派(Allocation) - 分派方式是否隨機且具隱匿性...？

Consented subjects were randomly assigned to either the control or experimental group based on their unique, episode-specific account number.

評讀結果：隨機■是 □否 □不清楚

步驟 2：研究的品質有多好(內在效度)？

2-2每個組別，在研究開始時的情況是否相同？

Table 1 Baseline clinical characteristics of all subjects (n = 141) by study condition

Variables	CPM Group (n = 70)	Control Group (n = 71)	*P*
Initial range of motion (deg)			
Active knee flexion	61.3±7.8	63.6±7.4	.076*
Active knee extension	−4.7±3.4	−4.6±3.3	.861*
Initial FIM			
Motor score	43.2±4.7	42.7±4.1	.494*
Cognitive score	28.0±1.6	28.1±1.6	.794*
Total FIM score	71.3±5.5	70.8±4.7	.609*
Initial knee girth (cm)	47.0±5.9	46.5±5.4	.576*
Initial WOMAC			
Pain subscale	10.2±3.6	10.6±3.5	.578*
Stiffness subscale	4.6±1.4	4.7±1.5	.713*
Difficulty with ADL	35.3±11.8	34.4±12.0	.765*
Total score	50.2±15.7	50.3±15.0	.973*
Initial TUG (s)	39.3±15.6	40.9±18.2	.614*
Presurgical ambulation device			
Device (walker or cane)	17 (24)	22 (31)	.452†
No device	53 (76)	49 (69)	

NOTE. Values are mean ± SD, n (%), or as otherwise indicated.
* *P* value from paired *t* test (2 tailed).
† *P* value from Fisher exact test (2 tailed).

評讀結果：■是 □否 □不清楚

步驟 2：研究的品質有多好(內在效度)？

2-3維持(Maintenance) - 各組是否給予相同的治療？　是否有足夠的追蹤(Follow up)？

Active knee flexion ROM, Active knee extension ROM
length of stay, Estimate of function using the FIM
Timed Up and Go test, Girth measurement

(145-4)/145=97.2%
100%-97.2%=2.8%

WOMAC scores (Western
Ontario and McMaster Universities Osteoarthritis Index scores):
55%

評讀結果：■是 □否□ 不清楚

步驟 2：研究的品質有多好(內在效度)？

2-3維持(Maintenance) - 是否有足夠的追蹤(Follow up)？

CPM group=70
Control group=71

Table 1 & Table 2均以per-protocol進行分析.

評讀結果：□是 ■ 否□ 不清楚

步驟 2：研究的品質有多好(內在效度)？

評估(Measurement) - 受試者與評估者是否對治療方式及(或)評估目的維持盲法(blind)？

- The patients and therapists were not blinded to the study group.
- The discharge date and discharge destination were determined by the physician-led interdisciplinary team, who were blinded to the group assignment.

評讀結果：□是 ■否 □不清楚

步驟 3：研究結果的意義為何？

Table 2 Results of ANCOVA on outcome variables for the CPM and control groups at discharge

Outcome Variables	CPM Group (n=70)	Control Group (n=71)	df	F	*P*
Active knee flexion	83.5±10.0	86.4±7.9	1,138	3.100	.080
Active knee extension	−2.7±2.8	−3.3±3.3	1,137	1.580	.211
Total FIM score	107.0±4.1	107.8±3.2	1,138	2.140	.146
TUG score	19.9±7.5	19.8±6.1	1,102	0.394	.532
Knee girth measurement	46.1±5.3	46.2±5.0	1,131	1.860	.175
WOMAC score	30.2±14.6	33.3±14.4	1,57	1.120	.294

NOTE. Values are mean ± SD or as otherwise indicated.

一篇RCT是不夠的！

2014 Cochrane的Systemic Review怎麼說?

Continuous passive motion following total knee arthroplasty in people with arthritis (Review)

Harvey LA, Brosseau L, Herbert RD

THE COCHRANE COLLABORATION®

Continuous passive motion following total knee arthroplasty in people with arthritis

Analysis 1.1. Comparison 1 Main comparison, Outcome 1 Active knee flexion ROM - short-term effects.

Review: Continuous passive motion following total knee arthroplasty in people with arthritis

Comparison: 1 Main comparison

Outcome: 1 Active knee flexion ROM - short-term effects

Study or subgroup	CPM N	CPM Mean(SD)[degrees]	Control N	Control Mean(SD)[degrees]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Bruun-Olsen 2009	30	85 (13)	33	83 (16)		8.7 %	2.00 [-5.17, 9.17]
Chiarello 1997	8	74.7 (12.5)	10	71 (12.1)		4.3 %	3.70 [-7.76, 15.16]
Denis 2006	27	83.3 (11.9)	27	80.4 (11.8)		10.1 %	2.90 [-3.42, 9.22]
Huang 2003	23	81 (12)	21	71 (15)		7.4 %	10.00 [1.92, 18.08]
Lau 2001	30	78 (15)	30	74 (19)		6.7 %	4.00 [-4.66, 12.66]
Lenssen 2008	30	89.9 (9.1)	30	86.7 (8.5)		14.4 %	3.20 [-1.26, 7.66]
May 1999	12	79.7 (3.5)	7	79.4 (8.8)		9.3 %	0.30 [-6.51, 7.11]
McInnes 1992	47	82 (11.8)	45	75 (11.5)		13.6 %	7.00 [2.24, 11.76]
Ng 1999	16	67 (8.6)	16	71.9 (8.3)		11.1 %	-4.90 [-10.76, 0.96]
Sahin 2006	14	82 (6.1)	14	82.9 (5.9)		14.4 %	-0.90 [-5.35, 3.55]
Total (95% CI)	**237**		**233**			**100.0 %**	**2.40 [-0.22, 5.03]**

Heterogeneity: $Tau^2 = 7.31$; $Chi^2 = 15.77$, df = 9 (P = 0.07); $I^2 = 43\%$

Test for overall effect: Z = 1.79 (P = 0.073)

Test for subgroup differences: Not applicable

Continuous passive motion following total knee arthroplasty in people with arthritis

Analysis 1.3. Comparison 1 Main comparison, Outcome 3 Active knee flexion ROM - long-term effects.

Review: Continuous passive motion following total knee arthroplasty in people with arthritis

Comparison: 1 Main comparison

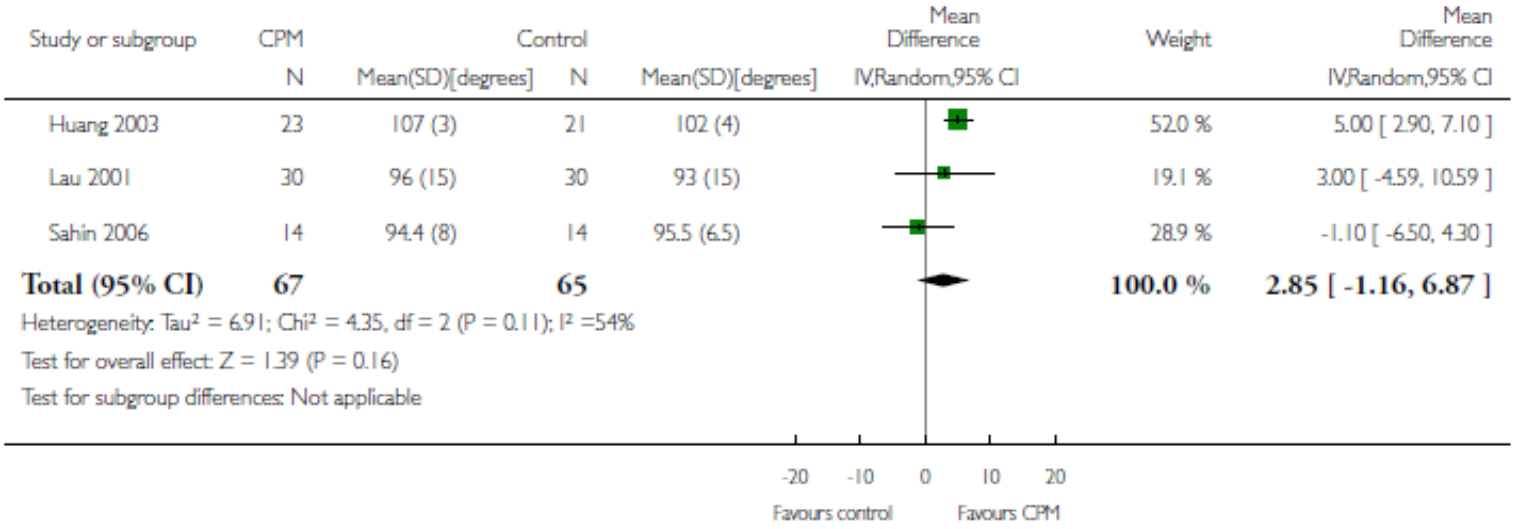
Outcome: 3 Active knee flexion ROM - long-term effects

Study or subgroup	CPM N	CPM Mean(SD)[degrees]	Control N	Control Mean(SD)[degrees]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Huang 2003	23	107 (3)	21	102 (4)		52.0 %	5.00 [2.90, 7.10]
Lau 2001	30	96 (15)	30	93 (15)		19.1 %	3.00 [-4.59, 10.59]
Sahin 2006	14	94.4 (8)	14	95.5 (6.5)		28.9 %	-1.10 [-6.50, 4.30]
Total (95% CI)	**67**		**65**			**100.0 %**	**2.85 [-1.16, 6.87]**

Heterogeneity: $Tau^2 = 6.91$; $Chi^2 = 4.35$, $df = 2$ ($P = 0.11$); $I^2 = 54\%$

Test for overall effect: $Z = 1.39$ ($P = 0.16$)

Test for subgroup differences: Not applicable



Continuous passive motion following total knee arthroplasty in people with arthritis

Main results

- We identified 684 papers from the electronic searches after removal of duplicates and retrieved the full reports of 62 potentially eligible trials. Twenty-four randomised controlled trials of 1445 participants met the inclusion criteria; four of these trials were new to this update.
- There was moderate-quality evidence to indicate that CPM does not have clinically important short-term effects on active knee flexion ROM: mean knee flexion was 78 degrees in the control group, CPM increased active knee flexion ROM by 2 degrees (95% CI 0 to 5) or absolute improvement of 2% (95% CI 0% to 4%).
- The medium- and long-term effects are similar although the quality of evidence is lower. There was low-quality evidence to indicate that CPM does not have clinically important short-term effects on pain: mean pain was 3 points in the control group, CPM reduced pain by 0.4 points on a 10-point scale (95% CI -0.8 to 0.1) or absolute reduction of -4% (95% CI -8% to 1%).
- There was moderate-quality evidence to indicate that CPM does not have clinically important medium-term effects on function: mean function in the control group was 56 points, CPM decreased function by 1.6 points (95% CI -6.1 to 2.0) on a 100-point scale or absolute reduction of -2% (95% CI -5% to 2%). The SMD was -0.1 standard deviations (SD) (95% CI -0.3 to 0.1).
- There was moderate-quality evidence to indicate that CPM does not have clinically important medium-term effects on quality of life: mean quality of life was 40 points in the control group, CPM improved quality of life by 1 point on a 100-point scale (95% CI -3 to 4) or absolute improvement of 1% (95% CI -3% to 4%).

討論: 我們的病人做完TKR後，可以不再用CPM嗎？

- Evidence
  - 本篇RCT及Cochrane的Systemic Review結果均顯示TKR術後使用CPM與傳統PT復健效果無顯著差異
- Expertise
  - 1.TKR術後病人常因怕痛不敢動，CPM的應用可依病人耐受度調整角度做被動運動
  - 2. 如能在術前衛教術後如何活動，並在術後有效的控制疼痛，做主動運動則更佳
- Expectation
  - 病人和家屬覺得有CPM幫助還不錯，尤其是開完刀常因怕痛會不敢動

臨床應用-

- 病人做完TKR後，是否可以不常規使用CPM？


Thank You