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ORIGINAL ARTICLES

A new standard of Efficacy for Low Level Laser Therapy (LLLT) in Pain Attenuation in Japan (a secondary publication)

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The assessment of the efficacy of low level laser therapy (LLLT) for pain attenuation varies among institutions, all having their own method of assessment with no common standards. At the author's institution in the beginning, the patients were asked how they assessed their pain relief immediately after the treatment. They were to choose from excellent, good, fair, no change and poor. The overall efficacy rate was calculated by the numbers of patients scoring excellent and good, expressed as a percentage of the total number of patients.
However, a large number of institutions have utilized the Visual Analogue Scale (VAS) or the Pain Relief Score (PRS) for the assessment of treatment; but even then, the evaluation could not be considered uniform. Therefore, the standardization of the efficacy rate was continuously discussed among the practitioners of LLLT, dating back to the 9th annual meeting of the Japan Laser Therapy Association (JaLTA) in 1997. It took four years (including the 1997 meeting) until finally an agreement was reached and a new standard of efficacy was presented at the 12th JaLTA meeting in 2000, based on the PRS.
The new standard defined excellent as pain reduction in any treatment session from 10 to 0 or 1, good as reduction from 10 to 2~5, fair as reduction from 10 to 6~8, no change as a reduction from 10 to 9~10 and poor was defined as exacerbation of pain from 10 to 11 or greater. Efficacy rate was calculated by the number of patients scoring excellent and good expressed as a percentage of the total number of patients. For the purpose of reference, the VAS was to be used for patients receiving the treatment for the first time.

Introduction

In 2012, after the banquet held at the 24th Japan Laser Therapy Association (JaLTA) meeting, the first had the opportunity to speak with many past presidents and presidents-elect concerning the contents of the 25th meeting which was held in 2013. At this gathering, Dr. Yoshida, who presided over the 25th meeting, asked us all what he should do for the 2013 JaLTA Silver Anniversary (25 years) meeting. The discussion resulted in the reconsideration of the method for the evaluation of the efficacy for pain attenuation with LLLT. The reason for this is that although the Association had taken four years (from the 9th to the 12th meeting) to create a standard, it had not been reflected in recent papers. Therefore a symposium was planned for the Silver Anniversary meeting to discuss whether the standard is best left as it is, or should a new standard for the new era be created. The role of the first author was to speak about the standard, from a view point of a primary member who was involved in its creation, and the current paper summarizes this presentation.

The first Author and Low Level Laser Therapy (LLLT)

The first author started LLLT for pain attenuation in the

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Received Date: April 10th, 2014
Accepted Date: August 25th, 2014

* This article is based on a study first reported in The journal of Japan Laser Therapy Association, Vol. 12.2:43-48, 2013

spring of 1984 which was before this Association was even founded (the first meeting was held in 1989), under the tutelage of Dr. Toshio Ohshiro, the second author, the Clinical Director of the Ohshiro Clinic, President of the Japan Medical Laser Laboratory and one of the founders of JaLTA. The result was very favorable and the first author presented the result of LLLT in 670 pain patients at the 5th congress of the Japan Society for Laser Surgery and Medicine (JSLSM) held at Sapporo in November 1984. The following year, in 1985, the first author's presentations at meetings and conferences in Hawaii, Tokyo and Kurume aroused numerous questions and debates concerning LLLT. By November of that year, Professor Kazuhiko Atsumi, who at the time was the Fellow of the American College of Surgeons (FACS) of Tokyo University Faculty of Medicine, Institute of Medical Electronics, and his wife, a medical doctor, came to visit the first author's institution and to observe the actual treatment. Originally the visit was planned for just the morning hours, but Professor Atsumi requested an extension of the stay until the evening, where he monitored the treatments extensively while his wife interviewed the patients in the office. The treatment method at the first author's institution was convincing enough for Professor Atsumi to allow the first author to treat the Professor's chronic frozen right shoulder whereafter he was able raise his right arm which he had not been able to do for several years. After the treatment, Professor Atsumi judged that what the first author had presented was, in fact, true. During the drive to the airport for the return Prof. Atsumi and his wife to Tokyo, Dr. Atsumi told the first author to join him and also to make a presentation at the 6th congress of the American Society of Laser Surgery and Medicine being held at Boston, in May 1986.

The course of events during that time led the first author to believe deeply within himself that the treatment method and the method of its evaluation were correct in all aspects. The first author used the same method of evaluation and reported the results repeatedly at congresses and meetings both in Japan and abroad.

Original Method of Evaluation and its Reconsideration

During the earlier years, the first author asked the patients about the efficacy of the treatment, immediately after the treatment on a five-point scale: excellent, good, fair, little or no change and poor. Efficacy was rated by the combined numbers of patients scoring excellent and good, leaving out the unstable "fair" evaluation, expressed as a percentage of the total patient population. The first author's early results gave a very high efficacy rate of 83.6% **(Table 1)**. However, at the 6th annual meeting of JaLTA (1994), Dr. Satoru Takeyoshi, who would become the president of the 8th annual meeting, and who at the time was the head of the department of anesthesiology, Matsuyama Red

Table 1: Treatment Efficacy

April, 1984-February, 1997

Disorder	Number of cases	Efficacy (%)					Efficacy Rate(%)
		extremely effective (+++)	effective (++)	somewhat effective (+)	no change (±)	exacerbation (-)	(+++)+(++)
myalgia	10,935	40.8	43.0	13.7	2.5		83.8
lumbago	8,077	42.3	42.1	13.1	2.5		84.4
osteoarthritis of the knees	3,630	54.6	35.2	8.6	1.6		89.8
peri-arthritis of the shoulders	2,208	38.9	44.0	14.9	2.2		82.9
sciatic neuralgia	1,373	40.5	42.9	14.0	2.5	0.1	83.4
rheumatism	775	25.3	45.1	25.9	3.7		70.4
dysthesia	452	28.7	51.3	16.3	3.7		80.0
arthritis of the elbows	355	32.1	38.8	20.1	9.0		70.9
tenosynovitis	200	32.6	28.6	23.0	5.8		61.2
tinnitus	120	24.4	46.1	21.7	7.8		70.5
trigeminal neuralgia	106	20.7	29.2	37.2	12.9		49.9
costal neuralgia	81	48.9	45.5	2.8	2.8		94.4
occipital neuralgia	91	30.9	53.1	13.6	2.4		84.0
total	28,403	42.0	41.6	13.7	2.7	0.0	83.6

Cross Hospital, pointed out to the first author that such a method of evaluation was unreliable. At the Japan Society of Pain Clinicians, such problems associated with the evaluation of efficacy had been posed earlier, but the first author, who regrettably only participated in meetings of the JSLSM and JaLTA, continued to use this less than precise method of evaluation, until February of 1997.

After listening to Dr. Takeyoshi's statement, the first author contemplated changing his method of evaluation, but was reluctant to do so. The first author was elected as president for the 9th annual JaLTA meeting and felt that it was important to continue with the previous evaluation method and report the results using a consistent method. As a result, revision of the evaluation method was prolonged even further.

At the time though, the first author has overlooked few very important points. In April, 1992, just before the 4th annual JaLTA meeting (July, 1992. Presided over by Dr. Osamu Kenmotsu, FACS, Department of Anesthesiology, University of Hokkaido) a book was published entitled "Diode Laser and the Treatment of Pain Illustrated" (Medical View Inc. edited by Dr. Kenmotsu), where it was stated that the evaluation of treatment efficacy was to use the pain relief score (PRS). [1] The PRS starts each pain treatment session with a score of 10, and the patient scores their pain relief on a descending scale to zero (pain free). "Effective" was deemed as a pain reduction from 10 to 7 or less. This was more precise than Dr. Takeyoshi's previous statement, which was that effective should be a pain reduction from 10 to 5 or less.

In April 1996 a second edition of the book (again edited by Dr. Kenmotsu) was released. [2] In this edition the recommended evaluation of the efficacy of laser therapy for pain was to use a visual analog scale (VAS) to determine the pain score and a reduction from 10 to 7 or less was considered effective.

Looking back at it now, all respective institutions had their own method of evaluation and no standardized method existed at the time.

The Process of Creating a Standard within JaLTA

At the 8th annual meeting presided over by Dr. Satoru Takeyoshi, held in 1996, [3] a plenary lecture titled "How to evaluate the treatment efficacy for pain: From the experience at an anesthesiologist's pain clinic" was presented by Dr. Takefumi Yuge, FACS, Department of Anesthesiology and Resuscitation, Hiroshima University, Faculty of Medicine. The main theme of this lecture was on how to achieve objectivity of treatment results in the pain clinic setting. Dr. Yuge spoke of many facets of evaluating pain, such as VAS, Face Score, Thermography and Activities of Daily Living (ADL). However, he did not give any definitive conclusion, stating only "… that this is the starting line for the search of indices for pain attenuation treatment efficacy".

This lecture had an enormous impact on the first author, who could almost believe that this lecture had been planned for his sake. However, there was not enough time for the first author to change his evaluation method and upon presiding at the 9th annual meeting [4], the first author felt a strong need to include a symposium on the evaluation of treatment efficacy and had asked many doctors for their cooperation for the discussion.

The symposium was titled "The evaluation of treatment efficacy for the treatment of pain by LLLT". This symposium was moderated by Dr. Kenmotsu and Dr. Satoru Takeyoshi, head of the Department of Anesthesiology, Matsuyama Red Cross Hospital. The speakers were Dr. Rie Numazawa from the Department of Anesthesiology, Hokkaido University; Dr. Takeyoshi the moderator, Dr. Hiroshi Terashima from the Department of Orthopedics, Toho University; Dr. Kousei Yang from the Department of Orthopedics, Hyogo College of Medicine; Dr. Junichi Obata from the Japan Rheumatism and Laser Laboratory; Dr. Setsuro Ogawa from the Department of Anesthesiology, Nihon University and Dr. Ryuzou Shiobara from the Department of Neurosurgery, Keio University. Although no definitive conclusions were drawn at this meeting, a general agreement on the direction where the Association was heading was however reached. There were numerous opinions related to VAS, PRS, ADL and the Quality of Life (QOL) scoring systems, all having their merits and shortcomings. The most voiced opinion was for the use of the VAS, PRS or both. The response to this symposium was sensational. A consensus was reached that such a discussion should be continued, and the same symposium was planned for the next year.

The 10th annual meeting was held in 1998, under the presidency of Dr. Hajime Suzuki, FACS of the Department of Anesthesiology, Nihon University (at the time, the Director in chief of Surugadai Nihon University Hospital). [5] Again the symposium "The evaluation of treatment efficacy for the treatment of pain by LLLT" was placed on the program.

The speakers were the first author; Dr. Kouji Ohtsuka from the Department of Anesthesiology,

Hokkaido University; Professor Isao Matsumoto from the Department of Anesthesiology, Saitama Medical University; Dr. Takeyoshi and Dr. Terashima for the second straight year, and also the president of the 2013 25th annual meeting, Dr. Kenji Yoshida from the Aichi Gakuin University, School of Dentistry. The symposium was moderated by Dr. Satoru Takeyoshi and Dr. Setsuro Ogawa.

President Suzuki, a giant in the field of anesthesiology, had a definitive opinion that the VAS should be used, the basis being that the Japan Association for the Study of Pain had debated the subject for the previous 20 years and had decided on using the VAS. However the President also stated that diagnosis of pain should not solely rely on the VAS, and that a more general judgment should be made for a diagnosis.

Dr. Kazuhiko Iijima, former assistant professor of the Department of Anesthesiology, Chiba University and the Director of Makuharidai Clinic; and Dr. Obata, the Director of Japan Rheumatism and Laser Laboratory, also supported the VAS but the first author felt and stated that the PRS was easier for evaluation. Dr. Takeyoshi stated that PRS was fine as long as the pre- and post-treatment VAS was recorded. Dr. Mitsuo Motegi, the first president of the Association, and Dr. Hiroshi Terashima, both from the Department of Orthopedics, Toho University, stated that in the field of orthopedics, evaluative methods such as Range of Motion (ROM) and Japan Osteoarthritis Association (JOA) scores already existed and should not be changed. Dr. Yoshida, also introduced the classification of temporomandibular joint dysfunction to the symposium.

Once again, the symposium ended with no conclusions drawn, but a proposal from the moderators was made and approved that a working group be formed to continue the discussion for this difficult project.

At the 11th annual meeting in 1999, presided over by Professor Takashi Harada from the Department of Rehabilitation, Toho University, the discussion continued. A special symposium "Standard for the Evaluation of Pain for this Association" was held, [6] but at this point the main theme had shifted from trying to create a single standard to discussing whether or not standardization was possible. The symposium was moderated by the second author and Dr. Osamu Kenmotsu, and the speakers were the first author, Dr. Ohtsuka from the Department of Anesthesiology, Hokkaido University; Dr. Takeyoshi, the second author (2 papers), Dr. Ogawa who had become the FACS of the Department of Anesthesiology, Nihon University; Dr. Terashima and Dr. Yang. A special feature of that year's symposium was that President Harada had assigned the working group to create a working standard prior to the symposium, in order for the speakers to accumulate their data in a uniform format. A meeting for this was held in February of 1999.

The working standard **(Table 2)** limited the disorders to be included in the study to peri-arthritis of the shoulder joint, chronic lumbago, osteoarthritis of the knees and post-herpetic neuralgia. Each respective disorder had more detailed inclusion criteria. The patients were to be treated for 10 sessions. A VAS prior to the beginning of the sessions and after the 10 sessions ended, was recorded, while the PRS of pre- and post-treatment were recorded after each session. After

Table 2: Inclusion Criteria for the Specific Diseases

Dr. Takashi Harada, Department of Rehabilitation, Toho University School of Medicine

Shoulder Pain: Peri-arthritis of the shoulder joint
1. Age: Over 40 years old
2. Cause: History of trauma is irrelevant
3. Pain: pain on exertion, nocturnal pain
4. Limitations on range of motion: limited abduction and flexion of the arms
5. No swelling or redness of the shoulder joint

Lumbago: Chronic Lumbago
1. Age: Over 20 years old
2. Cause: any cause
3. Background of the pain: Pain due to musculo-fascial lumbago, damaged intervertebral discs and osteoporosis may be included but no case with neural dysfunction.
4. Pain: Trigger points may or may not exist.
5. The nature and the position of the pain may change.

Gonalgia: Osteoarthritis of the knee joint
1. Age: Over 50 years old
2. Cause: irrelevant
3. Pain: Includes starting pain or pain after fatigue. Pain alleviated by hyperthermia. Difficulty in "seiza" (kneeling with the tops of the feet flat on the floor, and sitting on the soles)
4. Findings of the knee joint: Joint effusion is frequently seen. Slight decrease in ROM.

Post-herpetic Neuralgia
1. PHN of at least one month since the onset.
2. The span (years) of the neuralgia should not be considered.
3. No cases with motor-palsy

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the 10 sessions, the patients were asked to grade their satisfaction on a 4 point scale (Satisfactory Index: SI), those being, very satisfied, satisfied, unsatisfied, exacerbation, where the overall SI was the sum of those scoring very satisfied and satisfied, expressed as a percentage of the total patient population.

Each speaker studied the results from many aspects but as result, the correlation between PRS and SI stood out, and a conclusion was reached that pain reduction from 10 to 5 or less should be considered as effective, from the standpoint of patient satisfaction.

As the final words of this symposium, the second author proposed the following conditions to be studied for the 12th annual meeting. [7)]

1. PRS was to be used to evaluate efficacy
2. Extremely effective was defined as a reduction to 0~1, effective as a reduction to 2~5, slightly effective as reduction to 6~8, little or no change as a reduction to 9~10, and exacerbation as an increase to 11 or greater.
3. For reference purposes, record of the primary pain using the VAS scale was required.
4. That this method of evaluation be used for the next 3 to 5 years
5. A total of 20 institutions, 10 orthopedics and 10 anesthesiology institutions should be included for the accumulation of data.
6. The data should be counted at each respective institution by March of the following year and sent to the second author at the Japan Medical Laser Laboratory.
7. The data received would be collated and correlated by the second author, who would present the final result at the 12th annual meeting of the Japan Laser Therapy Association.

Thereby, at the 12th annual meeting, presided by Professor Takefumi Yuge from the Department of Anesthesiology, Hiroshima University, the homework workshop "Laser Parameters for the Treatment of Specific Diseases Using the New Efficacy Evaluation Standard" was held. The moderators were again, the second author and Dr. Osamu Kenmotsu while the speakers were also the same as the previous year, being the first author, Dr. Ohtsuka, Dr. Takeyoshi, Dr. Yang, Dr. Terashima, Dr. Ogawa, the second author with the addition of Dr. Hiroshi Niinai from the Department of Anesthesiology and Resuscitation, Hiroshima University. The number of speakers and institutions were fewer than originally planned with 8 speakers from 8 institutions.

Each respective institution analyzed the data according to the proposal by the second author and stipulations set by Dr. Harada and a conclusion was reached that no further revision to these proposals was required and that this study should be continued using this evaluation standard.

Data from the respective institutions were collated by the second author, for both the 11th and 12th annual meetings. At the 11th meeting the SI was evaluated using the 4 point scale of very satisfied, satisfied, unsatisfied and exacerbation. However, at the 12th annual meeting, a 5 point scale with the addition of slightly satisfied was used and examined. In either case, overall satisfaction was the sum of the percentage of patients of only very satisfied and satisfied, but on a 4 point scale for SI, satisfaction was achieved more easily and included a score reduction on the PRS from 10 to 7. However with the addition of slightly satisfied, statistical analysis clearly showed that a PRS reduction from 10 to 5 was required to achieve patient satisfaction **(Figure 1)**.

This fact was not surprising to the first author but only served to cement the intuitive knowledge gained through his own experience. He had presented his results of a national questionnaire contrasting the evaluation of the efficacy of LLLT on a 4 point scale of extremely effective, effective, no change and exacerbation and that on a 5 point scale, where slightly effective was included. The results using the 4 point scale was more forgiving than the 5 point scale (in either case efficacy was rated as the sum of the percentage of extremely effective and effective) allowing for a higher efficacy rate.

The Conclusion Reached by the Association

The conclusion reached by the Japan Laser Therapy Association, from the examination of PRS and its correlation with SI was that for the evaluation of the efficacy of LLLT, PRS must be used where extremely effective was defined as a score reduction from 10 to 0~1, effec-

Table 3: The comparison of the number of patients between the 11th and 12th JaLTA

11th JaLTA (7 institutions)		12th JaLTA (8 institutions)	
shoulder	53 cases	shoulder	106 cases
hip	93 cases	hip	130 cases
knee	59 cases	knee	85 cases
PHN	51 cases	PHN	156 cases
total	256 cases	total	477 cases

tive as a score reduction from 10 to 2~5, slightly effective as a score reduction from 10 to 6~8, no change as a score reduction from 10 to 9,10 and exacerbation as an increase from 10 to 11 or greater. Efficacy is calculated from the percentage of patients reporting a score reduction of 10 to 5 or less **(Table 4)**.

The results presented at the 12th annual meeting were the same as those presented at the 11th meeting, and ever since then the Japan Laser Therapy Association has advocated and endorsed the use of this standard for the evaluation of LLLT in the treatment of pain attenuation.

This is how the standard for the evaluation of LLLT in the treatment for pain attenuation came to its fruition after 4 years of discussion starting from the 9th annual meeting to the 12th annual meeting of our Japan Laser Therapy Association.

As for Shiroto Clinic

As for the first author, these chain of events dictated change. At the first author's institution the evaluation of efficacy was changed and efficacy was rated as a PRS score reduction from 10 to 7 or less during the period of March, 1997 to February, 2000 (Efficacy Rate: ER 73.5%, **Table 5**). Since March, 2000, efficacy was rated from a PRS score reduction from 10 to 5 or less (ER 67.8% **Table 6**).

It is easily acceptable that a stricter standard would result in a decrease in the efficacy rate; however the voices from the patients had not changed during this period. This may seem confounding at first but since the treatment itself had not changed, it appeared only natural. The first author focused his attention on the SI, one of the two major facets of the evaluation

Table 4: JaLTA's standard for the evaluation of efficacy (with a baseline pains core of 10)

PRS

Extremely effective :	0 ~ 1	→ greater than or equal to 0 , less than 2
Effective :	2 ~ 5	→ greater than or equal to 2 , less than 5
Slightly effective :	6 ~ 8	→ greater than or equal to 6, less than 8
No change :	9 ~ 10	→ greater than or equal to 9 but less than or equal to 10
Exacerbation :	11 ~	→ greater than 10

The Efficacy Rate is thesum of the number of patients scoring extremely effective and effective, expressed as a percentage of the total number of patients Toshio Ohshiro

Table 5: Treatment Efficacy

March, 1997 - February, 2000

Disorder	Number of cases	Efficacy (%)					Efficacy Rate(%)
		extremely effective (+++)	effective (++)	somewhat effective (+)	no change (±)	exacerbation (-)	(+++)+(++)
myalgia	1,546	19.7	51.0	26.3	3.0		70.7
lumbago	1,457	27.5	48.7	20.9	2.9		76.2
osteoarthritis of the knees	772	21.8	51.7	23.6	2.9		73.5
peri-arthritis of the shoulders	298	21.1	58.3	19.6	1.0		79.4
sciatic neuralgia	465	30.4	47.5	20.6	1.5		77.9
rheumatism	65	2.9	37.3	50.8	9.0		40.2
dysthesia	103	25.9	43.0	28.0	3.1		68.9
arthritis of the elbows	75	19.5	47.2	27.8	5.5		66.7
tenosynovitis	43	26.2	44.5	23.0	6.3		70.7
tinnitus	25	13.3	56.7	23.3	6.7		70.0
trigeminal neuralgia	2	0	100.0	0.0	0.0		100.0
costal neuralgia	16	3.3	53.3	26.7	16.7		50.6
total	4,867	23.4	50.1	23.7	2.8	0.0	735

standard. Upon reexamination, the first author found that while the SI of patients treated for less than 10 sessions (group A) was low at only 62%, the SI for patients treated for 10 sessions or more (group B) was 100%, with a total SI of 73.3% **(Table 7)**.

As for the efficacy ratio at the first author's institution since March, 2000 through February, 2002, evaluated according to the Association's standard, the efficacy ratio dropped to 67.8%. Reexamination of the data from this period showed that the average PRS score reduction was from 10 to 5.1. From the standard of evaluation of efficacy, effective was deemed as a PRS reduction from 10 to 5. The resulting average of reduction to 5.1 denotes that the efficacy rate at the first author's institution may have decreased, but in actuality pain attenuation was achieved to a certain point, since patient satisfaction was high despite the apparently low efficacy rate.

Final Words

This Standard of the Evaluation for the Efficacy of Pain Attenuation with LLLT was inaugurated at the 12th annual meeting, in 2000. However recently, the number of papers not adhering to this standard and using individual methods for evaluation has grown. This may be due to changes in the membership of the Association to a younger generation; new members who do not even know that such a standard exists.

The first author feels that the younger members should discuss this issue concerning the Standard, and should reach a conclusion on whether or not any changes are required and re-unify the Standard of the Evaluation for the Efficacy of Pain Attenuation with LLLT, thereby adding to the relevance and scientific merit of papers on this subject.

Table 6: Treatment Efficacy

Disorder	Number of cases	Average age	Laser irradiation (sec)	Number of sessions	Average PRS	Efficacy (%)				Efficacy Rate(%)
						extremely effective	effective	somewhat effective	no change	
myalgia	802	55.2	398	13.8	4.6		59.1	29.6	11.3	59.1
lumbago	1,087	56.4	375	13.6	5.0	3.0	64.1	26.4	6.4	67.1
osteoarthritis of the knees	493	65.1	286	20.1	5.2	1.1	75.6	19.8	3.5	76.7
peri-arthritis of the shoulders	303	60.7	378	17.1	4.9		69.7	27.2	3.0	69.7
sciatic neuralgia	32	52.3	684	14.3	3.9		100.0			100.0
rheumatism	489	59.7	293	18.0	5.3	2.4	72.2	20.6	4.8	74.6
dysthesia	58	49.6	363	7.8	4.1		50.0	16.7	33.3	50.0
arthritis of the elbows	51	55.1	297	13.2	5.1		50.0	41.7	8.3	50.0
tenosynovitis	15	60.3	279	10.4	4.2		100.0			100.0
tinnitus	4	34.5	465	3.8	4.8		50.0	50.0		50.0
trigeminal neuralgia	3	43.0	418	13.0	3.8		100.0			100.0
herpes zoster	11	65.2	409	19.8	5.4		100.0			100.0
tenosynovitis	28	41.8	435	7.8	4.3		50.0	33.3	16.7	50.0
total	3,376	58.0	359	15.4	4.9	23.4	66.2	25.5	6.9	67.8

Table 7: Satisfactory Index(SI) per number of sessions

(%)

	Group A	Group B	total
shoulder	59.1	100.0	70.0
hip	57.8	100.0	66.7
knee	83.3	100.0	91.7
total	62.0	100.0	73.0

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[Acknowledgements]

Editor's Note: This paper was originally published in Japanese in The Journal of Japan Laser Therapy Association, Vol.12.2:43-48, 2013, and has been specially translated for inclusion in Laser Therapy