

Effect of Stress-Free Therapy[®] on Knee Osteoarthritis

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ABSTRACT

This study was aimed to develop a novel, non-invasive treatment system, named "pinpoint planter long-wavelength infrared light irradiation (PP-LILI)", which may be able to reduce pain, and improve visual analogue scale (VAS) scores in patients with knee osteoarthritis (OA). The study involved 10 female patients with knee OA (Japanese adults: average age, 75.0 ± 5.8 years). All patients received PP-LILI on the foot for 30 min once a week for four weeks using a stress-free apparatus (infrared wavelength, 9,000 - 12,000 nm; power, 30 mW). VAS and, range of motion (ROM) were evaluated at 0 and 4 weeks before and after treatment. Japanese Orthopaedic Association (JOA) score was evaluated at 0 and 4 weeks just before the start of the program. In response to therapy, VAS decreased significantly after the 4-week program in the conservative treatment plus PP-LILI group. As for ROM, no statistically significant differences were observed in any of the phases. JOA scores increased significantly after the 4-week program in the conservative treatment plus PP-LILI group. This study suggests that the PP-LILI system can improve VAS and JOA scores of patients with knee OA, reduce pain, and contribute to the treatment of knee OA.

Keywords : pinpoint planter long-wavelength infrared light irradiation (PP-LILI), Stress-free Therapy[®], knee osteoarthritis (knee OA), Visual Analogue Scale (VAS), Japanese Orthopaedic Association (JOA) score

ストレスフリー療法[®]の変形性膝関節症への有効性の検討

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要旨

ピンポイント遠赤外線照射 (PP-LILI) を用いるストレスフリー療法[®] は末梢深部体温を上昇させ、血圧やストレスマーカーを減少させることが証明されている。今回我々は、変形性膝関節症 (以下、膝OA) 患者にストレスフリー療法[®] を施行し、有効性を検討した。大学関連クリニックで保存治療を受けている膝OAの患者、女性6例 (計10膝) (平均年齢75.0 ± 5.8歳) を対象として検討した。ストレスフリー療法[®] 治療器 (遠赤外線波長9000~12000nm/出力30mW) にて、中脛・足三里・F点 (足底) の4か所に30分間の照射を行った。各Phase 0, 2, 4週間目に施療直前・直後の関節可動域 (以下、ROM), Visual Analogue Scale (以下、VAS) を測定した。JOA scoreは各Phaseの0週の施療前、4週の施療前に測定した。VASは保存治療にPP-LILIを併用した群で有意な改善を認めた。ROMは統計的有意差を認めなかった。JOA scoreは保存治療にPP-LILIを併用した群で有意な改善を認めた。膝OA患者において保存治療にPP-LILIと併用した群でVASとJOA scoreで有意な改善を認めた。ストレスフリー療法[®] は今後、膝OAの臨床症状の改善を期待できる有効な治療法になる可能性があることが示唆された。

キーワード：ピンポイント遠赤外線照射 (PP-LILI), ストレスフリー療法[®], 膝OA,

Visual Analogue Scale (VAS), JOA score

INTRODUCTION

We recently reported on the effects of Stress-free Therapy[®] (Registered Trademark No. 5495960) consisting of PP-LILI, which increases peripheral deep-body temperature and decreases blood pressure and stress markers.¹⁾ Knee OA, characterized by destruction of articular cartilage, is one of the most common diseases. Muscle weakness, pain, and limitation of ROM, are among the major health issues faced by patients with knee OA. Symptoms worsen with disease progression, eventually impair daily activities, such as walking, squatting, and running. Knee OA leads to other health problems due to restricted mobility. The goals of knee OA treatment include reducing pain, improving joint function, and restoring quality of life and ability to perform daily activities.²⁾ We evaluated the efficacy of PP-LILI Stress-free Therapy[®] on pain, VAS, ROM, and JOA scores of patients with knee OA.

MATERIALS AND METHODS

The study involved 10 female patients with knee OA (average age, 75.0 ± 5.8 years). All patients received conservative treatment (physical therapy). Patients with knee OA (N = 10) successively underwent three different phases of treatment: 1) a conservative treatment group (Phase 1); 2) a conservative treatment

plus placebo group (Phase 2); and 3) a conservative treatment plus PP-LILI group (Phase 3) (Figure 1). Four points were irradiated for 30 min once a week for four weeks using a stress-free apparatus (Controlled-Medical – Device – Approval – No. 224 AFBZX00075000; probe diameter, 20 nm; infrared wavelength, 9,000 – 12,000 nm; power, 30 mW) Four parts of irradiation regions were as follows: the bilateral pinpoint planters were the intersections of the centers of the heads of the first and second metatarsal bones of the sole and a vertical line drawn from the medial malleolus; the remaining points were placed on acupuncture points, with one on the Zusanli point (World Health Organization [WHO] established number, ST36), i.e., at the outside of left knee, and the other one on the Zhongwan point (WHO established number, CV12), i.e., at the center between the lower end of the sternum and the umbilicus (Figure 2). Pain was assessed using the VAS scale on a scale of 1–10. The ROM of the knee was measured in a supine position using a goniometer (passive motion between maximal extension and flexion). VAS and, ROM were evaluated at 0 and 4 weeks before and after treatment in each phase. JOA score was evaluated at 0 and 4 weeks just before the start of the program in each phase. Statistical evaluation was performed using the sign test and the paired t-test. *P* values < 0.05 were considered statistically significant. This study was conducted after review and approval (2304) by the Ethics Committee of Ryotokuji University. Written informed consent was obtained from each patient after a full explanation of the nature and aims of the study.



Figure 1.

- Phase 1 : Conservative treatment group
- Phase 2 : Conservative treatment plus placebo group
- Phase 3 : Conservative treatment plus PP-LILI group

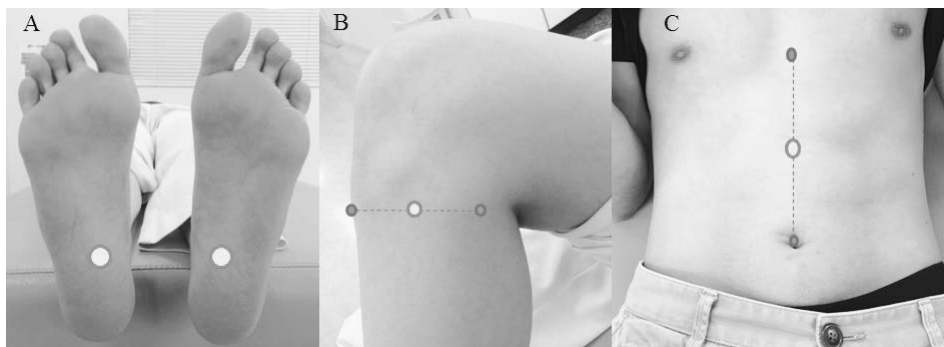


Figure 2. Stimulation Points.

The four irradiation regions were as follows: the bilateral pinpoint planters were the intersections of the centers of the heads of the first and second metatarsal bones of the sole and a vertical line drawn from the medial malleolus (A) ; the remaining points were placed on acupuncture points, with one residing on the Zusanli point WHO established number, ST36) , i.e., at the outside of left knee (B), and the other one on the Zhongwan point (WHO established number, CV12), i.e., at the center between the lower end of the sternum and the umbilicus (C).

RESULTS

Changes in Visual Analogue Scale (VAS)

We evaluated VAS scores at week 0 (0W), and week 4 (4W) just before and just after of the treatment in all phases. We set VAS to 10 just before of all treatments, and obtained the following results. For Phase 1 patients (conservative treatment group), the mean VAS score were 5.50 ± 1.65 (mean \pm standard deviation (SD)), and 5.50 ± 1.65 at 0W and 4W after treatment, respectively. Similarly, for Phase 2 patients (conservative treatment + placebo group), the mean VAS score were 5.40 ± 1.65 , and 5.40 ± 1.65 at 0W and 4W after treatment, respectively. For Phase 3 patients (conservative treatment + PP-LILI group), the mean VAS score were 5.40 ± 1.65 , and 4.50 ± 2.59 at 0W and 4W after treatment, respectively. A significant decrease ($P = 0.027$) was observed in after-treatment scores only in Phase 3 (Figure 3).

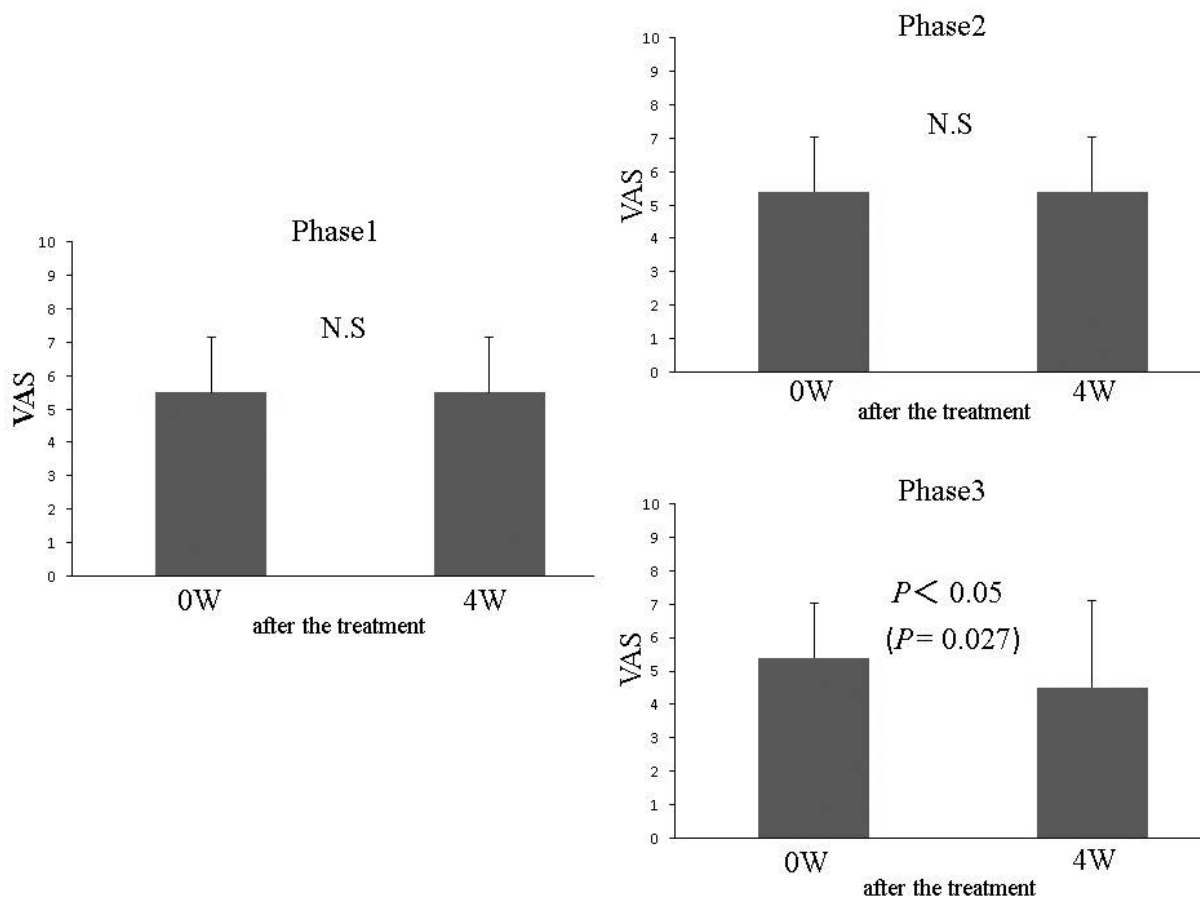


Figure 3. Changes in Visual Analogue Scale (VAS) score. (mean \pm SD, N = 10)

Phase 1 : Conservative treatment group

Phase 2 : Conservative treatment plus placebo group

Phase 3 : Conservative treatment plus PP-LILI group

Changes in passive range of motion (ROM)

We examined passive ROM just before and just after of the treatment in all phases, and obtained the following results. For Phase 1 patients (conservative treatment group), the mean passive ROM score were -4.00 ± 8.76 (mean \pm SD), and 0 at 0W and 4W after treatment, respectively. For phase 2 patients (conservative treatment + placebo group), the mean passive ROM score were 0.50 ± 1.58 , and 0.50 ± 1.58 at 0w and 4W after treatment, respectively. For phase 3 patients (conservative treatment + PP-LILI group), the mean passive ROM score were 0.50 ± 1.58 , and 1.00 ± 2.11 at 0w and 4W after treatment, respectively. No statistically significant differences were observed in after-treatment scores in any of the phases (Figure 4).

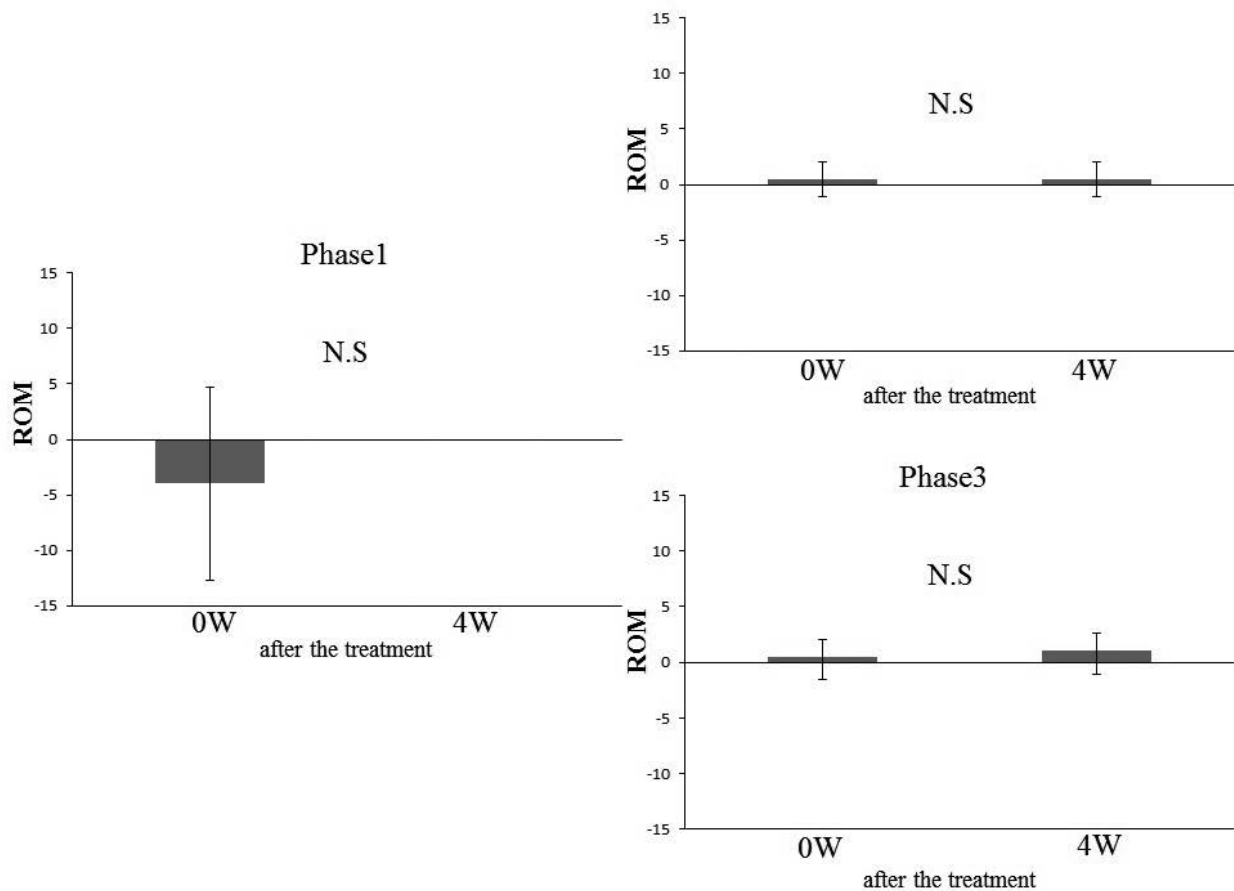


Figure 4. Changes in ROM (passive) score. (mean \pm SD, N = 10)

Phase 1 : Conservative treatment group

Phase 2 : Conservative treatment plus placebo group

Phase 3 : Conservative treatment plus PP-LILI group

Changes in Japanese Orthopaedic Association (JOA) score

Analysis of JOA scores revealed the following results. For phase 1 patients (conservative treatment group), the mean JOA score were 73.0 ± 9.78 (mean \pm SD), and 72.0 ± 9.78 at 0w and 4W just before the start of the treatment, respectively. For phase 2 patients (conservative treatment + placebo group), the mean JOA score were 73.0 ± 9.78 , and 72.0 ± 9.78 at 0W and 4W just before the start of the treatment, respectively. For phase 3 patients (conservative treatment + PP-LILI group), the mean JOA score were 73.0 ± 9.78 , and 76.0 ± 12.2 at 0W and 4W just before the start of the treatment, respectively. A significant increase ($P = 0.025$) was observed in before-treatment scores only in phase 3 (Figure 5) .

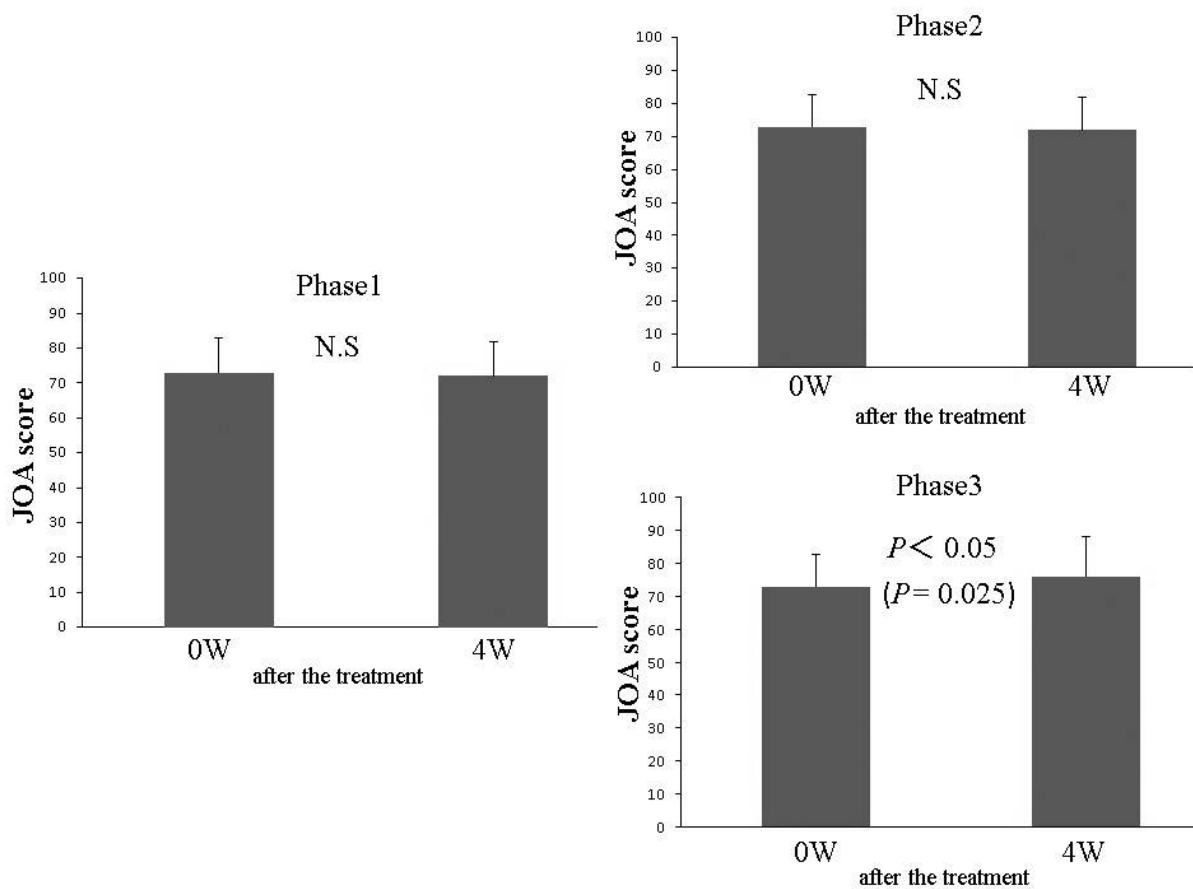


Figure 5. Changes in JOA score. (mean \pm SD, N = 10)

Phase 1 : Conservative treatment group

Phase 2 : Conservative treatment plus placebo group

Phase 3 : Conservative treatment plus PP-LILI group

DISCUSSION

OA is the most common disease of the joints; it is associated with cartilage and subchondral bone destruction, plus inflammation of the synovial membrane as well as with joint malfunction and chronic disability in the elderly. The pain experienced by patients with OA is a severe problem, causing immobility and restricting daily activities. The aim of current OA therapy is the pain control. Physiological stress

stimulates the sympathetic nervous system, causes vasoconstriction, and reduces microcirculation in the body. Moreover, the hypothalamus is stimulated to secrete corticotropin-releasing hormone (CRH), which induces the release of adrenocorticotrophic hormone (ACTH) and glucocorticoid cortisol from the anterior pituitary gland and the adrenal cortex, respectively.³⁾ High concentrations of ACTH were observed during pain after hip or knee arthroplasty, and the level of ACTH release correlates with the severity of postoperative pain.⁴⁾ Plasma ACTH also decreases during mud therapy that has been used to treat diseases since ancient times. Levels of plasma cortisol decreased significantly after only a single session of mud therapy in patients with OA.⁵⁾ We reported that Stress-free Therapy[®] consisting of PP-LILI increased the peripheral deep-body temperature and decreased the blood pressure and the level of stress markers.¹⁾ In response to Stress-free Therapy[®], both, a significant decrease in VAS scores and an increase in JOA scores was observed in patients with knee OA. Taken together, these results suggest that Stress-free Therapy[®] suppresses stress hormones and decreases the physiological stress in patients with knee OA.

OA is caused by various mediators, of which the key role is attributed to interactions within the cytokine network. Being among the critical mediators, inflammatory cytokines, including IL-1- β , TNF, IL-6, IL-15, IL-17, and IL-18, are considered as the most important mediators of processes implicated in OA pathophysiology. Anti-inflammatory cytokines, such as IL-4, IL-10, and IL-13, are also thought to be important mediators.⁶⁾ These three cytokines inhibit the synthesis of inflammatory cytokines, such as IL-1, TNF- α , and IL-1- β in OA.⁷⁾ IL-1- β and TNF are the predominant proinflammatory cytokines involved in OA. Levels of IL-1- β and TNF are elevated in the synovial fluid, synovial membrane, subchondral bone, and cartilage in patients with OA.⁸⁾ IL-1- β suppresses type II collagen⁹⁾ and aggrecan expression in chondrocytes.¹⁰⁾ TNF suppresses the synthesis of proteoglycan, link protein, and type II collagen in chondrocytes.¹¹⁾ IL-1- β and TNF stimulate the release of matrix metalloproteinase-1 (MMP-1), MMP-3, and MMP-13 in chondrocytes.^{12, 13)} These three proteases are important regulators of cartilage and subchondral bone destruction. IL-1- β and TNF- α expression in osteoarthritic chondrocytes of rats were significantly down-regulated in acupuncture group.¹⁴⁾ IL-6 is also an important proinflammatory cytokine involved in OA pathophysiology. Levels of IL-6 are found to be increased in synovial fluid and sera obtained from patients with OA.¹⁵⁾ IL-6 collaborates with IL-1- β and oncostatin to upregulate MMP-1 and MMP-13 expression in bovine and human cartilage explant cultures.^{16, 17)} IL-6 and sIL-6R reduce the expression of type II collagen in chondrocytes.¹⁸⁾ Low-level laser therapy with 50 mW was efficient in decreasing the expression of IL-1- β and IL-6 on joint inflammation in rats.¹⁹⁾ IL-17 is a proinflammatory cytokine which is considered an important mediator in the OA pathophysiology. IL-17 downregulates chondrocytes proteoglycan synthesis in intact murine articular cartilage, which is considered to be mediated by nitric oxide.²⁰⁾ IL-17 and IL-1- β induce MMP-13 production in OA chondrocytes mainly through AP-1-mediated transcriptional activity.²¹⁾ IL-10 is an anti-inflammatory cytokine. PP-LILI elevated IL-10 levels in healthy volunteers.²²⁾

Recently, we reported that PP-LILI is a useful approach for elevating peripheral deep-body temperature and decreasing blood pressure. PP-LILI also suppressed the secretion of stress markers, such as ACTH, salivary amylase, and cortisol. We are now applying PP-LILI as Stress-free Therapy[®] to type 2 diabetes

mellitus patients for prevention of vascular dementia and Alzheimer's disease and to patients with metabolic cardiovascular disease.^{23, 24)} We reported that PP-LILI is useful for normalizing blood glucose levels by reducing stress hormones, such as cortisol, and by improving insulin sensitivity.²⁵⁾ Moreover, we found that this therapy significantly increases cerebral blood flow in patients with metabolic cardiovascular disease.²³⁾ We reported that PP-LILI is useful in increasing blood flow to the facial artery, elevating high-density lipoprotein cholesterol levels, and reducing insulin resistance.²⁴⁾ We expect Stress-free Therapy[®] to play a major role in the prevention and treatment of knee OA. We are currently planning to evaluate further analyses for the mechanism and the efficacy of Stress-free Therapy[®].

CONCLUSIONS

This study demonstrated that the PP-LILI system is effective in improving VAS and JOA scores in patients with knee OA, thereby improving daily activities. Consequently, it may contribute to the prevention and treatment of knee OA.

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