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# The Immediate Analgesic Effect and Impact on Gait Function of Transcutaneous Electrical Nerve Stimulation in Late-Stage Elderly Individuals with Knee Pain: Examination of Gait Function Using an IoT-Based Gait Analysis Device

**Taisuke Ito**

Waseda Elderly Health Association Co. Ltd., Tokyo, Japan
Email: t_ito@waseda-e-life.co.jp

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## Abstract

Purpose: This study verified the effects of transcutaneous electrical nerve stimulation (TENS), which can be worn during walking and exercise, in elderly individuals with late-stage knee pain who exercise regularly. Methods: Thirty-two late-stage elderly individuals were evaluated for knee pain during rest, walking, and program exercises, with and without TENS. Gait analysis was performed using an IoT-based gait analysis device to examine the effects of TENS-induced analgesia on gait. Results: TENS significantly reduced knee pain during rest, walking, and programmed exercises, with the greatest analgesic effect observed during walking. The greater the knee pain without TENS, the more significant the analgesic effect of TENS. A comparison of gait parameters revealed a significant difference only in the gait cycle time, with a trend towards faster walking with TENS; however, the effect was limited. Conclusion: TENS effectively relieves knee pain in late-stage elderly individuals and can be safely applied during exercise. Pain management using TENS provides important insights into the implementation of exercise therapy in this age group.

## Keywords

Late-Stage Elderly, Knee Joint Pain, Exercise, Transcutaneous Electrical Stimulation, IoT-Based Gait Analysis Device

## 1. Introduction

Physical activity is crucial for supporting the independence of late-stage elderly individuals, as it not only extends lifespan but also promotes healthy longevity and survival rates [1]. However, the long-term continuation of exercise is extremely challenging, with reports indicating that approximately 50% of people quit within 3 - 6 months of starting an exercise program [2]. In Japan, a system of community-based day-service programs has been established within the Long-Term Care Insurance (LTCI) system [3], where late-stage elderly individuals participate in exercise programs managed by physical therapists 1 - 2 times per week. These programs have revealed certain effects in maintaining physical function [4], with reports on the effectiveness of strength training, balance training, and gait practice [5] [6] [7] [8]. To achieve preventive care for the elderly, it is crucial to continuously implement exercise therapy, including walking training using this system, thereby preventing a decline in skeletal muscle mass and extending healthy life expectancy. However, some elderly people experience knee pain, which hinders walking training and exercise therapy.

Knee osteoarthritis (OA) is a common condition in the elderly [9], and its main symptom is pain, which may lead to muscle stiffness, deformity, swelling, and lower limb dysfunction [10] [11], thereby reducing the quality of life (QoL) of patients [12] [13] [14]. Elderly individuals without knee OA often report knee pain [15]. Effective pain management is necessary for implementing gait practice and exercise therapy because inappropriate pain management can exacerbate joint dysfunction and delay recovery.

Effective implementation of walking training and exercise therapy requires the alleviation of knee pain. However, inappropriate pain management strategies have been reported to exacerbate knee joint dysfunction and delay pain recovery [16], making exercise therapy implementation challenging and thereby leading to poor exercise adherence [17].

According to the 2007 guidelines of the Osteoarthritis Research Society International (OARSI), an international society for osteoarthritis, and a 2000 Cochrane systematic review, transcutaneous electrical nerve stimulation (TENS) is recommended as a noninvasive, side-effect-free, and easy-to-use pain management method for OA [18] [19].

TENS applies low-frequency electrical currents to the skin near painful areas, primarily targeting sensory nerves. While using TENS for the knee, the electrodes are placed on the L3 and L4 dermatome regions, allowing effective analgesia by inputting sensory and nociceptive stimuli to the same spinal cord level [20]. Furthermore, TENS has been reported to significantly reduce pain in older adults with knee pain due to osteoarthritis [21].

In recent years, TENS devices that can be worn during walking and exercise therapy have been developed and commercialized to address knee pain that occurs at rest and during walking and exercise therapy, and their effectiveness has been demonstrated [22]. However, the effects of TENS in late-stage elderly individuals with targeted knee pain have not yet been verified.

Therefore, this novel study aimed to verify the effects of TENS, which can be worn during walking and exercise, in late-stage elderly individuals with knee pain who regularly exercise under the LTCI system. This study investigated the immediate analgesic effects of TENS on knee pain during rest, walking, and exercise. Additionally, we conducted gait analysis with and without TENS application to evaluate the improvement in motor function associated with pain relief and to determine whether TENS worn during walking and exercise interferes with joint movement or proper physical activity. Gait analysis was performed using a simple IoT-based gait analysis device equipped with an accelerometer.

## 2. Participants and Methods

### 2.1. Participants

The study included 32 late elderly adults (3 males and 29 females) from among users who regularly exercised under the LTCI system. These participants, who had persistent knee pain and difficulty walking or exercising, had a mean age of 84.6 ± 4.4 years, a mean height of 148.3 ± 22.2 cm, and a mean weight of 60.1 ± 21.3 kg. Participants were excluded if they met any of the contraindications for low-frequency therapy devices (use of an implanted medical electrical device, such as a pacemaker; impaired skin sensation or skin abnormalities; inability to express their will; or sensory impairment due to advanced peripheral circulatory disorders, such as diabetes). As this program is implemented under the LTCI system, participants can be considered in a state of frailty. However, their continuity in using the program is indicative of their ability to maintain their usual daily activities without hospitalization or other institutional care, even with support. Therefore, they can be considered elderly people who have followed a relatively normal aging process.

Each participant signed an informed consent form, based on the requirements of the Helsinki Declaration. This study was approved by the Ethics Committee of Omron Healthcare Co., Ltd. (approval number IRB-2157) and registered in the University Hospital Medical Information Clinical Trials Registry (UMIN000054311).

### 2.2. Methods

The exercise program that the participants are currently undertaking is designed by exercise providers, such as care staff, and is implemented at a pace of 1 - 2 times per week. Each session lasted 2 - 3 hours and was conducted with sufficient breaks. The content includes a variety of topics that target the whole body, such as learning about health and healthcare, stretching and gymnastics in a sitting or standing position, strength training using machine exercises, light aerobic exercises using ergometers, and functional exercises using a suspension code. Before initiating the exercise program, vital signs and the physical condition of participants were checked, and the amount, time, and content of the exercise were adjusted accordingly.

The participants engaged in an exercise program to 1 - 2 times per week, including health and healthcare learning, stretching, strength training, and aerobic exercises. However, knee pain often limits the content, frequency, and intensity of exercises.

A knee-targeted TENS device (HV-F971; OMRON HEALTHCARE Co., Ltd.) was used. The electrodes were attached to two points in the L3 and L4 dermatomal regions below and medial to the patella (L3 region: 10 mm below the inferior border of the patella and 30 mm medial to the patellar midline; L4 region: 10 mm below the inferior border of the patella and aligned with the patellar midline and the right edge of the electrode). TENS stimulation parameters were a pulse width of 60 μs and a frequency of 1 - 200 Hz modulation, with an intensity set to the maximum tolerable level without discomfort [22]. Knee pain was recorded during rest, walking, and program exercises, with and without TENS application. Additionally, the gait function was measured under the same conditions and the parameters were compared.

Knee pain was measured using a Numerical Rating Scale (NRS) to record pain levels at rest, during walking, and program exercises with and without TENS application. The difference between the NRS without and with TENS was calculated and used as an indicator of the analgesic effect. The NRS is a graded scale that measures the severity of current pain on a scale of 0 - 10, with 0 indicating no pain and 10 indicating the worst imaginable pain.

Gait function was measured using a 3-axis accelerometer during a 10-meter walk test. Sufficient pre-training was performed before each trial. A 3-axis accelerometer (IoT-based gait analysis device AYUMI EYE [23]; Waseda Elderly Health Association Co., Ltd.) was used to measure gait function. The accelerometer sampling frequency was 31.25 Hz. The accelerometer had three axes (X, Y, and Z) that captured acceleration in the vertical, lateral, and anteroposterior directions, respectively. It was attached to the spinous process of the third lumbar vertebra. Each participant wore their shoes and performed the 10-meter walk test. Sufficient pre-training was conducted for the experimental trials. Tests were performed twice, and the average value of each parameter was calculated. The 10-meter walk test is a well-established measurement method used in many previous studies [24] and is valid when using accelerometers [23]. The first analysis items were the gait speed and stride length, which are basic gait parameters. The root mean square (RMS) was calculated to evaluate the spatial stability of the gait [25]. The RMS was normalized by dividing the square root of the mean square of acceleration by the square of the gait speed. The RMS values were calculated for each axis and the average was used. To evaluate the gait regularity, the mean and standard deviation of the stride time were calculated. For stride time, complete gait cycles were extracted by excluding the beginning and end of the analysis period, and the means and standard deviations were calculated. Differences in stance time were used to assess bilateral symmetry. The stance time was calculated as the time between initial contact on the left and right sides.

### 2.3. Statistics

In this study, the Wilcoxon signed-rank test was used to compare knee pain and gait parameters between the TENS non-application and application groups. The effect sizes were calculated for each variable using Cohen's d [26]. The relative magnitude of the effects was evaluated based on Cohen's guidelines, with $d \leq 0.20$ representing a small difference in means, $0.20 < d < 0.80$ representing a medium difference, and $d \geq 0.80$ representing a large difference in means. Cohen's d statistics were calculated when means and standard deviations were reported. Spearman's rank correlation coefficient was used to examine the correlation between knee pain severity without TENS and the analgesic effect of TENS. The statistical power was calculated based on the obtained effect sizes. Statistical analyses were performed using R 4.3.2, and the significance level was set at 5%.

## 3. Results

TENS significantly reduced knee pain at rest, walking, and exercise, with the greatest analgesic effects observed during walking (**Table 1**). Specifically, **Table 1** shows a reduction in pain scores from 1.71 (±2.57) to 0.69 (±1.69) at rest ($p = 0.003$), from 4.29 (±2.95) to 1.25 (±1.95) during ambulatory activities ($p < 0.001$), and from 2.32 (±2.60) to 1.30 (±1.73) during exercise ($p = 0.001$). These results highlight the utility of TENS as a potent analgesic tool, especially effective in reducing pain during movement.

The greater the knee pain without TENS, the more significant the analgesic effect of TENS (**Table 2**). This correlation was observed in all three conditions: rest pain, walking pain, and program exercise pain. Specifically, the correlation analysis showed strong negative correlations between the initial pain levels without TENS and the subsequent analgesic effects of TENS. For resting pain, the correlation coefficient was −0.697 ($p < 0.001$) with a statistical power of 0.997, indicating a substantial reduction in pain with TENS usage. During ambulatory activities, the correlation was even stronger, at −0.800 ($p < 0.001$) with a statistical power of 1.000. Similarly, for exercise-induced pain, the correlation coefficient reached −0.829 ($p < 0.001$) with a statistical power of 1.000. These results suggest that TENS is particularly effective in reducing higher initial pain levels across different activities.

A comparison of gait parameters showed a significant difference only in gait cycle time, with a trend towards faster walking with TENS. However, the effect size was moderate, indicating a limited impact on gait performance (**Table 3**). Specifically, while there was no significant improvement in gait speed (0.93 ± 0.30 m/s without TENS vs. 0.94 ± 0.29 m/s with TENS; $p = 0.459$), and stride length slightly decreased (51.32 ± 11.30 cm to 51.02 ± 11.33 cm; $p = 0.655$), both parameters showing small effect sizes. The RMS of the reciprocal of stride time decreased from 3.20 ± 2.18 to 2.91 ± 1.92 ($p = 0.124$), suggesting a trend towards a smoother gait, though the change was not statistically significant. Stride time, however, showed a significant reduction from 1.09 ± 0.22 seconds to 1.07 ± 0.19

**Table 1.** NRS for knee pain with and without TENS.

| | without TENS | with TENS | p-value | Cohen's d | Power |
|---|---|---|---|---|---|
| Resting Pain | 1.71 ± 2.57 | 0.69 ± 1.69 | 0.003 | 0.376 | 0.540 |
| Ambulatory Pain | 4.29 ± 2.95 | 1.25 ± 1.95 | 0.000 | 0.789 | 0.991 |
| Exercise-induced Pain | 2.32 ± 2.60 | 1.30 ± 1.73 | 0.001 | 0.394 | 0.579 |

NRS: Numeric Rating Scale, TENS: Transcutaneous Electrical Nerve Stimulation, Cohen's d: The effect size between with and without TENS conditions, Power: The statistical power.

**Table 2.** The correlation between pain levels without TENS and the analgesic effects observed with the use of TENS.

| | Correlation coefficient | p-value | Power |
|---|---|---|---|
| Resting Pain | −0.697 | 0.000 | 0.997 |
| Ambulatory Pain | −0.800 | 0.000 | 1.000 |
| Exercise-induced Pain | −0.829 | 0.000 | 1.000 |

TENS: Transcutaneous Electrical Nerve Stimulation, Power: The statistical power.

**Table 3.** Gait parameters in conditions with and without TENS.

| | without TENS | with TENS | p-value | Cohen's d | Power |
|---|---|---|---|---|---|
| Gait speed (m/s) | 0.93 ± 0.30 | 0.94 ± 0.29 | 0.459 | 0.134 | 0.110 |
| Stride length (cm) | 51.32 ± 11.30 | 51.02 ± 11.33 | 0.655 | 0.081 | 0.065 |
| RMS (1/m) | 3.20 ± 2.18 | 2.91 ± 1.92 | 0.124 | 0.274 | 0.324 |
| Stride time (s) | 1.09 ± 0.22 | 1.07 ± 0.19 | 0.014 | 0.427 | 0.648 |
| SD of Stride time (s) | 0.05 ± 0.04 | 0.05 ± 0.03 | 0.692 | 0.073 | 0.059 |
| Asymmetry instance time (s) | 0.04 ± 0.04 | 0.04 ± 0.04 | 0.098 | 0.292 | 0.359 |

TENS: Transcutaneous Electrical Nerve Stimulation, Cohen's d: The effect size between with and without TENS conditions, Power: The statistical power, SD: Standard Deviation.

seconds ($p = 0.014$) with a moderate effect size (Cohen's d = 0.427), reinforcing the observation of a slightly faster gait cycle with TENS. No significant changes were observed in the standard deviation of stride time or asymmetry instance time ($p = 0.692$ and $p = 0.098$, respectively).

## 4. Discussion

This study demonstrated that TENS is effective in reducing knee pain during rest, walking, and exercise in late-stage elderly individuals with regular exercise habits under the LTCI system. The analgesic effect of TENS was more pronounced during activities that elicited knee pain, such as walking and exercising than at rest.

This study investigated the effectiveness of TENS for knee pain in late-stage elderly individuals who exercised regularly using an LTCI system. We examined the immediate analgesic effects of TENS on knee pain during rest, walking, and exercise. These results suggest that TENS can potentially alleviate knee pain in late-stage elderly individuals by reducing pain at rest, during walking, and during program exercises. Furthermore, gait analysis was conducted with and without TENS, confirming that TENS did not hinder proper physical activity, including joint movements.

In this study, the use of a TENS device that can be worn during walking and exercise significantly reduced pain at rest, walking, and programmed exercises. This pain-relieving effect was particularly pronounced during walking. Furthermore, it was observed that the stronger the knee pain without TENS application, the greater the pain-relieving effect of TENS application. These results suggest that the pain-relieving effect of TENS is greater during walking and exercise, which are activities that induce knee pain than during rest.

According to the gate control theory, a pain-relieving mechanism of TENS, pain-relieving effects can be effectively obtained by inputting electrical sensory stimulation to the same spinal cord level as the nociceptive input at the spinal cord level, where pain and other nociceptive stimuli are input. In this study, the electrodes were attached to the dermatomes L3 and L4, and we assume that the gate control theory by ascending neurons was effectively reflected, resulting in the pain-relieving effect of TENS on L3 and L4.

In addition, only gait cycle time was significantly different in the evaluation of motor function associated with knee pain relief. Although no significant difference was observed in gait speed itself, the effect was limited; however, there was a tendency to walk fast.

TENS, which can be used during walking affects gait performance and may cause gait performance to improve further. However, in this study, many of the participants were late-stage elderly individuals whose gait patterns were already fixed, and although pain was immediately reduced, it did not lead to a change in gait patterns.

Although pain relief was achieved with TENS therapy for knee pain in late-stage elderly individuals, it did not affect the results of the Timed Up and Go Test [21]. The results of this study suggest that the direct impact of TENS on motor performance in late-stage elderly individuals is limited. However, the movement of the knee, which is the TENS application site, was not significantly hindered during walking. While direct measurements of knee movement were not conducted in this study, the absence of negative changes in the recorded gait parameters suggests that the knee movement was likely not substantially altered.

The TENS used in this study did not cross the knee joint, and the electrode application site was below the patella; therefore, muscle contraction around the application site was less likely to occur, reducing the risk of hindering movement, and the shift of the electrodes due to skin stretching was considered to be small. The fact that TENS can be worn continuously without changing gait patterns while reducing knee pain is vital for late-stage elderly individuals to use TENS continuously.

Although TENS is generally effective in reducing knee pain [18] [19] [22] [27], its direct effect on enhancing muscle strength enhancement is limited [22]. When TENS is used for rehabilitation or functional recovery, its primary role is pain management, which makes physiotherapy and exercise more effective. In other words, muscle strengthening by TENS is not direct, but may indirectly support the maintenance or improvement of muscle strength by making exercise and gait training easier through pain reduction. Continuous exercise is essential for maintaining and improving physical function in late-stage elderly individuals [28]. In particular, TENS can provide immediate pain relief for late-stage elderly individuals with chronic knee pain and reduced physical activity, easing the performance of effective gait training and exercise. This contributes to the maintenance of muscle strength, walking ability, and Activities of Daily Living.

This study had several limitations. First, participants were selected solely on the presence of knee pain without a medical diagnosis of conditions such as osteoarthritis. Additionally, as the study population comprised late-stage elderly individuals, measuring the effects under placebo conditions was not feasible because of concerns about the physical impact, and the limited number of participants in the same environment precluded the inclusion of a placebo group. Therefore, further detailed investigations are required. Second, this study evaluated only the immediate effects and did not assess the durability of pain relief provided by TENS. Although the direct pain-reducing effect of TENS is of interest, the potential for long-term improvements in muscle strength to indirectly reduce joint load and pain should also be considered. As gait speed is a representative measure of fundamental physical capacity in the elderly [29] [30], a longitudinal evaluation of gait ability is particularly important. Third, the male-to-female ratio of the study population was imbalanced. Future studies should include a larger sample size and more male participants to explore the long-term analgesic effects of TENS and the trajectory of gait performance.

This study aimed to examine the effects of TENS in elderly patients with late-stage knee pain. Demonstrating the efficacy of TENS in this population provides crucial insights into the continued management of regular exercise and the overall health of late-stage elderly individuals. In future research, pain reduction with TENS may not only maintain and improve ambulation but also increase daily activity and prevent sarcopenia and frailty.

## 5. Conclusion

TENS is effective in relieving knee pain in late-stage elderly individuals and can be safely applied during exercise. Pain management using TENS provides important insights into the implementation of exercise therapy in this age group.

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## Conflicts of Interest

The author Taisuke Ito is affiliated with the Waseda Elderly Health Association Co., Ltd.

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