COMBINATION THERAPY COMPRISING LOW LEVEL LASER THERAPY (LLLT) AND BRACE THERAPY FOR CHRONIC LOWER BACK PAIN PATIENTS

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Low Level Laser Therapy (LLLT) in combination with a sacroiliac brace was used on 33 patients with chronic lower back pain to examine the effectiveness of this combination therapy A semiconductor laser (1000 mW, CW, 830 nm) was used. Due to the short duration effect of LLLT previously reported, we tested the effect of combination therapy using LLLT and a sacroiliac brace. Our results showed that the number of patients who had lower back pain in their activities of daily living (ADL) or work decreased, and this combination therapy improved both their ADL and quality of life (QOL). Chronic lower back pain patients who had just started visiting our hospital obtained satisfactory results with LLLT but the latency period was short. In order to maintain the effects of LLLT, we controlled the patients' posture with a sacroiliac brace, which was able to prevent chronic pain for a longer period. The combination treatment was well-tolerated, side-effect free and offered good efficacy in improving both pain and range of motion of the lumbar spine.

Key Words: Spinal disease, combination therapy, sacroiliac brace, laser therapy

Introduction

Chronic lower back pain is one of the most frequent troubles which we see in the outpatient clinic in our institute. We define chronic pain in this report as "pain which lasts for three to six months or longer, the inflammation or tumor of which can be excluded by medical check-ups, and whose cause is not something that requires surgery". Chronic pain can be very debilitating, and decreases patients' Activities of Daily Living (ADL) and Quality Of Life (QOL). Very often patients

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Regarding the effect of Low Level Laser Therapy (LLLT) on chronic lower back pain, the short duration of the effect, also known as the treatment latency, has reportedly been a problem $^{1-4)}$. It therefore makes sense to use LLLT in combination with some other form of therapy to increase the treatment latency period. In many cases, chronic lower back pain is caused by ADL or work posture changes. This study was thus designed to assess the efficacy of LLLT used in combination with a readily available sacroiliac brace designed by ourselves to prevent chronic lower back pain caused by these factors, and to maintain the treatment latency of the LLLT.

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Case	Age	Sex	Diagnosis	Pa Pre	in Score (V Post	AS)* Rating	Pre	FFD (cm)** Post	Rating
1	60	F	Spinal canal stenosis	70	30	Е	15	15	Р
2	50	F	Spondylolysis	60	40	G	2	0	Р
3	56	F	lumbago	50	50	Р	15	10	G
4	72	F	lumbar disc lesion	60	40	G	3	1	Р
5	70	М	lumbar disc hernia	40	40	Р	10	10	Р
6	60	М	spondylolisthesis	60	40	G	12	10	F
7	59	М	spinal canal stenosis	70	50	G	25	20	F
8	40	F	lumbar disc hernia	60	50	F	5	0	F
9	55	F	spondylolisthesis	50	50	Р	10	5	F
10	70	М	spinal canal stenosis	70	40	E	30	10	Е
11	53	М	spinal canal stenosis	70	60	F	10	8	Р
12	63	F	lumbar disc hernia	70	70	Р	0	0	Р
13	59	М	spondylolisthesis	70	50	G	20	10	G
14	54	F	lumbar disc lesion	30	20	F	20	15	F
15	54	F	lumbago	90	50	E	50	20	Е
16	65	М	spinal canal stenosis	40	20	G	30	20	G
17	64	F	lumbago	40	40	Р	20	10	G
18	39	М	lumbago	70	50	G	50	40	G
19	70	F	spondylolisthesis	40	20	G	0	0	Р
20	26	М	lumbago	90	70	G	50	30	Е
21	50	F	spondylolisthesis	40	30	F	10	0	G
22	55	F	lumbago	40	30	F	10	5	F
23	60	F	lumbar disc hernia	30	20	F	10	10	Р
24	70	F	lumbago	80	60	G	25	15	G
25	62	М	lumbar disc hernia	40	20	G	20	5	G
26	63	F	lumbar disc hernia	50	40	F	10	0	G
27	65	М	spondylosis deformans	40	30	F	30	5	G
28	48	М	lumbago	70	30	E	25	0	Е
29	49	F	lumbar disc hernia	60	50	F	20	5	G
30	48	М	lumbar disc hernia	30	30	Р	10	0	G
31	69	М	lumbar disc lesion	20	20	Р	15	0	G
32	47	М	lumbago	30	20	F	40	35	F
33	59	F	lumbago	60	30	E	30	30	Р

Table 1. Case Outlines and results

*VAS; Visual Analogue Scale: **FFD; Fingertip-Floor-Distance: Pre; Before treatment:

Post; After 10 weeks' treatment: E: excellent; G; good: F; fair: P; little or no change

Note that patients 1, 5, 12, 19, 23 and 33 had a zero score for their pretreatment and posttreatment FFD,

and have therefore been excluded from the comparisons for the FDD ratings.

[Subjects and Methods]

Subjects

Thirty-three patients with chronic lower back pain were treated at the rehabilitation department of our hospital, including eighteen female patients and fifteen male patients. Their ages ranged from twenty-six to seventy-two, with an average of 57.1 years **(Table 1)**. Their low back pain had been present for an average of 4.5 months (range 3 to 6 months). As for the diseases involved, lumbago was seen in 10 patients, lumbar hernia in 8, spondylolisthesis and spinal canal stenosis in 5 each, lumbar lesions in 3 and spondylolysis in 2 **(Table 2)**. The most frequent cause was agerelated chronic back pain without any neurological basis.

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Methods:

1. Low Level Laser Therapy (LLLT):

We used a semiconductor laser treatment device delivering 1000 mW (Fig. 1) ⁵⁾, all specifications being shown in **Table 2** (MDL-2001, Matsushita Electric Corporation, Tokyo, Japan). The LLLT treatment points were tender points on the lower back and the sacroiliac bone (four points) with two 30-s treatments on each point (total irradiation time per session 4 min per patient), giving a radiant fluence (energy density) of 20.1 J/cm^2 per point per irradiation, twice weekly for 10 weeks. The laser used in the contact mode. We

evaluated the treatment effect after the tenth treatment. The target points are shown in **Fig. 2**.

Pain attenuation was assessed using a 101 point visual analog scale (VAS) where 100 was the worst pain and zero was pain-free. The result was assessed as excellent (30 point improvement or more), good (20 – 29 point improvement), fair (10 – 19 point improvement), little or no change (0-9 point improvement) and worse (exacerbation of pain). As for the range of trunk motion, the fingertip to floor distance (FFD) (**Fig. 3**) was used. An improvement of 20 cm or over in the FFD was rated as excellent, 10-19 cm as good, 5-9 cm as fair, 0-4 cm as little or no change and an increase in



Fig. 1: The LLLT device used in the present study

 Table 2. Low Level Laser Therapy device Specification

Laser Element	Semiconductor Laser Diode		
	Ga-Al-As : Gallium-Aluminum-Arsenide		
Model &	MDL-2001 model		
Manufacturer	Matsushita Electric Corporation,		
	Tokyo, Japan		
Wavelength	830 nm±15 nm		
Output	1000 mW±20%		
Mode	Continuous wave mode		
Irradiation time	30 sec		
Energy density	20.1 J/cm ²		
Power Supply	100 VAC, 50-60 Hz		



Fig. 2: LLLT irradiation points COMBINATION THERAPY FOR LOWER BACK PAIN



Fig. 3: Fingertip to floor distance (FFD)

FFD as worse.

For those patients who failed to score excellent or good in both the VAS or FFD scores, use of the sacroiliac brace was continued for 4 weeks after the study to help improve their result, and they were assessed after that 4-week period.

2. Sacroiliac brace (Fig. 4)

This brace, invented by our department, enables stabilization of the sacroiliac joint by controlling the patient's posture.

Distinctive Features:

- 1. It adjusts to the body very well because it is made of compressed urethane.
- 2. There are two 100 g "weights" in the back placed over the sacroiliac joints.
- 3. It supports the lower abdominal muscles.
- 3. Having informed patients about the trial and its purpose, we received written informed consent from all patients and their families to partici-

pate in the study as one of the criteria of participation.

4. Statistical Analysis (of LLLT treatment)

Statistical verification of VAS and FFD improvements after laser irradiation was performed with Wilcoxon's signed rank sum test, using SPSS8.1 J for Windows. Values below five% were deemed significant.

Results

We treated 33 chronic lower back pain patients with combination therapy of LLLT and a sacroiliac brace to ease their severe chronic pain.

1. Results of the combination treatment are shown in Tables 1 (overall scores), 3 (VAS) and 4 (FFD). According to the VAS results, 5 patients were evaluated as excellent, 11 as good, 10 as 'fair', and 7 as little or no change. No patient got worse. Combining the excellent and good scores gave an overall efficacy



a : frontal view



b: lateral view



c : rear view (dorsal view) Fig. 4: Views of the sacroiliac brace developed in our institute

in the VAS of 48.5%. According to the FFD results, 4 patients were evaluated as excellent, 12 as good, 9 as fair, and 10 as little or no change. No patient got worse, and patients 12 and 19 were omitted from the scoring because they had a zero score both before and after treatment, so their improvement could not be rated. The overall efficacy in the FDD was calculated as 51.6%. In 9 of the 33 patients, excellent or good scores were seen in both the VAS and FFD **(Table 1)**.

In the 17 patients who achieved fair or poor scores in the VAS assessment, use of the sacroliliac brace alone was continued for 4 weeks, and the results evaluate. In 13 of these patients, the VAS rating improved to good. Three of the 17 patients complained that they were unable to get keys, coiuns and so on out of their trouser pockets because of the position of the prace, and 1 patient complained that the weights fitted to the back of the brace were too heavy. 2. Statistical Analysis of the LLLT treatment results

The VAS improved significantly (p<0.001) after laser irradiation, and the FFD improved significantly (p<0.001) after laser irradiation (Wilcoxon's signed rank sum test).

Discussion

Chronic lower back pain is not caused solely by to spinal diseases and it is important also to consider the possibility of non-orthopaedic diseases. In gynecology, for instance, as pregnancy progresses, lumbar lordosis worsens, which causes lower back pain. In internal medicine, lower back pain as referred pain from pancreatic or renal diseases are not uncommon. In urology, renal diseases are also often complicated with chronic lower back pain. In surgery, chronic inflammatory diseases of the retroperitoneal organs cause lower back pain as well. From the psychological standpoint lower back pain is an indefinite complaint which can be caused by psychosomatic conditions. When chronic lower back pain is to be treated, it is therefore important carefully to rule out non-orthopaedic diseases as differential diagnoses.

Among the many orthopaedic diseases that are associated with lower back pain are chronic intervertebral disc hernia and other lesions, spondylolysis, and spinal canal stenosis, spinal tumors, inflammation, and trauma. With regard to these typical diseases, very few cases need urgent surgery. As a general rule, conserva-

The score is 100 when the pain is the most severe.	
The score is 0 when there is no pain.	

Table 3. Visual Analogue Scale(VAS)

Evaluation	Improvement Score of Pain after LLLT Irradiation	Number of Cases
• Excellent	30 and over	5
• Good	20 - 29	11
• Fair	10 – 19	10
 Poor/Unchanged 	9 or under	7
• Worse		0

Table 4. Fingertip to Floor Distance(FFD)

To indicate the degree of improvement in the FFD, we measured the distance between the fingertips and the floor when the patient bent over. For example, when the FFD was 30 cm before LLLT irradiation and 10 cm after the irradiation, the degree of improvement in the FFD was assessed as 20 cm.

Evaluation	FFD improvement degree	Number of Cases
• Excellent	20 cm or over	4
• Good	10 – 19 cm	13
• Fair	5 -9 cm	7
 Poor/Unchanged 	0-4 cm	9
• Worse		0

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tive treatment is considered appropriate in many cases, which generally includes medication, thermotherapy, pelvic traction, electrical therapy, and bracing.

However, medication easily causes harmful side effects such as digestive problems or allergies. With thermotherapy, there is the potential for scald injury. With pelvic traction, the appropriate weight has to be ascertained on a patient-by-patient basis. Electrical therapy requires a skilled and trained parctitioner. As for bracing, although generally a lumbar corset is traditionally used, the problem is the complicated way of bracing because of the large size of these garments ⁶, ⁷).

With Low level laser therapy (LLLT) combined with sacroiliac bracing as described in the present study, good results were achieved. From the literature, when LLLT treatment is used as monotherapy, the effect lasts for only six to twelve hours in the worstcase scenario, and patients need frequent outpatient treatment to control their lower back pain 8,9,10). In many cases, it is difficult for patients to attend the outpatient department as frequently as required due to a busy life style through ADL or work. To deal with such patients we started sacroiliac brace treatment when LLLT treatment did not have sufficient latency. Using the sacroiliac brace that we invented, we achieved satisfactory results in controlling lower back pain ¹¹). We were pleased to see when we could ease the chronic lower back pain with LLLT in a relatively short period. However, sacroiliac brace treatment was found to be

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especially effective with patients whose chronic lower back pain had lasted for a long period due to work posture or housework.

The efficacy in the present study was diseaserelated, and this has to be taken into consideration. Lumbar disk hernias and lesions seemed to respond worst, whereas spinal canal stenoses and lumbago in general responded very well. Perhaps prolonged treatment with our combined therapy would have better results in the recalcitrant conditions, and further studies are warranted.

Our study has limitations. A larger patient population would lend greater statistical power. We did not have controlled groups to compare the efficacies of LLLT on its own and the sacroiliac brace on its own. We also did not have follow-up periods after the 10week treatment to assess the post-therapy latency of the combination treatment. Further studies are however warranted based on the efficacy seen in the preset study.

Conclusions

The combination therapy described herein comprising twice-weekly treatment over 10 weeks with an LLLT system and a sacroiliac brace over was well-tolerated and effective in both attenuating pain and increasing lumbar range of motion for patients with a variety of conditions associated with chronic spinal pain.

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