Effectiveness of Intensive Rehabilitation on Functional Ability and Quality of Life After First Total Knee Arthroplasty: A Single-Blind Randomized Controlled Trial

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ABSTRACT. Moffet H, Collet J-P, Shapiro SH, Paradis G, Marquis F, Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: a single-blind randomized controlled trial. Arch Phys Med Rehabil 2004;85:546-56.

Objective: To evaluate the effectiveness of a new intensive functional rehabilitation (IFR) program on functional ability and quality of life (QOL) in persons who underwent a first total knee arthroplasty (TKA).

Design: Randomized controlled trial.

Setting: Ambulatory care.

Participants: Seventy-seven people with knee osteoarthritis.

Intervention: Two months after TKA, subjects were randomly assigned to either a group with IFR (n=38), who received 12 supervised rehabilitation sessions combined with exercises at home between months 2 and 4 after TKA, or to a control group (n=39), who received standard care. All participants were evaluated by a blind evaluator at baseline (2mo after TKA), immediately after IFR (2mo later; POST1), and 2 and 8 months later (POST2 and POST3).

Main Outcome Measures: The primary outcome measure with respect to effectiveness was the 6-minute walk test (6MWT) at POST2. Secondary outcome measures were the 6MWT at the other evaluations and the Western Ontario and McMaster Universities Osteoarthritis Index and Medical Outcomes Study 36-Item Short-Form Health Survey.

Results: Subjects in the IFR group walked longer distances (range, 23–26m) in 6 minutes at the 3 POST evaluations than subjects in the control group. At POST1 and POST2, they also had less pain, stiffness, and difficulty in performing daily activities. Positive changes in QOL in favor of the IFR were found only at POST2.

Conclusions: The IFR was effective in improving the short-term and mid-term functional ability after uncomplicated primary TKA. The magnitude of the IFR effect on the primary outcome was modest but consistent. More intensive rehabilitation should be promoted in the subacute recovery period after TKA, to optimize functional outcomes in the first year after surgery.

Key Words: Arthroplasty, replacement, knee; Quality of life; Randomized controlled trials; Recovery of function; Rehabilitation.

REDUCTION IN PAIN and improvement in physical function and quality of life (QOL) are the main expected outcomes after total knee arthroplasty[1-6] (TKA). Scientific and clinical evidence supports the success of TKA for the relief of knee pain and symptoms of osteoarthritis (OA), as well as a high rate of patient satisfaction.[7-9] However, the functional benefits of this surgical procedure are not as convincing, because quantitative evaluations of knee function have shown that large functional deficits persist 1 year after surgery and even longer.[10-14]

Residual strength deficits as large as 35% were found in the knee extensor muscles 1 and 2 years after TKA for severe OA.[10,11] Although a large improvement occurred in most of the kinematic and kinetic variables of gait from the second month to the end of the first year after TKA,[12] important clinical deficits persisted more than 1 year after TKA.[10,12,13,15-17] Reductions in gait speed ranging from 15% to 30% have been reported 6 months and 1 year after TKA.[10-12] These speed deficits were similar in magnitude to the ones reported preoperatively[12] and 5.5 to 9 years (19%–33%) after TKA.[15,18] During stair ascent, a locomotor task with a high degree of difficulty, the speed deficit was even greater (women, 43%; men, 51%) 1 year after TKA.[11] As with gait, the speed deficit was accompanied by abnormalities in leg movements, moments of force, and muscle activations during stair ascent and descent progression more than 2 years after TKA.[11,17,19,20] In a study[14] 18 months after TKA, only 47% of the subjects perceived that they were better able to climb stairs than they were before surgery. Finally, despite the significant improvement seen in patients' health-related quality of life (HRQOL), especially in physical function, role–physical, and bodily pain, in the first year after TKA, HRQOL remained significantly lower than age-related population norms, especially for persons younger than 75 years.[3,5-7,21-23]

In light of these findings, it is relevant to question the intensity and the duration of rehabilitation follow-up after TKA, which is often restricted to a few supervised sessions during the short in-hospital stay (7–10d), followed either by an unsupervised exercise program performed at home or by only a few physiotherapy (PT) visits at home in the first 2 months after TKA.[1,7,24] Until now, the impact of a more intensive functional rehabilitation (IFR) program—offered in the subacute stage and including both knee-specific and global lower-

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limb exercises, to improve locomotor performance and function in daily life activities—has not been evaluated in a randomized controlled study. However, the results of studies performed in arthritic populations strongly support the effectiveness of an adapted and intensive rehabilitation program, to promote better functional ability without inducing adverse joint effects.[25-29] In addition to improvements in functional ability, it is believed that such an intervention may positively influence long-term outcomes, such as health services utilization and knee prosthesis longevity.

We conducted a single-blind randomized trial to evaluate the effectiveness of an IFR program, given between the second and fourth months after surgery, on the functional ability and QOL of persons who underwent a first TKA. Physical function has been identified as among the most important dimensions to be measured when evaluating intervention effectiveness in persons with OA.[30] Because locomotor ability can mirror the evolution of physical function, the primary outcome measure was the distance walked in 6 minutes, 2 months after the end of the IFR program (POST2 evaluation).

METHODS

Participants

Subjects were recruited from the surgical waiting lists of 23 orthopedic surgeons working in the 5 main hospitals of the Quebec City metropolitan area. All subjects were required (1) to have a diagnosis of primary OA of the knee, (2) to be waiting for a first TKA, (3) to live in the Quebec City metropolitan area, and (4) to be ambulatory with or without a walking aid. They were excluded if they (1) were planning a second surgery of the lower limbs during the first year after TKA, (2) had associated conditions impeding their performance of locomotor tests, (3) had had surgery of the lower limbs affecting their gait pattern, (4) had neuromuscular or neurodegenerative diseases, (5) had a knee infection after TKA or other major complications (eg, loosening or embolia excluding thrombophlebitis), or (6) if they had problems after the instructions of the study protocol.

The study protocol was approved by the research ethics committees of the different hospitals and research center involved. All subjects participated voluntarily in the study and gave written informed consent.

Study Design

All participants were randomly assigned to 2 groups 2 months after TKA: the IFR group received a supervised rehabilitation program between months 2 and 4 after TKA, and the control (CTL) group followed the standard care. The functional ability and QOL of all participants were evaluated by a blind evaluator at baseline (2mo after TKA), immediately after the IFR (4mo after TKA: POST1), and 2 and 8 months later (6mo and 12mo after TKA: POST2 and POST3).

Interventions

All participants were taught a standardized home-exercise program by experienced physiotherapists after their knee surgery and before they left the hospital. This program comprised simple exercises to retrain lower-limb strength (quadriceps, hamstrings, hip abductors and extensors) and to increase knee mobility, as well as some advice about knee positioning, ice application, and gait retraining.

IFR Program

The IFR program was developed in accordance with motor learning and training specificity principles,[31-36] as well as with the results of other studies.[26,27,37-40] It started 2 months after TKA, because in the subacute recovery period, knee pain, effusion, and movement limitations are considerably improved and no longer restrict the practice of more intense functional exercises with partial and complete knee loading. The IFR program combined 12 supervised rehabilitation sessions with individualized home exercises performed on the days without supervised treatments. The same 2 physiotherapists gave the treatments and regularly adapted the IFR program to individuals' needs and tolerance, to ensure optimal intensity of the intervention all along the treatment period.

All subjects attended the 12 supervised rehabilitation sessions (duration, 60–90min) over a period of 6 to 8 weeks at the Quebec Rehabilitation Institute. We refer to the supervised rehabilitation sessions as S1 through S12. During these sessions, subjects were supervised and knee joint responses (range of motion, pain, effusion) were monitored to adjust and optimize the intervention. Each session included 5 components: warm-up, specific strengthening exercises, functional task-oriented exercises, endurance exercises, and cool-down (table 1). The specific strengthening exercises, performed in a supine or seated position, consisted of maximal isometric pain-free contractions (knee extensors and flexors), at different angles of knee flexion, and dynamic (concentric-eccentric) contractions against gravity (hip abductors). The isometric exercises were performed at multiple angles, because strength gains are known to be specific to the trained positions.[32,34] In the first session, these types of exercises were chosen over concentric exercises, because pain-free knee muscle contractions can easily be performed. Angles where deficits were known to be present were specifically targeted. The functional exercises had different degrees of difficulty and complexity according to (1) the amount of weight bearing (partial to total support on the operated leg), (2) support (with or without upper limb support), (3) side (bilateral or unilateral exercise), (4) resistance (with or without external load), and (5) complexity (isolated or combined motion). Endurance exercises were either walking, biking, or both, for a progressive duration of 5 to 20 minutes.

In the first 2 weeks (S1–S4), more attention was given to the warm-up, specific strengthening, and cool-down exercises, because they were less demanding on the knee joint. Simple functional exercises and endurance exercises of short duration (5min) were also started. During the second phase of rehabilitation (S5–S12), more time was spent practicing functional task-oriented exercises with increasing degrees of intensity and difficulty. The duration of the endurance exercises was gradually increased from 5 to 20 minutes. To control the intensity of these exercises, the patients' heart rates were monitored continuously with a Sport Tester PE 300 cardiotachymeter.[a] The first time the exercises were performed (S3), the participants tried to reach 60% of their predicted heart rate at maximal exercise. This was increased to a maximum of 80% of the predicted heart rate.[27,40] At the end of the program, instructions about the continuation of home exercises and return to sports were given. More details on the content of the IFR program are given in table 1.

Standard Care

Subjects in the CTL group did not follow the IFR program but received the usual care. For some, this included a series of supervised rehabilitation visits at home. No attempt to interfere with the usual care was made. Information about the frequency, duration, and content of the supervised rehabilitation interventions received by the subjects in the CTL group at home was obtained by questionnaire and by telephone interviews with the subjects and their physical therapists.

Table 1: Description of the Supervised Rehabilitation Sessions (S1–S12) and the Compliance of Subjects (IFR group) to Planned Treatment Modalities (%)

Modalities	Duration Intensity* (mean ± SD)	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
Warm-up and stretching exs (5–10min)													
1. Global flexion-extension of the lower limb	10.4±0.3 rep	‡	‡	‡	‡	‡	‡	‡	‖	‖	‡	‖	‖
2. Alternated dorsal plantarflexion of the ankles	8.8±1.0 rep	‡	‡	‡	‡	‖	‡	‡	‡	‡	‖	‖	‖
3. Stretching of the hamstrings	7.7±0.4 rep	37	42	37	34	34	37	42	34	37	37	26	29
4. Mobility exs of the neck, upper limbs, and back	NA	0	0	0	0	0	0	0	0	0	0	0	0
Specific strengthening exs (15min)													
1. ISOM knee extensors: flex 0°	10.5±0.7 rep	‡	‡										
2. ISOM knee extensors: flex 60°	10.2±0.3 rep	‡	‖										
3. ISOM hamstrings: flex 60°	10.4±0.5 rep			‡	‖	‖	71						
4. CONC-ECC hip abductors	16.9±0.6 rep	‡	‡	‡	‡								
Functional task-oriented exs (15–20min)													
1. Get up and sit down	16.5±0.8 rep	‡	‡	‡	‡	‡	‡						
2. Knee extensor strengthening in standing with Theraband	18.0±2.2 rep	‡	‡	47	32	18	13						
3. Controlled bilateral knee flexion-extension in standing	16.1±0.8 rep	‡	‡	74	74	‖	‡	‡	‡				
4. Unilateral knee flexion to 90° in standing	17.9±0.7 rep							‡	‡	‡	‡		
5. Climbing on a platform or a flight of stairs	24.1±4.0 steps			‡	‡	‡	‡	‡	‡	‡	‡	‡	‡
6. Walking backward, on a slope and/or laterally while crossing lower limbs	23.9±2.0m to 31.4±3.0m			‡	‡	‡	‡	‡	‡	‡	‡	‡	‡
7. Walking in place, with large amplitude of hip and knee flexion and upper-limb movements	19.8±4.8 steps									‡	‡	‡	‡
Endurance exs† (5–20min)													
1. Walking	10.7±4.2min range, 6–17min			42	63	‡	‡	‡	‡	‡	‡	‡	‡
2. Stationary cycling	5.2±1.0min range, 4–7min			0	3	8	8	11	16	13	13	16	18
Cool down (10min)													
1. Slow walking	1.7±0.6min	5	13	3	5	8	8	11	26	21	26	26	26
2. Stretching exs¶	6.8±1.0 rep/exs	63	‖	‖	66	‖	58	66	63	55	58	55	60
3. Ice	11.8±0.4min	18	21	18	21	18	11	8	8	8	5	8	5

NOTE. Empty cells indicate that the modality was neither planned nor given at the corresponding session.
Abbreviations: CONC-ECC, concentric-eccentric; exs, exercises; ISOM, isometric; NA, not applicable; rep, repetitions; SD, standard deviation.
*The mean duration intensity at which a modality was received during the planned treatments. Only the data from the subjects who performed the exercise or received the modality were used to calculate a mean per session and then a mean ± SD over the sessions. For example, a mean of 10.5±1.4 repetitions of ISOM knee extensors strengthening (flexion, 0°) was performed during the first 2 sessions (S1, S2) by more than 90% of the subjects in the IFR group.
†One or both of the endurance exercises had to be performed for a duration increasing from 5 to 20 minutes.
‡At least 90% of the participants in the IFR group received the modality with the expected duration and/or intensity.
‖Between 75% and 89% of the participants in the IFR group received the modality with the expected duration and/or intensity.
¶Global flexion-extension of the lower limb, alternated dorsal plantarflexion of the ankles, and/or stretching of the hamstrings.

Outcome Measures

The primary outcome measure with respect to the effectiveness of the IFR program was the distance walked in 6 minutes 2 months after the completion of the program (POST2 evaluation). Secondary outcome measures were the distance walked in 6 minutes at POST1 and POST3 and, for all POST evaluation times, the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index total score and subscale scores (pain, stiffness, difficulty) and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) scales and summary indices (8 health dimension scales, arthritis-specific, and generic physical and mental summary measures) were used.

Participants' demographic and clinical characteristics were obtained at baseline. Cointerventions, health complications, and level of physical activity[41] were documented at each follow-up.

Functional Ability Outcomes

Six-minute walk test. The 6-minute walk test (6MWT) measures the maximal distance covered by a subject walking at free speed during 6 minutes. It is perceived as an adequate measure of physical function and locomotor ability by subjects with disability and was recommended for this purpose in research projects with older adults and populations with cardiac problems.[42,43] It has also been used to measure the effectiveness of interventions in populations with knee OA.[26,28,44] It was chosen as the primary outcome measure because of its sound measurement properties and especially because of its excellent

responsiveness, which is known to increase over time (after 3mo after surgery) in persons with TKA.[45,46] In contrast, the responsiveness of the WOMAC has been found to be better than the 6MWT in the early stages of recovery (first 3mo).[46]

In our study, the 6MWT was performed once in a 50-m–long corridor. Subjects walked back and forth over this distance as many times as possible for a period of 6 minutes. A walking aid was used, and rest periods were allowed when needed. The construct and concurrent validity of this test have been extensively shown in populations with cardiopulmonary problems.[42,47-49] In populations with OA, good concurrent validity was also shown with respiratory measures,[44,50] knee extensor strength,[50] and stride characteristics.[28] Additionally, it has a good test-retest reliability, even without any familiarization trials,[43,47,50] and was found to be the most responsive locomotor test among those administered to persons after TKA.[45,46] Improvements ranging from 30 to 60m (or 15%–18%) were considered clinically significant in persons with pulmonary diseases.[47,51-53]

WOMAC Osteoarthritis Index. The WOMAC is a disease-specific questionnaire developed specifically for people with OA of the hip and knee. Using visual analog scales, its 24 items probe 3 dimensions—pain (5 items), stiffness (2 items), and functional difficulty (17 items)—judged important by such individuals. The total score (n=23 items) and the dimension scores (range, 0–100, with 100 indicating the worst possible state) correspond to the sum of the related items divided by the total number of items considered. The WOMAC questionnaire is well recognized for its good validity, reliability, and responsiveness.[45,46,54-57] The French-Canadian version of WOMAC was used.[58]

QOL Outcome

The SF-36 questionnaire is an HRQOL outcome measure with good metrologic properties.[55-57,59-62] It is increasingly used in populations with OA.[21,55,59,60,63,64] It contains 36 items that assess 8 different health dimensions: physical functioning, social functioning, role–physical, bodily pain, mental health, role–emotional, vitality, and general health. Health dimension scales were computed as described by the researchers[65] and were combined to obtain the summary indices: the Physical Component Summary (PCS), Mental Component Summary (MCS), and Arthritis-Specific Health Index (ASHI).[64,66] This last index was recently validated. It is calculated using a set of weights, which maximizes the specificity of the test for populations with arthritis.[64,66] Scores resulting from these summary indices vary from 0 to 100, with higher scores indicating the most favorable state of health. The French-Canadian translation of the SF-36 was used in our study.[67]

Sample Size

The sample size needed to detect a significant difference (2-sided, $P=.05$) of at least 15% between groups in the distance walked in 6 minutes (primary outcome; change from baseline) with an assumed standard deviation (SD) of 20% and a 0.8 power was 29 subjects per group. To compensate for a 15% to 20% loss of subjects between baseline and follow-up, 36 subjects per group (72 in total) were required.

The magnitude of the clinically important difference between groups was estimated from the study by Kovar et al[26] in which an improvement of 18% (95% confidence interval [CI], 10%–27%) in 6-minute walk distance was found in subjects with knee OA after a 12-week supervised fitness walking program. In the same study, an SD of less than 10% was obtained. Considering that our population was different (post-TKA subjects for severe OA), we decided to adopt a more conservative attitude, by assuming a larger variability (SD=20%) of the responses to the interventions (standard care, IFR). Thus, with an SD of 10% and the same number of subjects (29/group), it would be possible to detect as statistically significant a difference of 8%, if such a difference exists with a power of 80%.

Randomization

A stratification by hospital with blocking within strata (block size: 4 or 2 randomly distributed) was used to ensure a good balance between both groups in terms of characteristics and size. A computer-generated randomization list[b] was prepared by the statistician and given to the study's clinical coordinator in a series of sealed envelopes. After patient eligibility was confirmed and the baseline evaluation was performed, the study coordinator proceeded to randomization by opening the appropriate numbered envelope. Subjects were informed of the result by phone the day after their baseline evaluation (POST1). Precise directives were given to the subjects by the study's clinical coordinator, according to their assigned group. The randomization code was given to the investigators when the study was completed.

Blinding

Blinding of subjects and treatment providers was not possible in our study. However, to minimize bias, an objective criterion was chosen as the primary outcome measure, standardized outcome assessment procedures were defined, and training was given to the evaluators. All evaluators and investigators were blinded to group assignment for the duration of the study. The statistician performed the analyses and presented unblinded data to the investigators after the completion of the study. All decisions related to data analyses were taken while the investigators were still unaware of group assignment.

Statistical Methods

Descriptive statistics of both group statuses at baseline were calculated. Considering the selective loss to follow-up that occurred in the CTL group (fig 1), a per-protocol analysis was performed. This analysis was restricted to subjects who fulfilled the protocol in terms of eligibility and outcome assessment. Results of this per-protocol analysis are reported in this article. An intention-to-treat analysis, based on all participants as originally assigned, was also performed. Because of the imputation of data from the last available assessment to all subsequent evaluations in only the CTL group subjects, the analysis favored the IFR group (especially at POST3). Therefore, we chose to present the per-protocol analysis, which showed the most conservative treatment effect.

Change scores were calculated by subtracting the baseline scores from the follow-up scores. The change scores were compared between groups (IFR, CTL) at each time period, using an analysis of covariance (ANCOVA) with the baseline level of each outcome measure used as a covariate to improve the precision of the effect estimates. Group differences in the magnitude of adjusted change from baseline (treatment effects) and their 95% CIs were computed for all outcome measures.

RESULTS

Seventy-seven subjects were recruited between January 1997 and April 1999. Thirty-eight subjects were randomly assigned to the IFR group and 39 subjects to the CTL group. Both groups were comparable at baseline, according to their clinical and demographic characteristics (table 2). They also had comparable levels of functional ability and QOL at baseline (table 2).

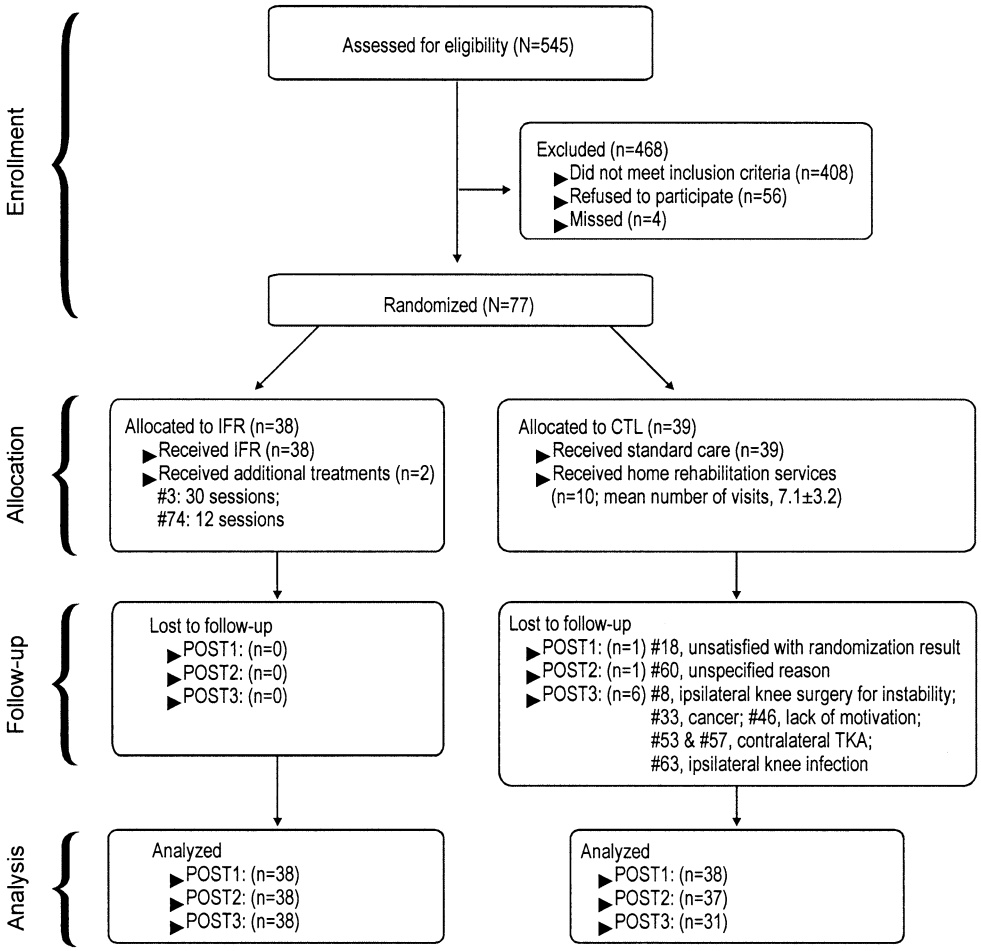

Fig 1. Participant flow through each stage of the trial.

Compliance with the IFR program was very high. The mean duration of the IFR program was 6±1 weeks (range, 3.9–8.9wk). All subjects in the IFR group participated in the 12 planned supervised sessions, with very good compliance with most of the planned modalities (table 1). Only 2 subjects benefited from additional supervised sessions after the end of the IFR program (fig 1). These additional rehabilitation sessions were given by other physical therapists unaware of the content of the IFR program. A quarter (26%) of the subjects in the CTL group received home PT services, with a mean of 7±3 visits (range, 2–12 visits) between months 2 and 4 after TKA. Ninety percent of the participants completed all stages of the study. The flow of participants through each stage of the study is illustrated in detail in figure 1.

Outcomes

Subjects in the IFR group walked a significantly longer distance (25m, 9%) in 6 minutes at POST2 (primary outcome), POST1 (23m, 8%), and POST3 (26m, 9%; $P=.06$) than did subjects in the CTL group (table 3, fig 2). At POST1 and POST2, they also had less pain (11%, 10%), stiffness (9%, 16%), and difficulty in performing daily activities (7%, 8%). At POST3, no difference between groups was found in the WOMAC total and subscales (table 3, fig 3).

No difference was found between groups in the 8 SF-36 scales, except for role–physical at POST2, where the subjects in the IFR group tended to have a better score (mean difference, 18.8; 95% CI, −0.1 to 37.8; ANCOVA, $P=.052$). According to the QOL summary indices, a significant difference in favor of the IFR was found in the PCS at POST2 (table 4). The magnitude of the difference was, however, small (4.9%). The same conclusion applies for the MCS at POST2 (table 4).

Adverse Events and Loss to Follow-Up

No adverse event was reported in any group. A selective loss to follow-up occurred in the CTL group (8 subjects; fig 1). Most of these losses took place at the last follow-up (POST3; n=6) and were attributable to either the need for a contralateral knee surgery (n=2), a lack of motivation (n=1), or an unrelated health condition (cancer, n=1). Two subjects, however, had a problem with their operated knee, namely, an infection or an instability requiring a second surgery.

Cointerventions

The proportion of subjects taking medication did not differ significantly between groups at each follow-up. Only a few subjects received PT treatments more than 4 months after TKA, and they were evenly distributed in both groups: 2 subjects per group had PT treatments between POST1 and POST2, whereas only 1 patient per group had such treatments between POST2 and POST3. None of the participants consulted a professional in occupational therapy, chiropractic, or acupuncture at any point in time. In the period between 2 consecutive follow-ups, the same proportion of subjects per

Table 2: Baseline Characteristics of Both Groups of Subjects

Characteristic	Group CTL (n=39)	Group IFR (n=38)
Age (y)	68.7±8.3	66.7±8.7
Disease duration (y)	13.0±8.7	12.5±8.9
Gender: women	22 (56)	24 (63)
Right knee replacement	22 (56)	19 (50)
Previous orthopedic surgery	15 (39)	13 (34)
Taking drug to relieve knee pain	34 (87)	36 (95)
Impairment in other lower-limb joints	27 (69)	24 (63)
Comorbidity		
Cardiac disease	7 (18)	10 (26)
Chronic pulmonary disease	4 (10)	1 (3)
Hypertension	13 (33)	13 (34)
Diabetes	4 (10)	3 (8)
Kidney disease	1 (3)	0 (0)
Neurologic disease	1 (3)	1 (3)
Cancer	3 (8)	1 (3)
Practicing physical activity* of		
High intensity	0 (0)	1 (3)
Moderate intensity	5 (13)	5 (14)
Low intensity	13 (33)	16 (43)
6-minute walk distance (m)	288.6±81.0	299.2±89.4
WOMAC (%)		
Total score	26.2±18.8	29.7±19.0
Pain score	22.6±17.8	28.4±21.3
Stiffness score	36.3±25.3	39.1±27.5
Difficulty score	26.0±19.7	28.9±19.4
SF-36 summary measures		
PCS	35.3±8.4	32.8±7.6
MCS	55.6±10.6	52.5±11.6
ASHI	34.7±9.6	31.2±9.1

NOTE. Values are mean ± SD or n (%).
*Physical Activity Index.[41]

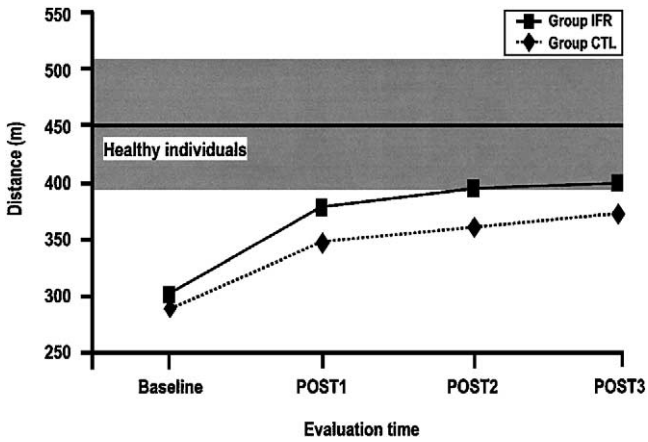

Fig 2. Distance walked in 6 minutes by subjects in both groups, at baseline and at follow-up evaluations. Shaded area represents the mean performance (±1 SD) of a group of 21 healthy, age-matched individuals (mean age, 67±8y).

group visited their orthopedic surgeon and general practitioner. Subjects in both groups reported similar levels of physical activity in the interval between 2 consecutive follow-ups, except for the time interval between baseline evaluation and POST2. During this period, a higher proportion of subjects ($P=.03$) in the CTL group (47%) were enrolled in low-intensity physical activities than were subjects in the IFR group (24%). However, participation in physical activities included in the IFR (home exercises and supervised sessions, including biking and walking activities) was not captured by the questionnaire, which may explain this result.

Table 3: Functional Ability Outcomes

Outcome Measure	Mean Value		Change From Baseline		Treatment Effect (95% CI)	*P* Value (ANCOVA)
	Group CTL	Group IFR	Group CTL	Group IFR		
6-minute walk distance						
POST1	346.7±95.3	377.7±74.5	57.6±39.5	78.5±56.3	22.5 (1.1–44.0)	.040
POST2	360.3±77.4	392.1±92.2	69.1±45.7	93.0±56.6	25.4 (2.7–48.1)	.029
POST3	369.7±80.1	399.7±94.2	75.2±50.7	100.6±66.5	26.4 (−1.3 to 54.0)	.061
WOMAC						
Total score						
POST1	19.4±17.6	13.5±14.1	−6.9±9.3	−16.2±17.0	7.9 (2.7–13.1)	.004
POST2	18.6±18.5	12.0±12.8	−7.3±13.6	−17.7±18.5	8.4 (2.4–14.5)	.007
POST3	15.3±16.3	11.6±13.8	−12.6±14.7	−18.0±20.5	4.3 (−2.1 to 10.7)	.190
Pain score						
POST1	17.2±17.1	9.6±11.5	−4.9±10.9	−18.8±18.6	10.6 (5.4–15.9)	.000
POST2	16.0±18.1	8.9±9.6	−5.6±13.6	−19.5±20.1	9.7 (3.9–15.5)	.001
POST3	11.8±13.0	9.4±12.4	−11.2±12.7	−19.0±21.7	3.9 (−1.6 to 9.5)	.161
Stiffness score						
POST1	28.8±25.7	22.1±25.3	−7.1±16.8	−17.0±28.7	8.5 (−0.9 to 18.0)	.077
POST2	25.2±24.9	16.2±19.6	−10.2±21.2	−23.0±31.0	16.3 (0.9–19.7)	.032
POST3	19.3±20.9	13.7±16.8	−17.2±22.8	−25.4±30.3	6.2 (−2.4 to 14.8)	.157
Difficulty score						
POST1	18.9±17.7	13.6±15.0	−7.5±11.0	−15.3±17.4	6.8 (1.2–12.3)	.017
POST2	18.6±18.7	12.4±14.4	−7.5±14.7	−16.6±18.4	7.7 (1.4–13.9)	.017
POST3	15.8±17.6	12.0±14.8	−12.5±16.6	−16.9±20.7	4.0 (−2.9 to 11.0)	.254

NOTE. The treatment effect is the between-group difference in the adjusted mean change values. Positive values indicate positive treatment effect in favor of the IFR group. Conversely, negative values indicate larger improvements in the CTL group than in the IFR group.

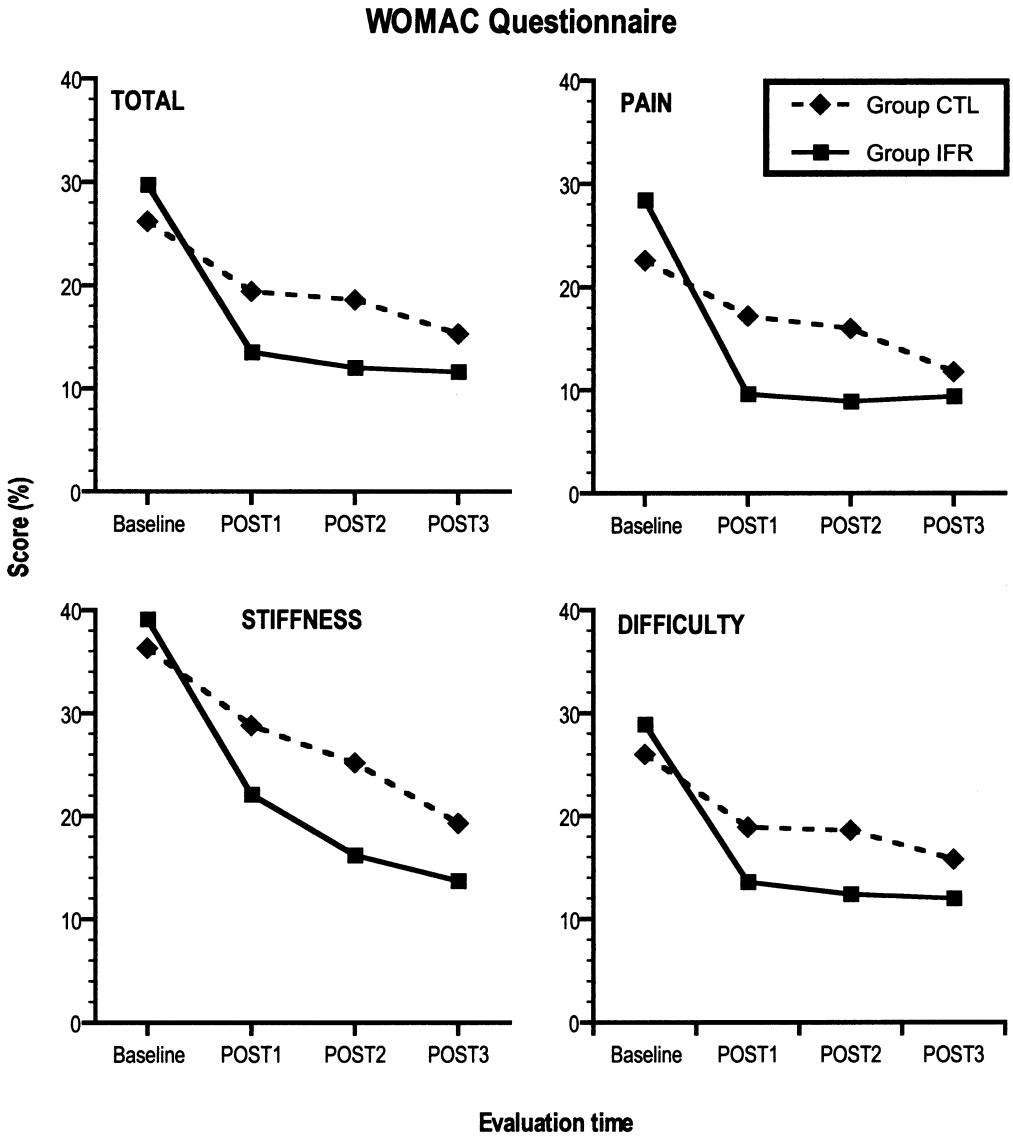

Fig 3. WOMAC questionnaire total and subscale (pain, stiffness, difficulty) scores for both groups of subjects, at baseline and at follow-up evaluations. A decrease in scores represents an improvement in knee pain, stiffness, and/or functional ability.

DISCUSSION

The results of our study confirm the effectiveness of an IFR program in promoting better functional ability at short-term and midterm after a first TKA for severe OA. Subjects in the IFR group walked significantly longer distances in 6 minutes than did subjects in the CTL group immediately and 2 months after the IFR program, and they tended to maintain their additional gains after 8 months. Moreover, they had less pain, stiffness, and difficulty in performing daily activities at the first 2 follow-up evaluations. At POST3, however, both groups had a low level (≃15%) of knee pain, stiffness, and difficulty in performing daily activities, and no further differences were found between groups. Finally, no significant differences were found between groups in QOL except at POST2 for the role–physical dimension and the PCS (intergroup difference=19% in role–physical; 5% in PCS in favor of the IFR group).

The magnitude of the IFR effect on the primary outcome was modest but consistent in terms of the gains in distance walked in meters. The additional distance covered in 6 minutes by the subjects in the IFR group varied from 23 to 26m at the 3 follow-up evaluations. This was sufficient to reach the lower limit of normal age-related performances at POST2 (fig 2). Compared with the baseline performance (mean, 299m), however, this represents, at best, a treatment effect of 9%. This is below the mean treatment effect (18%) reported by Kovar et al[26] for subjects with knee OA, but close to the lower limit of the reported CI for treatment effect (95% CI, 10%–27%). The longer duration of their supervised fitness walking program (12wk vs 6wk in our study) and their use of a nonsurgical population may explain the discrepancy in results. In our study, a longer duration and/or a higher intensity of IFR may have induced a larger effect on the outcomes. The effect of the IFR also approaches the lower limit of the clinically significant change (30–60m) proposed for populations with pulmonary diseases.[47,51-53] Unfortunately, no such information is available for our population. The fact that the effectiveness of the IFR has been established in comparison with the standard care, which included for a significant proportion (26%) of the subjects a series of supervised PT visits at home (mean, 7±3 visits; range, 2–12 visits) between months 2 and 4 after TKA,

Table 4: QOL Scales and Summary Results

SF-36 Scales and Summary Measures	Mean Value		Change From Baseline		Treatment Effect (95% CI)	*P* Value (ANCOVA)
	Group CTL	Group IFR	Group CTL	Group IFR		
Physical function						
POST1	56.8±23.7	58.9±23.8	9.3±18.2	14.9±19.7	4.6 (−3.7 to 12.8)	.277
POST2	58.3±18.9	62.4±23.8	10.0±21.7	18.3±20.3	6.3 (−2.2 to 14.8)	.146
POST3	60.3±20.4	63.8±24.3	13.1±20.1	19.7±22.2	5.3 (−4.0 to 14.6)	.262
Role–physical						
POST1	50.7±42.1	44.7±39.9	22.4±41.8	25.7±43.7	−1.9 (−19.5 to 15.8)	.834
POST2	52.7±44.4	69.1±38.3	23.6±54.0	50.0±42.7	18.8 (−0.1 to 37.8)	.052
POST3	72.6±36.1	70.4±37.6	41.9±45.8	51.3±40.7	1.3 (−16.2 to 18.8)	.881
Bodily pain						
POST1	57.5±19.4	58.8±22.9	5.6±23.9	14.3±21.8	4.4 (−4.5 to 13.3)	.328
POST2	63.2±22.2	63.6±22.7	10.7±22.5	19.2±25.0	4.0 (−5.6 to 13.6)	.413
POST3	63.6±19.0	63.7±21.4	8.7±23.9	19.2±24.7	3.4 (−6.3 to 13.0)	.489
Social function						
POST1	79.3±17.0	78.9±22.9	10.2±20.9	16.4±25.0	2.4 (−5.5 to 6.4)	.549
POST2	78.7±16.6	82.6±20.9	9.5±26.7	20.1±25.8	5.6 (−2.5 to 13.8)	.172
POST3	84.3±16.1	84.9±22.0	13.3±24.4	22.4±26.5	3.2 (−5.5 to 12.0)	.463
Mental health						
POST1	80.9±14.4	78.4±16.4	3.8±16.5	7.4±14.2	0.6 (−5.2 to 6.4)	.837
POST2	83.4±12.1	76.3±15.5	6.3±16.7	5.3±15.6	−4.6 (−10.1 to 0.9)	.100
POST3	82.7±14.0	76.4±17.7	5.8±17.6	5.4±20.0	−4.2 (−11.5 to 3.1)	.253
Role–emotional						
POST1	93.9±20.3	81.6±34.4	15.8±36.1	9.6±37.9	−10.4 (−22.2 to 1.4)	.083
POST2	94.6±20.1	86.0±30.6	17.1±44.2	14.0±40.7	−7.9 (−19.7 to 3.9)	.188
POST3	93.5±21.8	85.1±33.5	14.0±29.5	13.2±42.1	−6.0 (−8.9 to 6.8)	.350
Vitality						
POST1	71.1±14.7	67.4±20.0	7.5±14.0	9.1±13.9	−0.1 (−6.0 to 5.9)	.974
POST2	71.6±12.6	67.9±18.0	7.4±16.9	9.6±13.8	−0.7 (−6.7 to 5.3)	.812
POST3	73.2±14.2	70.1±20.1	9.5±15.1	11.8±17.8	0.0 (−7.4 to 7.3)	.993
General health						
POST1	74.8±14.9	71.9±23.2	−2.8±9.7	0.7±17.7	2.1 (−4.4 to 8.6)	.518
POST2	75.9±13.3	73.0±21.0	−2.1±13.1	1.8±15.2	1.7 (−4.5 to 7.8)	.593
POST3	73.6±15.5	75.4±20.4	−3.2±12.8	4.2±14.4	6.0 (−0.5 to 12.4)	.068
PCS						
POST1	38.3±9.7	38.8±9.9	3.1±7.8	6.0±9.0	2.2 (−1.6 to 5.9)	.249
POST2	39.3±9.1	42.8±9.3	3.8±9.2	10.0±8.6	4.9 (1.1 to 8.8)	.012
POST3	41.7±7.4	43.6±9.4	6.1±8.3	10.8±10.1	2.9 (−1.0 to 6.9)	.144
MCS						
POST1	58.5±7.5	55.7±9.0	3.2±9.0	3.2±8.9	−1.5 (−4.6 to 1.6)	.333
POST2	58.8±5.1	54.8±7.3	3.6±11.4	2.3±9.5	−3.4 (−6.1 to –0.7)	.015
POST3	58.4±7.1	55.0±10.0	2.9±8.3	2.5±11.9	−2.3 (−6.2 to 1.6)	.245
ASHI						
POST1	38.5±9.7	38.9±11.0	4.0±9.6	7.7±10.0	2.7 (−1.7 to 7.0)	.271
POST2	40.6±10.0	42.2±10.6	5.8±9.9	11.0±9.9	3.0 (−1.1 to 7.1)	.095
POST3	42.1±8.8	42.5±10.0	6.7±10.9	11.3±10.7	2.0 (−1.9 to 6.9)	.396

NOTE. The treatment effect is the between-group difference in the adjusted mean change value. A positive value indicates a larger improvement in QOL in the IFR group than in the CTL group.

may have minimized the difference between groups. Thus, the differences in outcomes between groups are probably less than would have occurred if the CTL group had received no rehabilitation intervention. Finally, in interpreting the magnitude of the IFR effect, it is also worthwhile to highlight the large variability in the response to the intervention (lower and upper limits of the treatment effect CI varied from –1.3 to 54m). Some subjects were definitely better responders to the IFR than others. Identification of subjects' characteristics and factors that are related to a better response to this type of intervention may help clinicians organize rehabilitation services more efficiently in the future.

The faster locomotor recovery, combined with the ability to perform daily activities with less pain, stiffness, and difficulty, most likely contributed to favoring a more active lifestyle, at least in the short-term and midterm, in subjects from the IFR group. This could have been a determining factor in avoiding physical immobility, which is a risk factor for developing health complications, isolation, and depression in the elderly.[68] The higher scores in the PCS (5%), ASHI (3%, trend $P=.09$), and especially in the role–physical domain (19%) of the SF-36 two months after the IFR (POST2) also support the positive impact of the intervention, because a 5-point difference between groups or over time is considered clinically relevant.[65]

According to Shields et al,[22] these higher scores mean that the subjects who received the IFR program had fewer problems with work or other daily activities because of physical health (role–physical meaning), had less physical limitation, had fewer disabilities and fewer decrements in well-being, and had higher energy levels and better health (PCS meaning) than did subjects in the CTL group.

The IFR program did not induce adverse joint effects, and overall compliance with the program was excellent. This suggests that a good balance was achieved between the dosage (duration, intensity, frequency) of the planned intervention and the objectives of developing a safe, readily accepted, and feasible rehabilitation program. Although only simple modalities were used in this program, its application required human resources to provide the participants with a high degree of supervision. In our experience, most participants need feedback and guidance to properly perform the exercises. Also, the dosage of the intervention has to be adapted to the individual's needs and tolerance. This program could have been implemented on a group basis; however, because the participants were recruited prospectively, individual supervision was offered in our study. In the future, other ways of implementing such a program (exercise class, community program, individual home-based program with periodic supervision) should be explored, as well as a higher dosage, to ensure that a larger number of people benefit from it and to obtain a larger treatment effect.

In addition to better knee function, compensation from adjacent lower-limb joints and the sound lower limb, better cardiorespiratory function, and other nonspecific effects of expectation may explain the better functional ability of the subjects in the IFR group. To better understand the impact of the IFR on functional ability (ie, 6-min walking distance) and, more specifically, on the operated knee function, biomechanical and spatiotemporal parameters of gait and stair ascent and knee extensor strength and mobility measures were also recorded. Detailed results concerning these explanatory outcomes will be provided in another article.

Finally, even though the IFR program promoted better functional recovery in the first 12 months after TKA, the level of functional ability of healthy age-matched individuals was not necessarily reached. For the distance walked in 6 minutes, a total of 30 of 69 subjects (43.5%) had a locomotor performance within the normal range values (mean, 448m; 95% CI, 423–473m) 1 year after TKA. Of these subjects, 20 were in the IFR group (mean, 483±46m) and 10 were in the CTL group (mean, 493±65m). Thus, at the last follow-up, 53% of the subjects in the IFR group had a normal performance as compared with 32% in the CTL group. With respect to QOL, both groups scored within the normative ranges of an age-matched Canadian population, except on 4 domains of the SF-36: physical function, bodily pain, role–physical, and social function. The largest reduction was observed in the physical function and bodily pain domains, which remained more than 10% below normal values.[69]

Our results apply to people who have undergone a first uncomplicated TKA for severe OA. It is not clear whether the same results could be obtained in subjects with other preoperative diagnoses (rheumatoid arthritis, trauma, avascular necrosis), after bilateral knee arthroplasty, after revisions, or in people with previous surgery in other lower-limb joints. The inclusion of subjects who had been operated on by several surgeons from 5 hospitals and the high participation rate in the intervention and follow-up evaluations contribute to the generalizability of the results.

CONCLUSIONS

The IFR was effective in improving the short-term and mid-term functional ability after uncomplicated primary TKA. More intensive rehabilitation should be promoted in the subacute recovery period after TKA, to optimize functional outcomes in the first year after surgery. Future work will highlight the long-term impact (3y after surgery) of the IFR program on functional ability and QOL, as well as its effects on the use of health services.

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References

1. Petty W. Total joint replacement: primary total knee replacement. Philadelphia: WB Saunders; 1991. p 507-31.
2. Rissanen P, Aro S, Slatis P, Sintonen H, Paavolainen P. Health and quality of life before and after hip or knee arthroplasty. J Arthroplasty 1995;10:169-75.
3. Salmon P, Hall GM, Peerbhoy D, Shenkin A, Parker C. Recovery from hip and knee arthroplasty: patients' perspective on pain, function, quality of life and well-being up to 6 months postoperatively. Arch Phys Med Rehabil 2001;82:360-6.
4. Tierney WM, Fitzgerald JF, Heck DA, et al. Tricompartmental knee replacement. A comparison of orthopaedic surgeons' self reported performance rates with surgical indications, contraindications, and expected outcomes. Knee Replacement Patient Outcomes Research Team. Clin Orthop 1994;Aug(305):209-17.
5. van Essen GJ, Chipchase LS, O'Connor D, Krishnan J. Primary total knee replacement: short-term outcomes in Australian population. J Qual Clin Pract 1998;18:135-42.
6. Williams JI, Llewellyn-Thomas H, Arshinoff R, Young N, Naylor D. The burden of waiting for hip and knee replacements in Ontario. J Eval Clin Pract 1997;3:59-68.
7. Jones AC, Voaklander DC, Williams D, Johanston C, Suarez-Almazor ME. Health related quality of life outcomes after total hip and knee arthroplasties in a community-based population. J Rheumatol 2000;27:1745-52.
8. Dickstein R, Heffes Y, Shabtai EI, Markowitz E. Total knee arthroplasty in the elderly: patients' self-appraisal 6 and 12 months postoperatively. Gerontology 1998;44:204-10.
9. Hawker G, Wright J, Coyte P, et al. Health-related quality of life after knee replacement. J Bone Joint Surg Am 1998;80:163-73.
10. Murray MP, Gore DR, Laney WH, Gardner GM, Mollinger A. Kinesiologic measurements of functional performance before and after double compartment Marmor knee arthroplasty. Clin Orthop 1983;Mar(173):191-9.
11. Walsh M, Woodhouse LJ, Thomas SG, Finch E. Physical impairments and functional limitations: a comparison of individuals 1 year after total knee arthroplasty with control subjects. Phys Ther 1998;78:248-58.
12. Moffet H, Ouellet D, Parent E, Brisson M. Time-course of natural locomotor recovery in the first year following knee arthroplasty. In: Arsenault AB, McKinley P, McFadyen B, editors. Proceedings of the Twelfth ISEK Congress; 1998 June 27-30; Montreal (QC). Montreal (QC): Univ of Montreal; 1998. p 230-1.
13. Skinner HB. Pathokinesiology and total joint arthroplasty. Clin Orthop 1993;Mar(288):78-86.
14. Roush SE. Patient-perceived functional outcomes associated with elective hip and knee arthroplasties. Phys Ther 1985;65:1496-500.
15. Skinner HB, French HG, Dhabel TA, Cook SD, Milicic M, Haddad RJ. Correlation of gait analysis and clinical evaluation of polycentric total knee arthroplasty. Orthopedics 1983;6:576-9.
16. Steiner ME, Simon SR, Pisciotta JC. Early changes in gait and maximum knee torque following knee arthroplasty. Clin Orthop 1989;Jan(238):174-82.

17. Andriacchi TP, Hurwitz DE. Gait biomechanics and the evolution of total joint replacement. Gait Posture 1997;5:256-64.
18. Olsson E, Barck A. Correlation between clinical examination and quantitative gait analysis in patients operated upon with the Gunston-Hult knee prosthesis. Scand J Rehabil Med 1986;18:101-6.
19. Andriacchi TP, Galante JO, Fermier RW. The influence of total knee-replacement design on walking and stair-climbing. J Bone Joint Surg Am 1982;64:1328-35.
20. Dorr LD, Ochsner JL, Gronley J, Perry J. Functional comparison of posterior cruciate-retained versus cruciate-sacrificed total knee arthroplasty. Clin Orthop 1988;Nov(236):36-43.
21. March LM, Cross MJ, Lapsley H, et al. Outcomes after hip or knee replacement surgery for osteoarthritis. A prospective cohort study comparing patients' quality of life before and after surgery with age-related population norms. Med J Aust 1999;171:235-8. Comment in: Med J Aust 1999;171:229-30.
22. Shields RK, Enloe LJ, Leo KC. Health related quality of life in patients with total hip and knee replacement. Arch Phys Med Rehabil 1999;80:572-9.
23. Ritter MA, Albohm MJ, Keating EM, Faris PM, Meding JB. Comparative outcomes of total joint arthroplasty. J Arthroplasty 1995;10:737-41.
24. Ouellet D. Capacité fonctionnelle et qualité de vie des patients atteints d'ostéo-arthrite avant et deux mois après une arthroplastie du genou [MSc thesis]. Quebec City (QC): Laval Univ; 1998.
25. Ekblom B, Lovgren O, Alderin M, Friedstrom M, Satterstrom G. Effect of short-term physical training on patients with rheumatoid arthritis I. Scand J Rheumatol 1975;4:80-6.
26. Kovar PA, Allegrante JP, MacKenzie R, Peterson MG, Gutin B, Charlson ME. Supervised fitness walking in patients with osteoarthritis of the knee. Ann Intern Med 1992;116:529-34.
27. Minor MA, Hewett JE, Webel RR, Anderson SK, Kay DR. Efficacy of physical conditioning exercise in patients with rheumatoid arthritis and osteoarthritis. Arthritis Rheum 1989;32:1396-405.
28. Peterson MG, Kovar-Toledano PA, Otis JC, et al. Effect of a walking program on gait characteristics in patients with osteoarthritis. Arthritis Care Res 1993;6:11-6.
29. Ettinger WH Jr, Burns R, Messier SP, et al. A randomized trial comparing aerobic exercise and resistance exercise with a health education program in older adults with knee osteoarthritis. The Fitness Arthritis and Seniors Trial (FAST). JAMA 1997;277:25-31.
30. Bellamy N, Kirwan J, Boers M, et al. Recommendations for a core set of outcome measures for future phase III clinical trials in knee, hip, and hand osteoarthritis. Consensus development at OMERACT III. J Rheumatol 1997;24:799-802.
31. Carr JH, Shepherd RB, Gordon J, Gentile AM, Held JM. Movement science: foundations for physical therapy in rehabilitation. Rockville (MD): Aspen; 1987.
32. Lindh M. Increase of muscle strength from isometric quadriceps exercises at different knee angles. Scand J Rehabil Med 1979;11:33-6.
33. Sale D, MacDougall D. Specificity in strength training: a review for the coach and athlete. Can J Appl Sports Sci 1981;6:87-92.
34. Sale DG. Neural adaptation to resistance training. Med Sci Sports Exerc 1988;20(Suppl):S135-45.
35. Sherman WM, Pearson DR, Plyley MJ, Costill DL, Habansky AJ, Vogelgesang DA. Isokinetic rehabilitation after surgery. A review of factors which are important for developing physiotherapeutic techniques after knee surgery. Am J Sports Med 1982;10:155-61.
36. Stokes M, Young A. Muscle weakness due to reflex inhibition: future research in different areas of rehabilitation. In: Proceedings of the 10th International Congress of the World Confederation for Physical Therapy: 1987 May 17-22; Sydney (Aust). Sydney: Australian Physiotherapy Association; 1987. p 416-20.
37. Bunning RD, Materson RS. A rational program of exercise for patients with osteoarthritis. Semin Arthritis Rheum 1991;21(Suppl 2):33-43.
38. Greenfield BH. Rehabilitation of the knee: a problem-solving approach. Philadelphia: FA Davis; 1993.
39. Perhonen M, Komi PV, Hakkinen K, von Bonsdorff H, Partio E. Strength training and neuromuscular function in elderly people with total knee endoprosthesis. Scand J Med Sci Sports 1992;2:234-43.
40. Semble EL, Loeser RF, Wise CM. Therapeutic exercise for rheumatoid arthritis and osteoarthritis. Semin Arthritis Rheum 1990;20:32-40.
41. Godin G, Shephard RJ. A simple method to assess exercise behavior in the community. Can J Appl Sports Sci 1985;10:141-6.
42. Langenfeld H, Schneider B, Grimm W, et al. The six-minute walk—an adequate exercise test for pacemaker patients? Pacing Clin Electrophysiol 1990;13:1761-5.
43. Harada ND, Chiu V, Stewart AL. Mobility-related function in older adults: assessment with a 6-minute walk test. Arch Phys Med Rehabil 1999;80:837-41.
44. Price L, Hewett JE, Kay DR, Minor MA. Five-minute walking test of aerobic fitness for people with arthritis. Arthritis Care Res 1988;1:33-7.
45. Kreibich DN, Vaz M, Bourne RB, et al. What is the best way of assessing outcome after total knee replacement? Clin Orthop 1996;Oct(331):221-5.
46. Parent E, Moffet H. Comparative responsiveness of locomotor tests and questionnaires used to follow early recovery after total knee arthroplasty. Arch Phys Med Rehabil 2002;83:70-80.
47. Guyatt GH, Thompson PJ, Berman LB, et al. How should we measure function in patients with chronic heart and lung disease? J Chronic Dis 1985;38:517-24.
48. Bittner V, Weiner DH, Yusuf S, et al. Prediction of mortality and morbidity with a 6-minute walk test in patients with left ventricular dysfunction. SOLVD Investigators. JAMA 1993;270:1702-7. Comment in: JAMA 1994;271:661-2.
49. Guyatt GH, Sullivan MJ, Thompson PJ, et al. The 6-minute walk: a new measure of exercise capacity in patients with chronic heart failure. Can Med Assoc J 1985;132:919-23.
50. Rejeski WJ, Ettinger WHJ, Schumaker S, James P, Burns R, Elam JT. Assessing performance-related disability in patients with knee osteoarthritis. Osteoarthritis Cartilage 1995;3:157-67.
51. Guyatt GH, Townsend M, Pugsley SO, et al. Bronchodilators in chronic air-flow limitation. Effects on airway function, exercise capacity, and quality of life. Am Rev Respir Dis 1987;135:1069-74.
52. Redelmeier DA, Bayoumi AM, Goldstein RS, Guyatt GH. Interpreting small differences in functional status: the Six Minute Walk test in chronic lung disease patients. Am J Respir Crit Care Med 1997;155:1278-82.
53. Leach RM, Davidson AC, Chinn S, Twort CH, Cameron IR, Bateman NT. Portable liquid oxygen and exercise ability in severe respiratory disability [published erratum appears in Thorax 1993;48:192]. Thorax 1992;47:781-9.
54. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt L. Validation study of WOMAC: a health status instrument for measuring clinically-important patient-relevant outcomes following total hip or knee arthroplasty in osteoarthritis. J Orthop Rheum 1988;1:95-108.
55. Wright JG, Young NL. A comparison of different indices of responsiveness. J Clin Epidemiol 1997;50:239-46.
56. Davies GM, Watson DJ, Bellamy N. Comparison of the responsiveness and relative effect size of the Western Ontario and McMaster Universities Osteoarthritis Index and the short-form Medical Outcomes Study Survey in a randomized, clinical trial of osteoarthritis patients. Arthritis Care Res 1999;12:172-9.
57. Brazier JE, Harper R, Munro J, Walters SJ, Snaith ML. Generic and condition-specific outcome measures for people with osteoarthritis of the knee. Rheumatology (Oxford) 1999;38:870-7.
58. Choquette D, Bellamy N, Raynauld JP. A French-Canadian version of the WOMAC osteoarthritis index [abstract]. Arthritis Rheum 1994;37(Suppl 9):226.
59. Kosinski M, Keller SD, Hatoum HT, Kong SX, Ware JE Jr. The SF-36 Health Survey as a generic outcome measure in clinical trials of patients with osteoarthritis and rheumatoid arthritis: tests of data quality, scaling assumptions and score reliability. Med Care 1999;37(Suppl 5):MS10-22.
60. Kosinski M, Keller SD, Ware JE Jr, Hatoum HT, Kong SX. The SF-36 Health Survey as a generic outcome measure in clinical trials of patients with osteoarthritis and rheumatoid arthritis: rel-

ative validity of scales in relation to clinical measures of arthritis severity. Med Care 1999;37(Suppl 5):MS23-39.
61. McHorney CA, Ware JE, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Med Care 1993;31:247-63.
62. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-83.
63. Keller SD, Majkut TC, Kosinski M, Ware JE Jr. Monitoring health outcomes among patients with arthritis using the SF-36 Health Survey: overview. Med Care 1999;37(Suppl 5):MS1-9.
64. Keller SD, Ware JE Jr, Hatoum HT, Kong SX. The SF-36 Arthritis-Specific Health Index (ASHI): II. Tests of validity in four clinical trials. Med Care 1999;37(Suppl 5):MS51-60.
65. Ware JE Jr, Snow K, Kosinski M, Gandek B. SF-36 Health Survey manual and interpretation guide. Boston: The Health Institute, New England Medical Center; 1993.
66. Ware JE Jr, Kosinski M, Keller D. SF-36 physical and mental health summary scales: a user's manual. Boston: The Health Institute, New England Medical Center; 1994.
67. Wood-Dauphinee S, Gauthier L, Gandek B, Magnam L, Pierre U. Readying a US measure of health status, the SF-36, for use in Canada. Clin Invest Med 1997;20:224-38.
68. Hébert R. Syndrome d'immobilisation. In: Arcand M, Hébert R, editors. Précis pratique de gériatrie. St-Hyacinthe/Paris: Edisem/Maloine; 1997.
69. Hopman WM, Towheed T, Anastassiades T, et al. Canadian normative data for the SF-36 health survey. Canadian Multicentre Osteoporosis Study Research Group. CMAJ 2000;163:265-71.

Suppliers

a. Polar Electro Inc, 370 Crossways Park Dr, Woodbury, NY 11797.
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