

1 **Title: Toe grip strength training improves gait performance and prevents falls in patients**
2 **after total knee arthroplasty**

3

4 Type of manuscript: Regular Article

5

6 Yuya Mawarikado^{1,2,5}, Yusuke Inagaki^{2*}, Tadashi Fujii³, Takanari Kubo⁴, Takahiko Fukumoto⁵,
7 Akira Kido², Yasuhito Tanaka⁶

8

9 ¹ Medicinal Biology of Thrombosis and Haemostasis, Nara Medical University, Kashihara, Nara,
10 Japan

11 ²Department of Rehabilitation Medicine, Nara Medical University, Kashihara, Nara, Japan

12 ³Department of Orthopaedic Surgery, Kashiba Asahigaoka Hospital, Kaizuka, Osaka, Japan

13 ⁴Department of Rehabilitation, Osaka Kawasaki Rehabilitation University, Kashiba, Nara, Japan

14 ⁵Graduate School of Health Sciences, Kio University, Koryo, Nara, Japan

15 ⁶Department of Orthopaedic Surgery, Nara Medical University, Kashihara, Nara, Japan

16

17 Number of tables and figures

18 Table: 5, Figure: 5

19

20 Running title: Effects of toe grip strength training

21

22 E-mail address

23 Yuya Mawarikado: ymawarikado@naramed-u.ac.jp

24 Yusuke Inagaki: yinagaki@naramed-u.ac.jp
25 Tadashi Fujii: tadashifujii@gmail.com
26 Takanari Kubo: kubot@kawasakigakuen.ac.jp
27 Takahiko Fukumoto: t.fukumoto@kio.ac.jp
28 Akira Kido: akirakid@naramed-u.ac.jp
29 Yasuhito Tanaka: yatanaka@naramed-u.ac.jp

30

31 ***Corresponding author**

32 Yusuke Inagaki

33 Department of Rehabilitation Medicine, Nara Medical University

34 840 Shijo-Cho, Kashihara, Nara 634-8521, Japan

35 Tel: +81-744-23-9961

36 E-mail: yinagaki@naramed-u.ac.jp

37

38 **Preprint**

39 This initial article was preprinted and published on Research Square.

40 DOI: <https://doi.org/10.21203/rs.3.rs-3862787/v1>

41

42

43 **Abstract**

44 Falls after total knee arthroplasty are common in knee osteoarthritis patients due to advanced age
45 and implant-induced sensory function changes. We reported the influence of toe grip strength on
46 falls in knee osteoarthritis patients. This study aimed to determine whether toe grip strength
47 training after total knee arthroplasty is related to the screening assessment and incidence of falls.
48 Elderly patients undergoing unilateral total knee arthroplasty were divided into toe grip strength
49 training group and control group. Six types of training were conducted on bilateral toes. The
50 primary outcomes were changes in toe grip strength and timed up and go test time from
51 preintervention to 12 weeks post-intervention. Secondary outcomes involved several factors,
52 including the occurrence of falls. The analysis included 37 participants in both groups. Toe grip
53 strength training group had a shorter timed up and go test and stronger bilateral toe grip strength
54 than control groups. The changes of timed up and go test time was significantly correlated with
55 the changes of toe grip strength on the affected side. There were significantly fewer falls in toe
56 grip strength training group than in control group between 3 and 12 months after total knee
57 arthroplasty. toe grip strength training was useful in improving walking ability and preventing
58 falls in postoperative total knee arthroplasty patients. The advantage of toe grip strength training
59 is that it is an unoperated muscle function, so the intervention can be conducted safely without
60 specialist supervision unless the toes are impaired.

61

62 Key words: Toe grip strength training; Timed up and go test; Falls; Total knee arthroplasty

63

64 足趾把持力トレーニングは人工膝関節全置換術後患者の歩行能力を改善し転倒を予防する

65

66 廻角侑弥^{1,2,5}, 稲垣有佐², 藤井唯誌³, 久保峰鳴⁴, 福本貴彦⁵, 城戸顕², 田中康仁⁶

67

68 1. 奈良県立医科大学 血栓止血医薬生物学共同研究講座

69 2. 奈良県立医科大学 リハビリテーション医学講座

70 3. 香芝旭ヶ丘病院 整形外科

71 4. 大阪河崎リハビリテーション大学 リハビリテーション学部

72 5. 畿央大学大学院 健康科学研究科

73 6. 奈良県立医科大学 整形外科学教室

74

75 人工膝関節全置換術後の転倒は、高齢であり関節インプラントによる固有感覚機能の変化の

76 ため頻繁にみられる。我々は、変形性膝関節症患者の転倒に対する足趾把持力の影響を報

77 告した。本研究は、人工膝関節全置換術後の足趾把持力トレーニングの効果が、スクリーニン

78 グ評価および転倒の発生率と関連するかどうかを明らかにすることを目的とした。片側人工膝

79 関節全置換術を受けた高齢患者を、足趾把持力トレーニング群と対照群にわけた。両側の足

80 趾に対して6種類のトレーニングが実施された。主要アウトカムは、介入前から介入後12週ま

81 での足趾の握力とtimed up and go testの計測時間の変化量とした。副次的アウトカムは、転

82 倒の発生を含む複数の要因とした。解析対象は両群共に37名であった。足趾把持力トレーニ

83ング群では、対照群に比べ、timed up and go testの計測時間が短く、両側の足趾把持力が強

84 かった。timed up and go testの計測時間の変化量は、患側の足趾握力の変化量と有意な相

85 関関係を認めた。人工膝関節全置換術後 3 ヶ月から 12 ヶ月の間に、足趾把持力トレーニング
86 群では対照群に比べて転倒が有意に少なかった。足趾把持力トレーニングは、人工膝関節全
87 置換術後患者の歩行能力向上と転倒予防に有用であることが判明した。足趾把持力トレーニ
88 ングの利点は、人工膝関節全置換術の非手術部位であるため、足趾に障害がない限り専門家
89 の監督なしに介入を安全に実施できることである。

90

91

92 **Introduction**

93 Total knee arthroplasty (TKA) is an effective treatment to reduce knee joint pain and
94 improve activities of daily living. However, according to previous reports, 17–38% of TKA
95 patients experience falls within 1 year after TKA¹⁻³. The reason is that TKA is a surgery mainly
96 undertaken for the elderly and, associated with altered sensory and motor functions of the knee,
97 which may impair balance control when standing and walking⁴. Although the general elderly
98 population also has a fall incidence of around 30%⁵, the falls after TKA can lead to severe
99 fractures, such as peri-implant fractures, and hinder the restoration of quality of life⁶. The Timed
100 up and go test (TUG), an assessment of combined movements such as standing, sitting and
101 walking, has been reported to be predictive of falls and is often used as a screening tool for falls
102 in clinical settings⁷. In postoperative TKA patients, who are often treated at an advanced age, the
103 TUG is effective in the clinical assessment of balance function and postoperative outcomes.

104 Toe grip strength (TGS) has recently gained interest, as previous reports have shown that
105 TGS affects falls in patients with knee osteoarthritis (KOA)⁸. Tsuyuguchi et al.⁹ reported that
106 nursing home residents who received TGS training showed significant improvements in TGS and
107 fall risk scores. Kojima et al.¹⁰ also reported that toe-grip exercises could improve TGS and
108 balance ability of home-based rehabilitation users. TGS training improves balance ability and fall
109 risk and is therefore expected to improve TUG, which is used as a screening assessment for falls.
110 For TGS is associated with TUG in healthy elderly patients¹¹, TGS training can contribute to
111 improved TUG times in postoperative TKA patients, many of whom are treated at an older age.
112 An advantage of TGS training for postoperative TKA patients is that it can be performed without
113 pain in the surgical area since it involves a non-surgical muscle function. Another advantage of
114 TGS training is that it is safe for postoperative patients to perform at home, as it can be

115 performed in a sitting position.

116 However, we were unable to find any previous reports on how the presence or absence of
117 TGS training relates to physical ability and fall incidence in patients after TKA. Our hypothesis
118 was that TGS training started after TKA would improve TGS and contribute to shorter TUG
119 times and reduced fall rates. Whether TGS training for postoperative TKA patients is useful for
120 improving physical ability and reducing the risk of accidents that may occur after TKA needs to
121 be clarified. The aim of our study was to evaluate how TGS training is related to physical ability
122 and fall incidence by dividing postoperative TKA patients into a TGS training group (T-group)
123 and a control group (C-group) in a non-randomized way.

124

125 **Methods**

126 *Study design and participants*

127 This was a nonrandomized controlled study with 2 parallel groups. Participants were
128 recruited from a single hospital in Japan, and elderly patients who underwent unilateral TKA
129 between May 2020 and December 2021 due to a diagnosis of KOA were included. The inclusion
130 criteria were as follows: 1) individuals who underwent unilateral TKA due to a diagnosis of
131 KOA; 2) individuals between 60 and 84 years of age; 3) individuals who had the ability to
132 ambulate independently or with a T-shaped cane before and 3 months and 1 year after TKA; 4)
133 individuals who were able to complete a physical therapy assessment and questionnaire; and 5)
134 individuals who provided informed consent to participate in the study. The exclusion criteria
135 were as follows: 1) individuals who were diagnosed with rheumatoid arthritis, idiopathic
136 osteonecrosis, neurological diseases, other musculoskeletal diseases or foot and ankle disorders;
137 2) individuals with toe flexion problems by hallux valgus, floating toe and nail deformities that

138 could significantly impair basic movements, such as walking; 3) individuals with severe
139 depression or dementia, which would hinder evaluation; and 4) individuals who fell during
140 hospitalization. The participants who met the selection criteria were divided into two groups
141 according to whether they wished to participate in the TGS training program: the T-group (the
142 group receiving TGS training and usual physiotherapy) and the C-group (the group receiving
143 usual physiotherapy only).

144

145 ***Ethical issues***

146 This study complied with the Declaration of Helsinki and was approved by the Research
147 Ethics Committee of Kashiba Asahigaoka Hospital (ID: 2020-04-21-007) and the registered
148 University Hospital Medical Information Network Clinical Trials Registry (ID:
149 UMIN000048550). Details of the study protocol and aim were explained to all participants, both
150 verbally and in writing. All study participants signed an informed consent form prior to
151 participating in the study.

152

153 ***Interventions for T-group participants***

154 TGS training in the T-group began the day after discharge from the hospital, lasted 12
155 weeks and was conducted in the participant's home. Six types of training were conducted on
156 bilateral toes based on previous studies (Fig. 1)⁹. The participant and examiner determined the
157 feasibility of the six types of training during hospitalization. Then, participants were asked to
158 exclude items that were difficult to implement and to implement the remaining items. For safety
159 reasons, all interventions were performed in a seated position in a chair. Participants were
160 instructed to record "done" in the designated training notebook when they completed the TGS

161 training using the default items and the frequency (Fig. 2). The therapist checked the training
162 notebook for outpatient physical therapy once or twice per week. Participants were asked to
163 conduct the program a minimum of four times per week. As common home exercises, both
164 groups were instructed to perform range of motion (ROM) knee flexion and knee extension
165 strength exercises. The quantity and frequency of common home exercises were individually
166 determined by the therapist in charge, depending on the participant's degree of improvement and
167 home environment.

168

169 *Study procedure*

170 The study protocol is shown in Fig. 3. Preoperative outcomes were assessed on the day
171 before TKA. Outcome measurements were evaluated in the rehabilitation room by the therapist
172 in charge. Outcome assessments were performed preoperatively and 12 weeks postoperatively by
173 the same therapist. However, the guidance of the intervention in the TGS group was provided by
174 a person independent of the assessors. Whether falls had occurred was determined by the nurse
175 on the day before TKA and at 12 weeks and 1 year after TKA. All patients started physical
176 therapy the day after TKA, which consisted of ROM exercises for the affected knee and gait
177 practice with a walker. No TGS training was provided during inpatient physical therapy.

178 The surgical technique for TKA and the choice of implant were selected by two
179 orthopaedic surgeons based on the suitability of the patient. The component was cemented, and
180 the incision was made with a para-patellar approach. All participants had the patella replaced.
181 Physical therapy during hospitalization was provided six days per week (excluding Sunday).

182

183 *Primary outcomes*

184 The primary outcomes were changes (Δ) in TGS and the TUG time from preintervention
185 to 12 weeks post-intervention. A toe grip dynamometer (T.K.K.3362; Takei Scientific
186 Instruments, Niigata, Japan) was used to measure TGS (Fig. 4) in a seated position with the hip
187 and knee joints flexed at 90° and the ankle in a neutral position. The examiner adjusted the
188 position of each participant's heel stopper so that at least the first to third toes could grasp the
189 grip bar of the device and secured the foot with the provided immobilization belt to prevent it
190 from moving. After practicing several times, the TGS of both sides was measured at maximum
191 force for approximately three seconds. TGS was measured twice, and the mean value (kg) was
192 calculated. Measurements were taken for both sides. The TGS has excellent intrarater reliability,
193 with an intraclass correlation coefficient (ICC) of 0.92¹².

194 The TUG¹³ test is a walking time test that involves standing up from a chair, walking for
195 3 m, turning, walking back to the chair, and sitting down. The test was developed as an
196 evaluation of mobility and screening for fall risk. The normal walking speed of the participants
197 was measured due to concerns about falls during the measurement. Two measurements were
198 taken and averaged (second). The TUG has excellent intrarater reliability, with an intraclass
199 correlation coefficient (ICC) of 0.94¹⁴.

200

201 *Secondary outcomes*

202 Secondary outcomes included background information, the occurrence of falls, pain,
203 isometric knee extension (IKES), the modified Fall Efficacy Scale (mFES) score, and the Knee
204 Injury and Osteoarthritis Outcome Score (KOOS).

205 Background information, including age, height, weight, body mass index (BMI), and
206 gender, was collected preoperatively; Kellgren-Laurence grading (K-L grade) was performed for

207 both sides by the orthopaedic surgeon using X-ray images. The type of implant (PS or CS), the
208 affected side and the number of hospitalization days were determined using electronic medical
209 records. Walking style was assessed preoperatively and at 12 weeks postoperatively by a
210 therapist.

211 The occurrence of falls was assessed by asking participants and their family members
212 who lived with them whether they had fallen. The reason that the participants' family members
213 who lived with them were also asked about falls was due to the participants' potential recall bias.
214 A fall was defined as "an event that resulted in a person coming to rest unintentionally on the
215 ground or other lower level, not as a result of a major intrinsic event or overwhelming hazard"¹⁵.
216 Falls were excluded if they were not related to gait, standing or transfer, for example, a fall from
217 a bicycle or ladder. Assessments were performed 1) on the day of admission prior to TKA, 2) at
218 the 12-week postoperative follow-up visit for falls (from discharge to 12 weeks postoperatively),
219 and 3) at the 1-year postoperative follow-up visit for falls (from 12 weeks to 1 year
220 postoperatively).

221 Pain levels at rest and during walking were measured using a visual analog scale (VAS)
222 with a 100-mm horizontal line ranging from 0 (no pain) to 100 (worst pain imaginable)¹⁶.

223 IKES was measured using a handheld dynamometer (μ -tas F1; ANIMA Corp.) with the
224 participant in a seated position with the knee at 90° of flexion¹⁷. Participants were instructed to
225 gradually increase the intensity of knee extension against the dynamometer for approximately 2 s
226 and maintain their maximal force output for approximately 3 s. Two measurements were taken
227 and averaged (kgf).

228 Fear of falling was assessed using the Japanese version of the mFES. The mFES consists
229 of 14 items (score range: 0–140 points) that are subjectively evaluated on a scale from 0 to 10 in

230 terms of a person's confidence in their ability to perform daily indoor and outdoor activities
231 without falling¹⁸. The mFES measures confidence in performing certain movements and actions
232 without falling, with higher scores indicating greater self-efficacy in preventing falls and less
233 fear of falling.

234 The KOOS consists of 42 factors separated into five subscales: pain (nine factors),
235 symptoms (seven factors), activities of daily living (ADL) function (17 factors), sport and
236 recreation function (five factors), and quality of life (four factors). Each of the five subscale
237 scores is calculated as the sum of the included factors. The scores are converted to a 0–100 scale,
238 with 0 representing extreme knee problems and 100 representing no knee problems, as is
239 common in orthopaedic scales¹⁹. A Likert scale is used for scoring; all factors have five answer
240 options ranging from 0 (no problems) to 4 (extreme problems), and scores between 0 and 100
241 represent the percentage of the total possible score achieved. In addition to the analysis and
242 interpretation of the five subscales separately, an aggregate score is calculated.

243

244 *Statistical analysis*

245 Data were analysed descriptively by calculating means and standard deviations or
246 numbers and percentages. For all analyses, the significance level was set to 5%. All statistical
247 analyses were performed using software (SPSS Inc.; SPSS version 26.0 for Windows). Statistical
248 analyses were carried out by researcher not part of the intervention and evaluation of this study.
249 Changes (Δ) were calculated as differences before and 12 weeks after the intervention²⁰. We
250 performed the Shapiro–Wilk test to examine normality.

251 Comparisons between groups of baseline variables and Δ variables were analysed with an
252 unpaired t test or the Mann–Whitney U test.

253 Intragroup comparisons before and 12 weeks after TKA in the T-group and C-group were
254 analysed with a paired t test or Wilcoxon's signed rank test.

255 Comparisons between groups regarding the occurrence of falls (preoperatively, 12 weeks
256 postoperatively, 1 year postoperatively), gender, K-L grade (both sides), type of implant, the
257 affected side, the number of hospitalization days, and walking style (preoperatively, 12 weeks
258 postoperatively) were analysed by the chi-squared test or Fisher's exact test.

259 To examine variables associated with Δ TUG time in the T-group, Pearson or Spearman
260 correlation coefficients were analysed.

261

262

263 **Data availability statement**

264 The datasets generated for this study will be made available upon reasonable request, which
265 should be directed to the corresponding author.

266

267 **Results**

268 *Comparison of baseline characteristics*

269 Figure 5 illustrates the study flowchart, which includes the processes of subject
270 enrolment, allocation, and analysis. Each groups included 37 participants. There were no
271 dropouts in either group. Table 1 shows the baseline characteristics for the T-group and C-group.
272 No significant differences were observed in any factors between the groups.

273

274 *Compliance rate of the exercise*

275 The compliance rate of 37 participants in the T-group who exercised at least four times a

276 week for 12 weeks was 100%. In short, all participants conducted TGS training at least four
277 times a week for 12 weeks.

278

279 ***Improvement from before to 12 weeks after surgery***

280 Table 2 shows a comparison of the degree of improvement from before to 12 weeks after
281 surgery. The T-group showed improvements in the TUG time, TGS on the affected side, TGS on
282 the unaffected side, walking pain on the affected side, walking pain on the unaffected side, the
283 mFES score, the KOOS Symptoms subscale score, the KOOS Pain subscale score, the KOOS
284 ADL subscale score, and the KOOS QOL subscale score. The C-group showed improvements in
285 the TUG time, resting pain on the affected side, walking pain on the affected side, walking pain
286 on the unaffected side, the mFES score, the KOOS symptoms subscale score, the KOOS Pain
287 subscale score, the KOOS ADL subscale score, and the KOOS QOL subscale score. Both groups
288 showed improvement at 12 weeks postoperatively compared to preoperatively.

289

290 ***Comparison of changes between the T-group and C-group***

291 Comparisons of changes in scores collected at baseline and post-intervention between the
292 two groups are shown in Table 3. The T-group showed significant improvements in Δ TUG time
293 and TGS on the affected side and on the unaffected side compared with the C-group.

294

295 ***Correlation analyses of Δ TUG time and changes in other factors***

296 The correlations between Δ TUG time and changes in other factors are shown in Table 4.
297 Δ TUG time showed a significant negative correlation with Δ TGS on the affected side.

298

299 *Comparison of falls and walking style in the T-group and C-group*

300 Table 5 shows a comparison of the occurrence of falls at each time point and walking style
301 at 12 weeks postoperatively. The T-group had a significantly lower number of falls than the C-
302 group at one year after TKA.

303

304 **Discussion**

305 The aim of our study was to evaluate how TGS training was related to physical ability
306 and fall incidence by dividing postoperative TKA patients into a T-group and C-group in a non-
307 randomized way. The T-group completed a training programme related to TGS at least 4 times
308 per week for 12 weeks after discharge home after TKA. The results of our study were consistent
309 with our hypothesis. The T-group had significantly improved TGS and TUG times from before to
310 12 weeks after surgery and had significantly fewer falls in the 1-year postoperative period
311 compared to the C-group. In the early postoperative period, knee joint function is still
312 recovering, and early intervention such as TGS training would be a useful and safe intervention
313 for postoperative TKA patients. To our knowledge, this study is the first to demonstrate that the
314 implementation of TGS training is associated with improved physical ability and reduced fall
315 incidence among postoperative TKA patients. Falls after TKA can lead to severe fractures, such
316 as peri-implant fractures⁶. No adverse events occurred in either group during the study period.
317 There were no dropouts. This is because TGS training is a nonsurgical and painless procedure.

318 In the T-group, bilateral TGS at 12 weeks postoperatively improved compared to the
319 preoperative values, and Δ TGS was significantly greater in the T-group than in the C-group.
320 Needless to say, the effect of the training programme was related to receiving TGS training
321 within a certain period of being discharged home. Not only was TGS enhanced by TGS training

322 in the T-group, but significant improvements were also found in the TUG time. Furthermore, the
323 significant negative correlation found between Δ TGS and Δ TUG time in the T-group indicated
324 that the TUG time was improved by the TGS training intervention. This is because no
325 interventions to improve TUG time were carried out other than TGS training in the T-group. The
326 reason why improvement in TGS was associated with an improvement in the TUG time in
327 postoperative TKA patients is that toe flexion in a terminal stance supports the rigid supination
328 of the foot for push-off that is needed for smooth progression of the body during walking²¹
329 Enhanced TGS may have contributed to a faster TUG time, as it enhanced the kicking force and
330 contributed to an increase in walking speed. As toe movement is a product of the interaction of
331 the flexor-extensor muscles that make up the lower part of the foot²², toe stability providing
332 postural stability while walking may also be the reason for the improvement in the TUG time.
333 We consider that TGS training may have contributed to postural stability during gait changes in
334 movements that require a change in direction, such as the TUG, and reduced the deceleration of
335 speed when changing direction.

336 We report novel information that the T-group had significantly fewer falls at 12 months
337 postoperatively than the C-group. Since TKA postoperative patients are older and at risk of
338 postoperative complications due to a certain number of falls, the association between fewer
339 postoperative falls and improved TGS is an important finding. The finding that the 12-week
340 postoperative TGS intervention sustained a reduction in falls up to 1 year postoperatively is a
341 very positive result. A valid explanation for the above result may be that the TGS intervention
342 helped participants develop and sustain the TGS exercise routine. As TGS is not a muscle
343 strength that is consciously used on a daily basis, it is possible that the T-group acquired an
344 awareness of exercising TGS as a result of participating in this trial. Another possible reason

345 could be the 100% adherence rate of the T-group to the exercise programme at 12 weeks
346 postoperatively, which is a very enthusiastic group of participants.

347 The first speculation that TGS training contributes to fall prevention is the prevention of
348 stumbling over steps in the home. As stumbles are caused by the toes catching on steps and other
349 surfaces, a functioning toe joint is thought to prevent stumbling. Especially after TKA surgery,
350 when the knee motion is tight, movement beyond the ankle joint is particularly important.
351 Second, it is thought that balance is maintained by a kinetic chain from the lower part of the foot
352 by stepping on the ground with the toe flexor muscle during changes in plantar pressure, such as
353 changes in direction. Biomechanical research is essential to verify these speculations in the
354 future.

355 This study had some major limitations. The first limitation is the lack of assessment of
356 foot function other than TGS. Participants who were unable to measure TGS or who were treated
357 by a doctor for their toes were not included, but the hallux valgus and arch angle were not
358 accounted for. It was previously reported that lower toe deformities change the load distribution
359 when walking because such a condition results in the toes being pulled back into extension, thus
360 reducing their contact area²³. Toe deformities alter weight distribution under the foot when
361 walking²³. This may also affect the TUG time. Second, previous studies have reported decreased
362 physical activity as well as hip weakness as risk factors for falls^{24, 25}. Because we did not
363 evaluate these factors and did not include these results in our analysis, we could not determine
364 the relative contribution of TGS to physical activity and muscle strength for the above factors in
365 older adults with KOA. Thirdly, the sample size is not calculated in a priori. Without sample size
366 calculations, it is unclear whether the intervention study was conducted with sufficient power.
367 Finally, participants were not randomly assigned, which may introduce selection bias into this

368 results. This limitation could affect the generalizability and validity. To improve the quality and
369 rigor, it is essential to acknowledge this potential bias and address it in future research.
370 Therefore, we plan to conduct a randomized controlled trial to verify the effectiveness of TGS
371 training and minimize the impact of selection bias on our conclusions.

372 The aim of our study was to examine how TGS training was related to physical ability
373 and the occurrence of falls in postoperative TKA patients in a nonrandomized trial, dividing them
374 into a training group and a control group. The results showed that TGS training was useful in
375 improving walking ability and preventing falls in postoperative TKA patients. The advantage of
376 TGS training is that it is an involuntary muscle function, so the intervention can be conducted
377 safely without specialist supervision unless the toes are impaired. We recommend TGS training
378 as a new training method for TKA patients, many of whom are elderly facing the risk of falls.

379

380 **References**

- 381 1. Swinkels A and Allain TJ. 2013. Physical performance tests, self-reported outcomes, and
382 accidental falls before and after total knee arthroplasty: an exploratory study. *Physiother
383 Theory Pract* 29: 432-442. doi: 10.3109/09593985.2012.755590.
- 384 2. Matsumoto H, Okuno M, Nakamura T, Yamamoto K, Osaki M and Hagino H. 2014.
385 Incidence and risk factors for falling in patients after total knee arthroplasty compared to
386 healthy elderly individuals. *Yonago Acta Med* 57: 137-145.
- 387 3. Tsonga T, Michalopoulou M, Kapetanakis S, Giovannopoulou E, Malliou P, Godolias G
388 and Soucacos P. 2016. Reduction of falls and factors affecting falls a year after total knee
389 arthroplasty in elderly patients with severe knee osteoarthritis. *Open Orthop J* 10: 522-
390 531. doi: 10.2174/1874325001610010522.
- 391 4. Gage WH, Frank JS, Prentice SD and Stevenson P. 2008. Postural responses following a
392 rotational support surface perturbation, following knee joint replacement: frontal plane
393 rotations. *Gait Posture* 27: 286-293. doi: 10.1016/j.gaitpost.2007.04.006.
- 394 5. Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, Rowe BH. 2003.
395 Interventions for preventing falls in elderly people. *Cochrane Database Syst Rev* 4:
396 CD000340. doi: 10.1002/14651858.CD000340.
- 397 6. Della Rocca GJ, Leung KS and Pape HC. 2011. Periprosthetic fractures: epidemiology
398 and future projections. *J Orthop Trauma* 25: S66-S70. doi:
399 10.1097/BOT.0b013e31821b8c28.
- 400 7. Taniguchi M, Sawano S, Maegawa S, Ikezoe T and Ichihashi N. 2021. Physical activity
401 mediates the relationship between gait function and fall incidence after total knee
402 arthroplasty. *J Knee Surg* 34: 1205-1211. doi: 10.1055/s-0040-1702165.

- 403 8. Mawarikado Y, Inagaki Y, Fujii T, Kubo T, Kido A and Tanaka Y. 2023. Relationship
404 between fall history and toe grip strength in older adults with knee osteoarthritis in Japan:
405 a cross-sectional study. *PLoS One* 18: e0282944. doi: 10.1371/journal.pone.0282944.
- 406 9. Tsuyuguchi R, Kurose S, Seto T, Takao N, Fujii A, Tsutsumi H, Otsuki S and Kimura Y.
407 2019. The effects of toe grip training on physical performance and cognitive function of
408 nursing home residents. *J Physiol Anthropol* 38: 11. doi: 10.1186/s40101-019-0202-5.
- 409 10. Kojima K, Kamai D, Yamamoto A, Tsuchitani Y, Kataoka H. 2021. The Effect of Toe-
410 grasping Exercises on Balance Ability in Home-based Rehabilitation: A Randomized
411 Controlled Trial by Block Randomization. *Phys Ther Res* 24: 272-279. doi:
412 10.1298/ptr.E10105.
- 413 11. Uritani D, Fukumoto T, Matsumoto D and Shima M. 2016. The relationship between toe
414 grip strength and dynamic balance or functional mobility among community-dwelling
415 Japanese older adults: a cross-sectional study. *J Aging Phys Act* 24: 459-464. doi:
416 10.1123/japa.2015-0123.
- 417 12. Arai R, Fuchigami M, Yamamoto K, Hatamura K, Tatsuki Y. 2022. Intra- and inter-
418 examiner reliability and minimal detectable change for different methods of measuring
419 toe grip strength in healthy adults. *J Phys Ther Sci* 34: 99-102. doi: 10.1589/jpts.34.99.
- 420 13. Podsiadlo D and Richardson S. 1991. The timed “up & go”: a test of basic functional
421 mobility for frail elderly persons. *J Am Geriatr Soc* 39: 142-148. doi: 10.1111/j.1532-
422 5415.1991.tb01616.x.
- 423 14. Hofheinz M. and Schusterschitz C. 2010. Dual task interference in estimating the risk of
424 falls and measuring change: a comparative, psychometric study of four measurements.
425 *Clin Rehabil* 24: 831-842. doi: 10.1177/0269215510367993.

- 426 15. Clark RD, Lord SR and Webster IW. 1993. Clinical parameters associated with falls in an
427 elderly population. *Gerontology* 39: 117-123. doi: 10.1159/000213521.
- 428 16. McCormack HM, Horne DJ and Sheather S. 1988. Clinical applications of visual
429 analogue scales: a critical review. *Psychol Med* 18: 1007-1019. doi:
430 10.1017/s0033291700009934.
- 431 17. Koblbauer IF, Lambrecht Y, van der Hulst ML, Neeter C, Engelbert RH, Poolman RW
432 and Scholtes VA. 2011. Reliability of maximal isometric knee strength testing with
433 modified hand-held dynamometry in patients awaiting total knee arthroplasty: useful in
434 research and individual patient settings? A reliability study. *BMC Musculoskelet Disord*
435 12: 249. doi: 10.1186/1471-2474-12-249.
- 436 18. Tinetti ME, Richman D and Powell L. 1990. Falls efficacy as a measure of fear of falling.
437 *J Gerontol* 45: P239-P243. doi: 10.1093/geronj/45.6.p239.
- 438 19. Barber SD, Noyes FR, Mangine RE, McCloskey JW and Hartman W. 1990. Quantitative
439 assessment of functional limitations in normal and anterior cruciate ligament-deficient
440 knees. *Clin Orthop Relat Res* 255: 204-214.
- 441 20. Faria R, Alava MH, Manca A and Wailoo AJ. 2015. NICE DSU TECHNICAL SUPPORT
442 DOCUMENT 17: THE USE OF OBSERVATIONAL DATA TO INFORM ESTIMATES
443 OF TREATMENT EFFECTIVENESS IN TECHNOLOGY APPRAISAL: METHODS
444 FOR COMPARATIVE INDIVIDUAL PATIENT DATA.
- 445 21. Hicks JH. 1954. The mechanics of the foot. II. The plantar aponeurosis and the arch. *J*
446 *Anat* 88: 25-30.
- 447 22. Yamashita K, Umezawa J, Nomoto Y, Ino S, Ifukube T, Koyama H, Kawasumi M and
448 Saito M. 2002. Evaluation of falling risk by toe-gap force on aged. *Trans Soc Instrum*

- 449 *Control Eng* 38: 952-957.
- 450 23. Mickle KJ, Munro BJ, Lord SR, Menz HB, Steele JR. 2011. Gait, balance and plantar
451 pressures in older people with toe deformities. *Gait Posture* 34: 347-351. doi:
452 10.1016/j.gaitpost.2011.05.023.
- 453 24. Dipietro L, Campbell WW, Buchner DM, Erickson KI, Powell KE, Bloodgood B, Hughes
454 T, Day KR, Piercy KL, Vaux-Bjerke A and Olson RD. 2019. Physical activity, injurious
455 falls, and physical function in aging: an umbrella review. *Med Sci Sports Exerc* 51: 1303-
456 1313. doi: 10.1249/MSS.0000000000001942.
- 457 25. Arvin M, van Dieën JH, Faber GS, Pijnappels M, Hoozemans MJM and Verschueren
458 SMP. 2016. Hip abductor neuromuscular capacity: a limiting factor in mediolateral
459 balance control in older adults? *Clin Biomech* 37: 27-33. doi:
460 10.1016/j.clinbiomech.2016.05.015.
- 461

462 **Acknowledgements**

463 We would like to thank AJE (<https://www.aje.com/jp/>) for English language editing.

464

465 **Author contributions**

466 Conceptualization: YM, YI, AK, YT; Data curation: YM, YI; Formal analysis: YM, YI;

467 Investigation: YM, YI, TK, TF; Methodology: YM, YI, TK, TF; Project administration: YM;

468 Resources: YM, TF; Software: YM, YI; Visualization: YM, YI; Writing – original draft: All

469 authors; Writing – review & editing: All authors

470

471 **Additional information**

472 Assessment data is available for "S1 dataset".

473

474 ***Competing interests***

475 The authors declare no competing interests.

476

477

478

479

480

481

482

483

484

485 **Figure legends**

486 Fig. 1

487 Towel-gathering exercise: The participants were instructed to gather a towel with their toes
488 without lifting their toes from the floor. This training was performed in three sets using a 1-m
489 towel in the sitting position. **a:** The feet are placed on the towel. The toes are used to gather the
490 towel towards the participant. **b:** A 500-mL PET bottle filled with water was placed on the end of
491 the towel as a load. **c:** Grasping and releasing a golf ball. The image shows a gold ball being
492 gripped between the toes. Participants were instructed to grip and release the golf ball repeatedly
493 using their toes. They performed the training for a total of 5 min. Rock-paper-scissor movements
494 were performed using the toes (**d:** clenching the toes, **e:** raising the big toe, **f:** keeping the toes
495 apart so that they did not touch each other). The participants practised making rock, paper, and
496 scissors shapes with their toes. They were instructed to perform three sets of 10 repetitions of
497 this technique.

498 **Fig. 2.**

499 **a:** The picture on the left shows the cover of the training notebook. Participants in the T-group
500 were asked to bring the training notebook with them each time they attended outpatient
501 physiotherapy. The page on the right describes the TGS training and notes the precautions. The
502 precautions describe that the TGS training should be carried out in a chair with stable footing. It
503 also describes that if toe pain or other symptoms appear, the physiotherapist in charge should be
504 consulted.

505 **b:** Both pages are two-month calendars (example calendars are shown for the months of May and
506 June). T-group participants were instructed to write a “○” on the days they performed the
507 training and an “×” on the days they did not perform the training.

508 **Fig. 3.**

509 The study instructions were explained verbally to all eligible participants, and written informed
510 consent was obtained. Participants were divided into two groups according to whether they
511 wished to participate in the toe grip-related training.

512 **Fig. 4.**

513 **a:** A toe grip dynamometer (T.K.K. 3361; Takei Scientific Instruments, Niigata, Japan) was used
514 to measure toe grip strength. **b:** Participants sat on the edge of a seat with their trunk in a vertical
515 position and their knees flexed approximately 90°.

516 **Fig. 5.**

517 Flowchart of the participants recruitment.

Fig. 1. Toe grip strength training



Gathered towel



Gathered towel with weights



Grasping and releasing a golf ball



Clenching the toes



Raising the big toe



keeping the toes apart so that they did not touch each other

Fig. 2. Notebook for training

a

Toe Grip Training Handbook

*Please bring this to every outpatient rehabilitation visit.



ID: _____

Name: _____

For patients undergoing toe grip training.

1. It has already been reported that stronger toe-flexor muscles improve walking speed and are less likely to cause falls.
2. Even if you have a wound or pain in the thigh area after artificial joint surgery, you can do this training with confidence as it is toe grip training.
3. You should carry out all training in a chair with stable footing.
4. The implementation period is approximately three months.
Please consult your physiotherapist about how to do it.
- *If you experience any pain in your toe, please consult your physiotherapist!**
5. Please mark a 'O' on the calendar for the days when it has been carried out.

b

“O” on days when you have done finger training, “X” on days when you have not done toe grip training.
Please do this at least four times a week.

May

SUN	MON	TUE	WED	THU	FRI	SAT
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

“O” on days when you have done finger training, “X” on days when you have not done toe grip training.
Please do this at least four times a week.

June

SUN	MON	TUE	WED	THU	FRI	SAT
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

Fig. 3. The study protocol from hospitalization to grouping

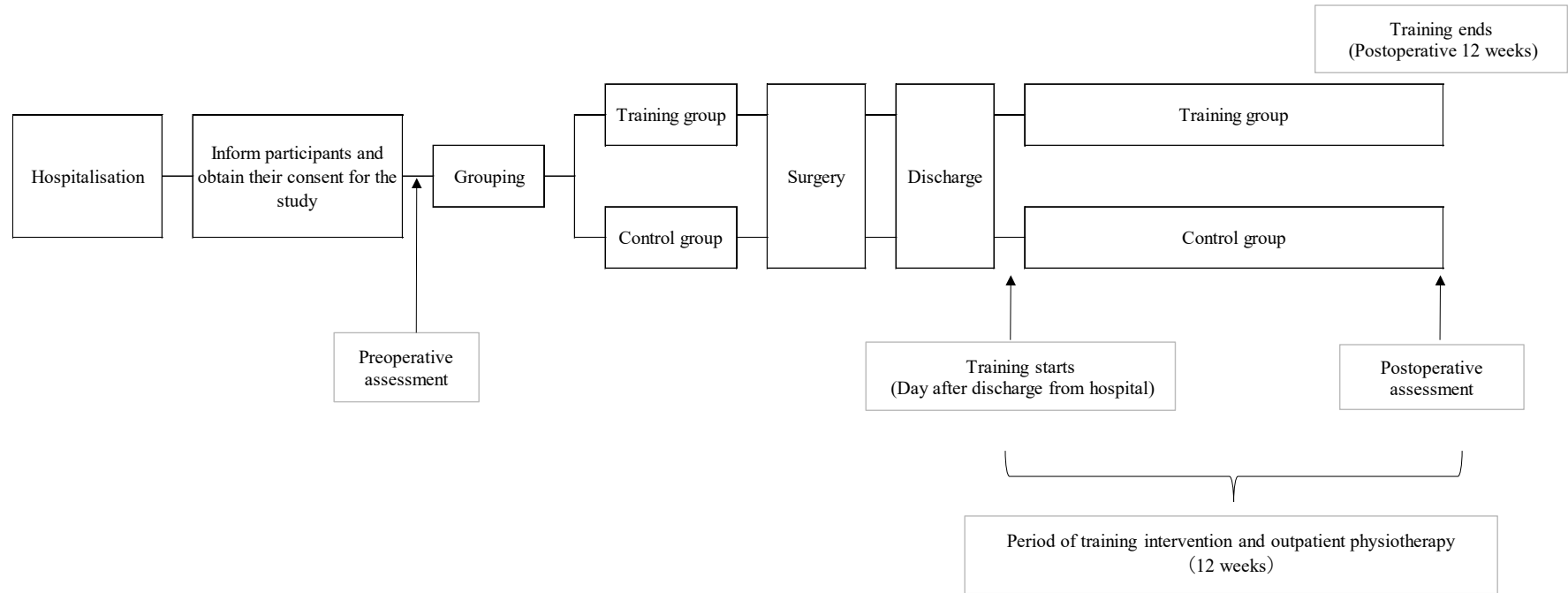


Fig. 4. The method of toe grip strength assessment



Fig 5. Flowchart of the participants recruitment

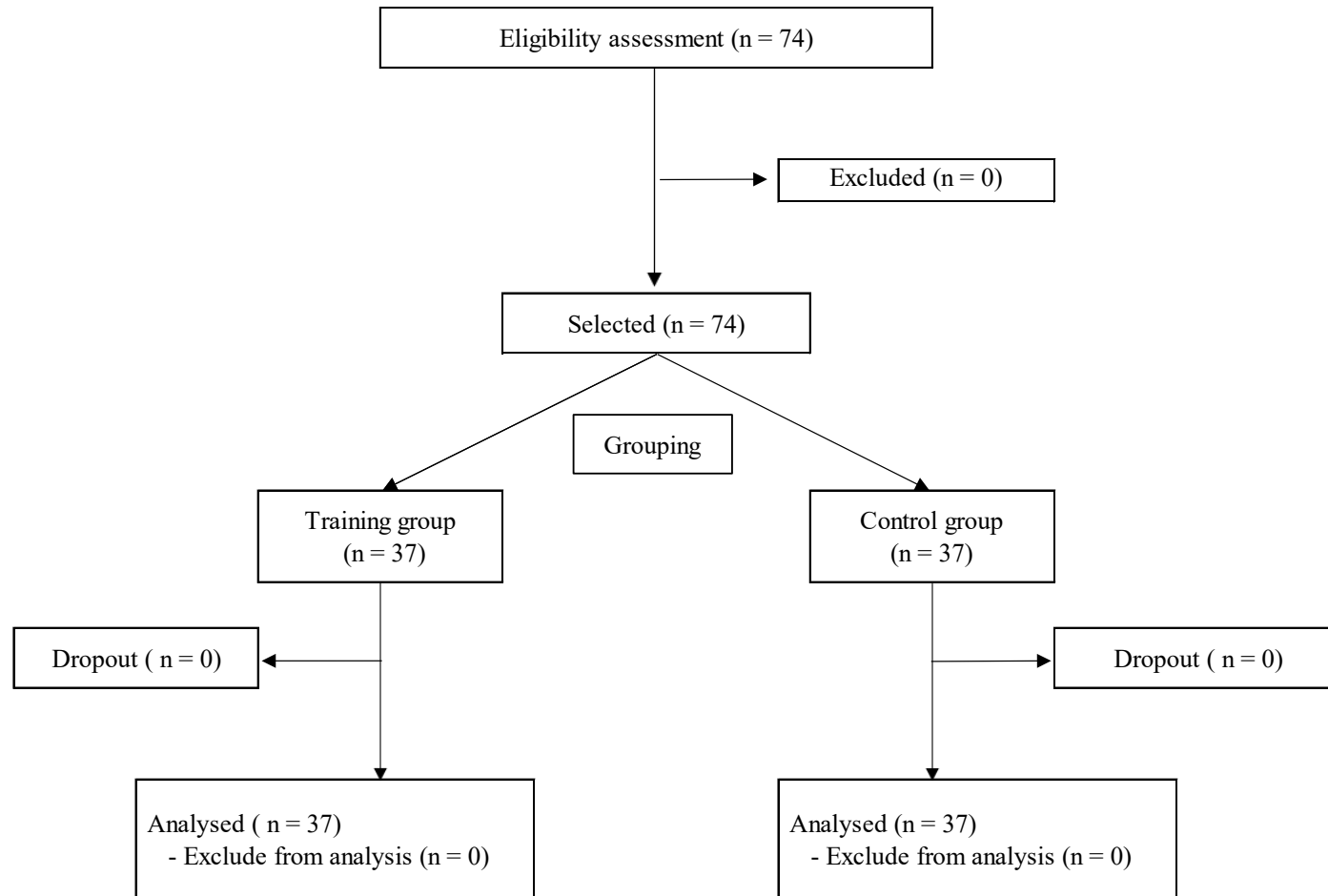


Table 1. A comparison of baseline values between training group and the control group

		Training group (n=37)		Control group (n=37)		p value
Age, year		75.1	± 6.3	75.4	± 5.8	0.696 ^m
Height, cm		155.1	± 7.6	154.5	± 8.1	0.770 ^m
Weight, kg		61.4	± 10.7	61.7	± 11.3	0.829 ^m
Body mass index, kg/m ²		25.4	± 3.5	25.8	± 3.6	0.683 ^{u-t}
Gender, male/female		8 / 29		6 / 31		0.553 ^c
K-L grade (affected side), I / II / III / IV		0 / 0 / 3 / 33		0 / 0 / 6 / 31		0.496 ^c
K-L grade (unaffected side), I / II / III / IV		1 / 2 / 21 / 13		1 / 0 / 19 / 17		0.452 ^c
Type of implant, PS / CS		34 / 3		30 / 7		0.174 ^c
The affected side, right/ left		21/16		20/17		0.815 ^c
Number of hospitalization days, n		15.9	± 2.8	16.4	± 4.1	0.279 ^m
Walking style preoperatively, cane/ walking alone		7 / 30		7 / 30		1.000 ^c
Preoperative fall, presence/absence		9 / 28		11 / 26		0.601 ^c
TUG-T, sec		11.9	± 3.5	12.6	± 4.5	0.585 ^m
TGS, kg	affected side	7.9	± 4.2	7.2	± 3.9	0.456 ^m
	unaffected side	8.6	± 3.8	8.2	± 4.9	0.446 ^m
Rest pain, mm	affected side	16.9	± 24.4	17.0	± 21.9	0.780 ^m
	unaffected side	3.6	± 12.7	7.5	± 15.2	0.308 ^m
Walking pain, mm	affected side	53.2	± 23.6	46.9	± 24.2	0.261 ^{u-t}
	unaffected side	16.9	± 21.6	17.8	± 22.9	0.726 ^m
IKES, kgf	affected side	13.7	± 6.0	15.9	± 9.2	0.615 ^m
	unaffected side	17.6	± 6.9	17.6	± 9.4	0.650 ^m
mFES, points		104.3	± 32.5	92.9	± 37.5	0.214 ^m
	Symptoms	63.2	± 17.4	59.8	± 17.9	0.413 ^{u-t}
	Pain	50.5	± 18.3	44.5	± 17.6	0.161 ^{u-t}
	ADL	61.8	± 18.4	56.6	± 18.3	0.223 ^{u-t}
KOOS, %	Sport/Rec	23.8	± 22.7	18.1	± 19.6	0.275 ^m
	QOL	30.8	± 17.1	27.9	± 14.4	0.756 ^m

Data are presented as mean ± SD and numbers. The significance level is 5%.

The statistical analysis used in the unpaired t-test, the Mann-Whitney U test and the chi-square test

u-t: The unpaired t-test, m; Mann-Whitney U test, c; Chi-squared test

K-L grade: Kellgren-Laurence grading, TUG-T: Timed up and go test, TGS: Toe grip strength,

IKES: Isometric knee extension strength, mFES: modified fall efficacy scale,

KOOS: Knee injury and osteoarthritis outcome score

Table 2. Measurements performed on the two groups

		Training group (n=37)			Control group (n=37)		
		Pre-evaluation	Post 3M evaluatio	p value	Pre-evaluation	Post 3M evaluatio	p value
TUG-T		11.9 ± 3.5	9.1 ± 1.5	0.001 ^w	12.6 ± 4.5	11.4 ± 3.0	0.014 ^w
TGS	affected side	7.9 ± 4.2	10.3 ± 4.7	0.001 ^w	7.2 ± 3.9	7.9 ± 4.9	0.078 ^w
	unaffected side	8.6 ± 3.8	11.4 ± 4.8	0.001 ^{p-t}	8.2 ± 4.9	8.2 ± 5.1	0.850 ^w
Rest pian	affected side	16.9 ± 24.4	6.1 ± 14.7	0.400 ^w	17.0 ± 21.9	8.1 ± 14.9	0.001 ^w
	unaffected side	3.6 ± 12.7	1.8 ± 6.3	0.253 ^w	7.5 ± 15.2	3.0 ± 10.2	0.050 ^w
Walking pain	affected side	53.2 ± 23.6	9.7 ± 14.7	0.001 ^w	46.9 ± 24.2	9.1 ± 12.1	0.001 ^w
	unaffected side	16.9 ± 21.6	6.6 ± 12.2	0.001 ^w	17.8 ± 22.9	2.4 ± 7.4	0.016 ^w
IKES	affected side	13.7 ± 6.0	14.2 ± 6.6	0.580 ^{p-t}	15.9 ± 9.2	14.9 ± 7.5	0.563 ^w
	unaffected side	17.6 ± 6.9	19.2 ± 7.4	0.078 ^{p-t}	17.6 ± 9.4	17.9 ± 8.9	0.563 ^w
mFES		104.3 ± 32.5	123.5 ± 19.4	0.002 ^w	92.9 ± 37.5	112.2 ± 28.3	0.001 ^w
	Symptoms	63.2 ± 17.4	75.3 ± 16.5	0.005 ^w	59.8 ± 17.9	68.2 ± 16.4	0.035 ^w
	Pain	50.5 ± 18.3	80.2 ± 14.4	0.001 ^w	44.5 ± 17.6	70.1 ± 18.4	0.001 ^w
KOOS	ADL	61.8 ± 18.4	80.6 ± 14.2	0.001 ^{p-t}	56.6 ± 18.3	73.2 ± 14.6	0.001 ^w
	Sport/Rec	23.8 ± 22.7	32.3 ± 30.4	0.111 ^w	18.1 ± 19.6	28.9 ± 23.6	0.075 ^w
	QOL	30.8 ± 17.1	55.9 ± 20.2	0.001 ^w	27.9 ± 14.4	47.5 ± 20.8	0.001 ^{p-t}

Data are presented as mean ± SD. The significance level is 5%.

The statistical analysis used in Wilcoxon signed rank test and the paired t-test.

w; Wilcoxon signed rank test, p-t; The paired t-test

TUG-T: Timed up and go test, TGS: Toe grip strength, IKES: Isometric knee extension strength, mFES: modified fall efficacy scale,

KOOS: Knee injury and osteoarthritis outcome score

Table 3. Comparison of changes(Δ) between training group and control group

		Training group (n=37)			Control group (n=37)			p value
Δ TUG-T		-2.8	\pm	3.2	-1.2	\pm	2.6	0.007 ^m
Δ TGS	affected side	2.4	\pm	3.6	0.7	\pm	2.5	0.007 ^m
	unaffected side	2.7	\pm	3.4	0.0	\pm	2.4	0.001 ^m
Δ rest pain	affected side	-10.7	\pm	17.8	-8.9	\pm	23.2	0.222 ^m
	unaffected side	-1.8	\pm	9.6	-4.5	\pm	13.2	0.708 ^m
Δ walking pain	affected side	-42.1	\pm	25.5	-37.9	\pm	30.0	0.515 ^{u-t}
	unaffected side	-10.2	\pm	24.0	-15.4	\pm	23.2	0.950 ^m
Δ IKES	affected side	0.5	\pm	5.7	-1.0	\pm	5.5	0.272 ^m
	unaffected side	1.7	\pm	5.6	0.2	\pm	4.9	0.240 ^{u-t}
Δ mFES		19.2	\pm	35.2	19.3	\pm	32.7	0.927 ^m
	Symptoms	12.1	\pm	23.0	8.4	\pm	25.0	0.514 ^{u-t}
	Pain	29.7	\pm	18.2	25.6	\pm	26.5	0.438 ^{u-t}
Δ KOOS	ADL	18.8	\pm	16.0	16.6	\pm	24.1	0.652 ^{u-t}
	Sport/Rec	8.5	\pm	37.3	10.8	\pm	33.2	0.780 ^{u-t}
	QOL	25.2	\pm	25.8	19.6	\pm	21.6	0.316 ^{u-t}

Data are presented as mean \pm SD. The significance level is 5%.

The statistical analysis used in the unpaired t-test and the Mann-Whitney U test.

u-t: The unpaired t-test, m; Mann-Whitney U test

TUG-T: Timed up and go test, TGS: Toe grip strength, IKES: Isometric knee extension strength, mFES: modified fall efficacy scale, KOOS: Knee injury and osteoarthritis outcome score

Table 4. Correlations between the degree of change(Δ) in improvement for each value in training group

	Age	BMI	Δ TGS		Δ rest pain		Δ walking pain		Δ IKES		Δ mFES
			affected side	unaffected side	affected side	unaffected side	affected side	unaffected side	affected side	unaffected side	
Δ TUG-T	-0.264	-0.085	-0.406*	-0.072	-0.004	0.139	0.144	0.087	-0.162	-0.103	0.302

Data are presented as the value of correlation coefficient. *: $p < 0.05$

TUG-T: Timed up and go test, BMI: Body mass index, TGS: Toe grip strength, IKES: Isometric knee extension strength, mFES: modified fall efficacy scale

Table 5. Comparison of falls and walking style in training group and control group

	Training group (n=37)	Control group (n=37)	p value
Preoperative fall, presence/absence (% faller)	9 / 28 (24.3%)	11 / 26 (29.7%)	0.601 ^c
Postoperative fall (3 months), presence/absence (% faller)	1/36 (2.7%)	5/32 (13.5%)	0.100 ^f
Postoperative fall (12 months), presence/absence (% faller)	6/31 (16.2%)	14/23 (37.8%)	0.036 ^c
Walking style preoperatively, cane/ walking alone	7 / 30	7 / 30	1.000 ^c
Walking style at 3 month postoperatively, cane/walking alone	5/32	8/29	0.359 ^c

Data are presented as numbers. The significance level is 5%.

The statistical analysis used in Chi-squared test and Fisher's exact test.

c; Chi-squared test, f; Fisher's exact test

