RESEARCH PAPER

Systematic Exercise Effects on Balance and Joint Mobility after Unilateral TKR (Cruciate-Retaining Vs Sacrificing)

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ABSTRACT
A drug molecule's physicochemical attributes like its bulk characteristics, solubility, dissolution, mechanical properties and stability are critical determinant of their bioavailability and therapeutic performance, yet often pose serious challenges during formulation development. Cocrystallization offers a unique approach to address these challenges by forming crystalline complexes of an Active Pharmaceutical Ingredient (API) with a suitable conformer, typically a Generally Recognized as Safe (GRAS) compound, in a defined stoichiometric ratio. Unlike salt forms, cocrystals are stabilized by interactions that are non-covalent in nature, like van der Waals forces, hydrogen bonds and π-π stacking, enabling modulation of key drug properties including solubility, permeability, dissolution, compressibility and stability. Nutraceuticals have emerged as promising conformers, offering dual benefit of altering physicochemical properties of API while also providing antioxidant and anti-inflammatory effects. This review highlights recent advances in the design, synthesis and characterization of drug-nutraceutical cocrystals. Exploring the ongoing formulation development and approved market products, the review highlights the potential of drug-nutraceutical cocrystals in advancing personalized medicine.

Keywords: *Cocrystals, Nutraceuticals, Bioavailability, Solubility, Cocrystallization*
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INTRODUCTION

Osteoarthritis is the universal chronic articular problem, frequently affecting the knee, resulting in pain, stiffness and affecting functional decline[1]. When conservative treatments fail, TKR is considered to alleviate pain and optimise wellness. [2-4] The outcomes of which are predicted by implant survival, range of motion (ROM), quadriceps strength, and the potential to resume activities of daily living (ADL). Achieving optimal postoperative function depended not only on surgical technique and implant design but also on a systematic rehabilitation [5-7.]

Traditional exercises like mobility and strength training have shown a subtle but valuable effect on functional status.[8]

Clinical investigations have shown significant improvement in physical function and health related quality of life, but the effects tend to dissipate by 3 to 4 months[6] indicating that exercises could be put forward to produce sustainable upgrades in these patients. Many studies have pinpointed shortfalls in the balance , such as low potential to determine joint awareness, setback in latent period of muscle, change in magnitude of muscle activation, and declined postural alignment in subjects after TKR [9,10,11]

Impaired coordination and balance can be contemplated as one of the important factors that may result in functional deficits after TKR. However, functional balance and stability after TKR with PCL retention or sacrifice prostheses have not been proven[12,13,14], and hence our analysis aimed to see the effect of systematic training on Unilateral TKR with PCL sacrifice and unilateral TKR with PCL retaining to improve balance, stability, gait, and knee Range of motion.

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MATERIALS AND METHODS

Study Framewok, Setting and Subjects

A randomised controlled trial study was supervised in the Department of Physiotherapy, Meitra Hospital, Calicut, Kerala, India, which extended for a span of two years. The study was longitudinally registered in the Clinical Trial Registry of India (CTRI/2020/06/026242, submitted on 30 June 2020). Patients included in this study were between 50–75 years age and of both sexes, diagnosed with Grade 4 knee osteoarthritis as per Kellgren and Lawrence radiological classification, and referred for total knee replacement (TKR). We excluded patients who had rheumatoid arthritis, revision or infected TKR, post-polio residual paralysis, neurological conditions affecting balance and who were contraindicated for exercise due to any medical condition.

Informed consent was taken before enrolment from 50 patients (n=25 each) posted for unilateral PCL retaining and PCL sacrificing Total Knee Replacement. In continuation with the screening of subjects, a comparative phase was conducted where the effectiveness of systematic exercises to improve knee ROM, balance, and stability following PCL retaining and PCL sacrificing in Unilateral TKR using the Berg balance, Timed Up and Go test, and Virtual reality. All patients received Smith & Nephew implants of either CR or PS design.

A consistent, systematic rehabilitation program lasting for a minimum of six months was provided to all participants. Restoration of knee range of motion (ROM), improving strength, enhancing balance, and promoting independent gait were the main focuses. In the early postoperative period, Continuous Passive Motion and Voluntary Muscle stimulation were given for 15 minutes from Day 1 to 3, followed by Joint mobilisation, strengthening, gait and balance training with withdrawal of the assistive device by the end of 2 weeks. Progressive balance and proprioceptive training, including step-ups, lateral shifts and transfers, were started after 2 weeks, and Advanced strengthening and single-leg balance activities for a period of 2 -6months.

Table 1: Structured Exercise Protocol

Timeline	Intervention	Details
Day 1–3	Continuous passive motion (CPM)	Up to 3 days postoperatively
	Voluntary muscle stimulation	Applied up to 3 days
Day 1–2 weeks	Knee, hip, and ankle mobilization & strengthening	10 reps, 10-sec hold, twice daily
	Gait training with walker	Focus on safe ambulation
	Balance training	Standing weight-shift exercises
After 2 weeks	Targeted hip and knee strengthening (side-lying, prone)	10 reps, 20-sec hold, twice daily
	Core strengthening in lying position	Added progressively
	Sitting single-leg knee extension	Functional strengthening
	Sit-to-stand transfers	Functional independence
	Gait training without support	Progression from walker
	Balance training	Step-ups, step-downs, lateral shifts, multidirectional steps
2–6 months	Graded hip and knee strengthening	15 reps, 20-sec hold, twice daily
	Bilateral calf raises and calf press	Progressive strengthening
	Progressive balance training	Single-leg stance, reaching, step exercises

Performance Indicators

Primary outcomes included Knee Range of Motion ROM measured using a standard goniometer, Balance assessed using the Berg Balance Scale (BBS), Functional mobility assessed by the Timed Up and Go (TUG) test, and Stability was assessed using a virtual reality–based baropodometric platform in which total surface area and weight distributions were measured.

Outcomes were assessed at five time points: preoperatively, postoperative day 3, at 2 weeks, 2 months, and at 6 months.

Stability Test

A virtual reality–based baropodometric platform designed to quantify postural control and weight distribution was used to evaluate the stability. Visual feedback and quantitative measures of balance were pre-installed in the system.

Participants were instructed to stand barefoot with equal weight distribution on both feet. An initial scan took a baseline baropodometric image of plantar pressure distribution. During testing, a square field with a red dot (representing the centre of pressure) was displayed on a monitor. Patients were asked to shift their body weight in the direction of the arrows on the screen while keeping their feet fixed. This led to a controlled anterior–posterior and medio-lateral weight transfers without stepping.

The centre-of-pressure excursions were recorded and calculated by the software.

Total surface area of sway (mm²), Front–back (F/B) ratio and Left–right (L/R) ratio.

These measures were used to evaluate postural stability and balance strategies.

The results of baropodometric images visually portrayed weight-bearing zones, while the stability performance was quantified by the numerical outputs. To ensure safety and reproducibility, all tests were administered under the supervision of a Physiotherapist.

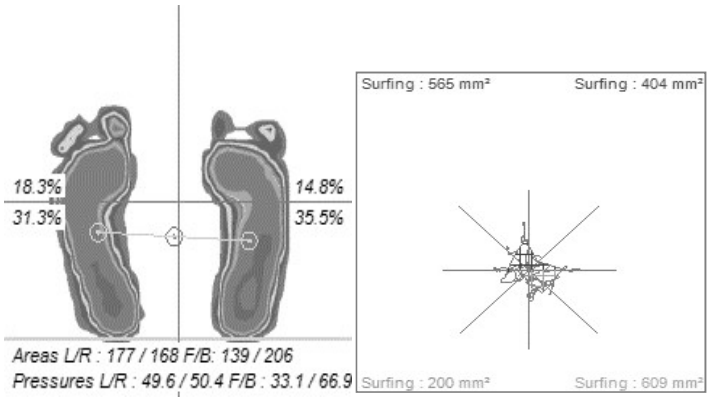

Fig.1 Footprint Acquisition of the baropodometric image and Graphical representation of Total Surface Area(mm^2)

Comparison of the range of motion of the study participants between the pre-operative and post-operative time points is shown in Table 2

Group	Category	Mean ± Standard Deviation	P value
Unilateral CR	**Preoperative**	111.20 ± 13.17	
	Postoperative	123.40 ± 5.14	**0.004***
Unilateral PS	**Preoperative**	108.80 ± 15.01	
	Post operative	123.40 ± 4.94	**0.004***

TABLE 2

We noted a statistically significant (P value < 0.05) difference between the preoperative and postoperative mean range of motion values among research participants who underwent various types of procedures

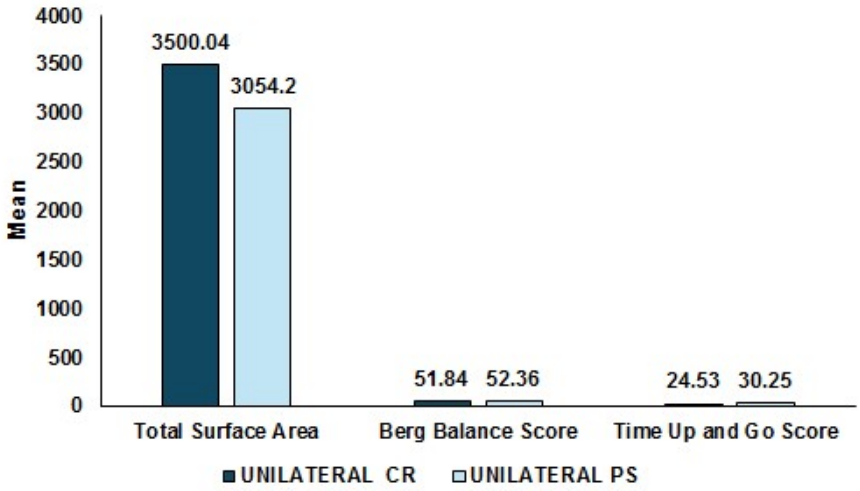

Fig 2. Mean comparison of various time points in Unilateral PS and CR

The Unilateral CR group demonstrated improvements in Total Surface Area and TUG scores, while the PS group showed a slight improvement in Berg Balance

Variables	Preop CR (Mean±SD)	Preop PS (Mean±SD)	P value	PostopCR (Mean±SD)	Postop PS (Mean±SD)	P value
Total Surface	2218. 32 ± 1064.43	2757.24 ± 1593.03	0.174	3500.04 ± 3228.90	3054.20 ± 2192.30	0.942

Area						
BBS Score	48.6 ± 5.6	47.20 ± 6.08	0.449	51.84 ± 3.07	52.36 ± 4.12	0.287
TUG Score	41.25 ± 16.41	34.28 ± 18.27	0.939	24.53 ±5.40	30.25 ± 20.15	0.002

Table 3. Comparison of the parameters between the preoperative and the postoperative time points in case of the PS and CR groups in the unilateral category

Values are presented as Mean ± SD. Independent-sample t-tests were used to compare CR and PS groups

RESULTS

SPSS version 27 was used for Data Analysis. Repeated-measures ANOVA was used to compare effects across time points, and independent-sample t tests were used for between-group comparisons. Statistical significance was set at $p < 0.05$.

The data The ANOVA results indicated a statistically remarkable aftermath on the Berg Balance Score ($p = 0.005$), as well as a significant decrease in Timed Up and Go (TUG) scores (p <188 0.001). Berg balance score of Unilateral TKR with cruciate retaining, the mean score differed statistically remarkable between time points ($F (2.80, 67.27) = 10.49$, P value <0.001). Post hoc analysis with a Bonferroni adjustment revealed that Berg balance was appreciably increased from the third day after surgery to six months. (-3.2 (95% CI, -12.53, -4.50) p value<0.001)

In unilateral TKR with CR the average tug score differed statistically remarkable between time points ($F (1.80, 43.36) = 23.79$, P value <0.001). Post hoc analysis with a Bonferroni adjustment disclosed that TUG score was statistically remarkably less from pre-operative to six months. (16.71 (95% CI, 6.721, 26.716) p-value <0.001).

However, no significant time effect was observed for the total surface area measured in the VR test ($p = 1.000$).

According to the data analysis, the CR group study participants improved better than the PS group study participants. Table 3 shows the pre-and postoperative mean comparisons of the Tug score, Berg balance score, and Total surface area.

The comparison of mean scores across periods reveals signs of improvement in the CR group. The CR group study participants outperformed the PS group in terms of total surface area and Tug score at six months post-operatively. However, the PS group has a higher BB score, but it was insignificant. Though the PS group has a higher Berg balance score, the difference, which is marginal, in relation to the data, we surmise that CR will be superior to PS.

DISCUSSION

Rehabilitation after TKR is essential and is associated with functional improvement.

Our study was designed to determine the effectiveness of systematic exercises on Unilateral Total Knee Replacement with CR and PS implants**.** Our patients were in the 50-75 year age group, with a representative age of 66 years. Our analysis revealed that these patients had improved mobility, with occasional pain transitioning to no pain, and could walk with ease without any aids, as well as ascend and descend stairs.

Vitalis [15]et al did a prospective comparative cohort study on CR & PS TKR. Both groups saw gains in joint flexibility, but a marked difference in flexion at one year was undetected. Both CR and PS TKA generated similar advancements in pain, well-being, emotional fitness, and knee mobility at one year. Prothesis configuration did not affect functional improvement or PROMs in their cohort, and their patients reported standardised advancements in pain relief, everyday tasks, and subjective well-being. Disregard of the implant type, a subtle variation in the range, can hardly have any influence on routine tasks for most subjects within the acute recovery time.

Targeted investigations reported that PS TKAs achieve a slight exceedance of flexion than CR TKAs[16,17]. Median flexion of 120° in PS knees vs. 115° in CR knees at 2 years ($p = 0.017$), marking a slight but marked flexion benefit with PS[16] was noted by Tille et al. Regardless of enhanced joint mobility in PS knees, in general PROMs and subjective well-being were statistically identical between CR and PS cohorts in their investigation.

But our analysis revealed that both CR and PS Range of Motion p-value was 0.004 postoperatively, indicating both implants had a negligible difference.

Liao et al[18] in their study suggested additional balance exercise for 8 weeks, found more improvement. Their study found an improvement in TUG at a 95 % Confidence Interval of 2.6 to 3.4 sec. Our study found the results after 2 months of structured exercises, post TKR p-value<0.00.

Hadamus[19] et al did a study to evaluate the potency of VR in enhancing postural alignment after TKR for a period of 4 week and didn't find any significant improvement as the 4-week period was too short.

This research is designed to determine that effectiveness pertaining to systematic exercises on unilateral Total knee replacement with CR and PS prosthesis. The results prove that the addition of systematic exercises for a 6-month duration has the potential to improve the performance-based measure of BERG Balance, TUG, Knee Range of Motion, Balance, and stability[20].

The systematic exercises following TKR led to an early short-term recovery in physical function, which further improved the capacity to do day-to-day things with less pain and difficulty, which helped a more active lifestyle at least in the short-term following post-TKR[21].

Eldien et al did a comparative study on long-term follow-up on CR and PS TKR to see the effect of dynamic balance and functional performance following rehab and found CR patients had increased BBS, decreased TUG between 3- 6 months compared to PS, but between 6-12 moths both groups were comparable.

Hossein[22] et al did a randomised clinical trial with 30 subjects post TKR and estimated plantar foot constraint, forefoot force, rearfoot force, and centre of pressure using a foot scanner and divided them to a standard exercise group and a balance exercise group. Balance exercises were more successful in enhancing foot load and stability in patients with total knee arthroplasty than solely routine exercise.

Our results showed CR -TKR had decreased TUG, while PS-TKR had increased BBS compared to CR, which was contextual.

Previous studies have reported that balance is a strong predictor of physical function and fall prevention following TKR. However, the studies have validated the positive correlation between balance exercises and physical function following TKR.[23,24,25]. The debility of the quadriceps muscle also resulted in poorer function in older adults and patients with knee OA.

Phunsuk et al[25] in their study aimed to evaluate score variation in the knee following late-stage of training at ≤ 12 weeks versus > 12 weeks after TKA. The training at ≤ 12 weeks primarily enhanced the functional ability. Whereas those lasting > 12 weeks showed marked improvement in functional ability

We found that strengthening exercises for 2- 6 months resulted in improved muscle strength with a grade 4/5 and better functional performance.

Mrinal et al[26] did research on 40 patients of two groups, one with conventional exercise and other group along with conventional had the addition of core exercises which resulted in better proprioception, function and AOL compared with only conventional ex.

Our study's findings revealed that, systematic exercises with core and balance exercises for 6 months, post-TKR increased the confidence level and functional ability. The enhanced function following the interventions had proven that the systematic exercises play an important role in physical function following TKR and it's a prime contributor to the functional activities and ADLs.

CONCLUSION

Systematic exercises following TKR resulted in enhanced function, and it was observed that the patients' balance and stability improved in 2 months and six months post-intervention. The timed up and go test, an act of physical function, demonstrated clinically significant changes at 2 months. The CR group study participants outperformed the PS group in terms of total surface area and Tug score at six months post-operatively, and hence we can deduce that CR will be superior to PS.

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Declaration of potential for bias
The authors declare no bias.

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Institutional Approval
All measures were done with the ethical standards.

Participant Consent
Subjects had to sign the approval form for the study.

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