THE EVOLUTION OF THE JAPAN LASER THERAPY ASSOCIATION (JALTA) METHODS AND STANDARDS FOR SCORING LASER THERAPY PAIN ATTENUATION: A RETROSPECTIVE TWO-YEAR OVERVIEW

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The scoring of pain attenuation in laser therapy (and other modalities) has traditionally been accomplished by using the visual analog scale (VAS), recognized as a very subjective method and thus open to possibly severe patient-specific skewing of the scoring data. An easy to use but objective method has yet to be developed. Through special symposia in their 11th and 12th meetings, (1999 and 2000), the Japan Laser Therapy Association (JaLTA) sought to improve the objectivity of the method of pain attenuation scoring while maintaining ease-of-use and minimizing expense, by comparing the results of questionnaires to participating institutes using laser therapy in pain attenuation for a specific set of four pain types; shoulder, lumbar and knee pain, and post-herpetic neuralgia (PHN). The VAS was initially used in combination with the pain relief score (PRS). Unlike the VAS, the PRS always has an initial value of 10 (maximum pain), and the patient's pain relief post-therapy is scored from 10 down to 0 (pain free). Ten sessions were set for both trials, and at the end of the tenth session, the patient's satisfaction index (SI) was recorded, in which the patients rated their satisfaction with the treatment over four grades in1999, ('Very satisfied', 'Satisfied', 'Dissatisfied' and 'Exacerbation'), which was subsequently increased to five grades in 2000, with the addition of 'Fairly satisfied' inserted before 'Dissatisfied'. In the 2000 meeting report, when the results of the five point SI were graphically compared with the overall PRS at the 10th treatment, a good statistical correlation was seen. In conclusion, it was decided that all JaLTA members should use the following assessment protocol: the VAS was to be used only at the initial consultation and the PRS exclusively hereafter, as the PRS incorporated VAS data but with the advantage of a standardized starting point and a larger movement on the scale; the SI should be assessed at the end of the 10th session, since the SI, while still subjec-tive, in combination with the averaged results of the PRS, can provide a more objective overview of the efficacy of the particular treatment regimen. Finally it was pro-posed that, after a suggested period of 3-5 yrs, these data for all pain entities should be collected in summary from JaLTA members, together with the treatment regimens, and could well be useful in the formulation of guidelines for the ideal and most satisfactory laser therapy regimen for each pain entity.

Key words: Laser therapy, visual analog scale (VAS), pain relief scale (PRS), satisfaction index (SI)

Introduction

Scoring laser therapy pain attenuation is well-recognized as a very inaccurate process, and, whether used with laser therapy or another traditional modality, has been traditionally accomplished by means of an interview session during which the pa-tients record their pre- and post-therapeutic level of pain on a variation of the visual analog scale (VAS). The VAS, while simple and easy to administer, is a very subjective method of scoring pain pre- and post-therapy and has the additional disadvan-tage that the patients' concept of pretherapy pain in particular is very dependent on their individual pain threshold. Accordingly, one patient who is accustomed to pain may well score the initial pretherapeutic pain level in a severe acute phase of rheu-matoid arthritis as '6' on the usual 11-point (10 maximum, 0 pain free) VAS, whereas a patient unaccustomed to pain might score the pain of a comparatively mild sprained muscle as '10'. The pain relief score (PRS) has recently been introduced as a slightly more accurate though still subjective method of recording pain attenuation, as it

always starts at a pretreatment value of 10 (pretreatment pain level), regardless of the patient's concept of their own level of pain. The patient then records after each treat-ment session how much they feel the pain has been reduced from the initial value of 10, or if the pain has been exacerbated then the appropriate value above 10 is scored. The patient's satisfaction with the therapy at the end of the course of treatment sessions is another subjective measurement which can be recorded as the 'satisfaction index' (SI).

More objective methods did and do exist, such as the various structured interview formats including the general quality of life (QOL) and activities of daily living (ADL) interviews, and the more specific interviews from recognized bodies, such as the Japan Orthopedics Association (JOA) interview. Measurement of changes in the range of movement (ROM) of affected joints is another example, which is, however, only applicable to joint pain removal with concomitant increased mobility. Thermography is useful for assessment of changes in the superficial post-laser therapeutic skin temperature in the region of interest (ROI) as an indicator of in-flammatory response control, but requires specialized and comparatively expensive equipment and the development of a good protocol to avoid exogenous thermal arti-facts such as environmental influences and the state of rest of the patient. Electromyelography can show alterations in neural activity. A simple-to-use, inexpensive and less subjective method of post-laser therapeutic pain attenuation therefore still needs to be developed, and the Japan Laser Therapy Association (JaLTA) addressed this need in special symposia in their 11th (1999) and 12th (2000) annual meetings.
The correlation of the PRS and the SI was considered as bringing a less subjective approach to the assessment of patients' responses. After the end of the trial period, ten sessions in the current study, the satisfaction of the patients with the final results of their laser therapy was assessed on a four point (1999) then five point (2000) scale, to give the SI. When the averaged SI was calculated and compared with the averaged final PRS, and the data analyzed for any significant relationship, it was thought that a more objective assessment of the efficacy of laser therapy would be achieved.

The current study, based on questionnaires to a number of laser-therapy-based treat-ment centers during both JaLTA meetings, therefore set out to analyze the above data in order to assess the relationship between PRS and SI for a specific set of four pain entities (shoulder, lumbar, knee pain and post-therpetic neuralgia. From this correlation for each of the pain types, the JaLTA hopes in the future, after a longer study period, to arrive at optimum and standardized treatment methods for these and other pain types, and also a more meaningful and accurate method of evaluating and reporting the results.

A: 1999 Criteria

Patients and Methods

Questionnaires were sent out to six geographically separate institutions actively practicing laser therapy for pain attenuation (Table 1) enrolling a total of 256 patients with four pain types: shoulder (53), lumbar (93), knee (59) and post-therpetic neuralgia (PHN) (51) associated with herpes zoster.

In all institutes, diode laser therapy was applied in the contact method. The system used delivered 830 nm in continuous wave, output power from 60 mW to 1000 mW, dose (energy density) 13-30 J/cm2 per point, over ten weekly sessions.

Table 1:
Participating institutions and coordinators (in alphabetical order of institution).

§Hiroshima University School of Medicine, Department of Anesthesiology and Critical Care Medicine	O. Yuge, H. Niinai
§Hokkaido University School of Medicine, Department of Anesthesiology and Critical Care Medicine	O. Kemmotsu, K. Otsuka
†Hyogo College of Medicine, Department of Orthopedic Surgery	K. Yhou
† Japan Medical Laser Laboratory	T. Ohshiro
†Matsuyama Red Cross Hospital, Department of Anesthesia	S. Takeyoshi
†Nihon University School of Medicine, Department of Anesthesia	S. Ogawa
† Shiroto Clinic	C. Shiroto
†Toho University School of Medicine, Department of Orthopedic Surgery	H. Terashima

§ Additional institutes for 2000 study only † Participated both in 1999 and 2000 studies

Table 2:
Data sheet management schedule.

- ✓ VAS before and after treatment
- ✓ PRS after 10 laser therapy sessions
- ✓ SI after 10 laser therapy sessions
- ✓ Relationship between PRS and SI for each of 4 pain types
- ✓ Relationship between PRS and SI overall

Table 3:
Averaged PRS and VAS scores (±SD) before and after the 10th treatment session compared for each pain entity and overall.

Score type	Year	Shoulder		Lumbar		Knee		PHN		Overall	
		Pre (± SD)	Post(± SD)	Pre (± SD)	Post (± SD)	Pre (± SD)	Post (± SD)	Pre (± SD)	Post (± SD)	Pre (± SD)	Post (± SD)
PRS	1999	10	3.29 (2.68)	10	4.14 (2.99)	10	4.68 (2.74)	10	4.38 (3.20)	10	4.05 (2.95)
	2000		3.15 (2.53)		4.38 (2.18)		3.70 (1.56)		4.54 (2.84)		3.94 (2.28)
VAS	1999	4.39 (2.19)	2.29 (1.58)6	5.45 (4.49)	2.31 (0.97)	5.23 (2.00)	3.08 (1.43)	6.88 (3.47)	2.54 (2.28)	5.23 (2.59)	2.23 (2.28)
	2000	–	–	–	–	–	–	–	–	–	–

Table 4:
Satisfaction index (SI) after the 10th treatment session compared for each pain entity and overall, expressed as a percentage with the patient number for each grade given in brackets. Results are also compared between the 1999 and 2000 data.

Pain type	Year	Patients	Very satisfied (VS)	Satisfied (S)	Fairly Satisfied (FS)	Dissatisfied (NS)	Exacerbation (E)
Shoulder	1999	53	11.3% (6)	71.7% (38)	–	13.2% (7)	3.8% (2)
	2000	106	26.4% (28)	37.7% (40)	25.5% (27)	8.5% (9)	1.9% (2)
[PRS/SI Correlation 2000]		[95]	[27.4% (26)]	[26.3% (25)]	[41.1% (39)]	[4.2% (4)]	[1.1% (1)]
Lumbar	1999	93	17.2% (16)	67.7% (63)	–	12.9% (12)	2.2% (2)
	2000	130	24.6% (32)]	26.9% (35)	43.6% (45)	12.3% (16)	1.5% (2)
[PRS/SI Correlation 2000]		[115]	[26.9% (31)]	[34.8% (40)]	[28.7% (33)]	[8.7% (10)]	[0.9% (1)]
Knee	1999	59	11.9% (7)	66.1% (39)	–	20.3% (12)	1.7% (1)
	2000	85	22.4% (19)	37.6% (32)	25.9% (22)	14.1% (12)	–
[PRS/SI Correlation 2000]		[71]	[23.9% (17)]	[23.9% (17)]	[40.8% (29)]	[11.3% (8)]	[–]
PHN	1999	51	13.7% (7)	47.0% (24)	–	37.3% (19)	2.0% (1)
	2000	156	30.8 % (48)	25.0% (39)	21.8% (34)	19.9% (31)	2.6% (4)
[PRS/SI Correlation 2000]		[111]	[30.6% (34)]	[20.7% (23)]	[27.9% (31)]	[19.9% (21)]	[1.8% (2)]
Overall	1999	256	14.1% (36)	64.1% (164)	–	19.5% (50)	2.3% (6)
	2000	477	26.6% (127)	30.6% (146)	26.8% (128)	14.3% (68)	1.7% (8)
[PRS/SI Correlation 2000]		[392]	[27.6% (108)]	[26.8% (105)]	[33.7% (132)]	[11.0% (43)]	[1.0% (4)]

Pre-and post VAS data for each pain type were recorded initially and at each session using a standardized scale, with the resultant score rounded up or down to the nearest 0.5 of a point, e.g, a score of 1.2 would be rounded down to 1.0, whereas 1.3 would be rounded up to 1.5. Figure 1 shows the visual analog scale used to record patients' pain scores in each institution. The side facing the patient is labeled 'worst pain' on the right and 'no pain' on the left, corresponding to 10 and 0, respectively, on the side facing the interviewer. The patient indicates their pain level by placing a finger on top of the scale at the appropriate point, and the interviewer reads off and records the score. The PRS was recorded in the same manner. At the tenth session, the SI for each pain type was calculated based on the four stage scale: 'Very satisfied' (VS - total pain removal), 'Satisfied' (S - good pain removal), 'Dissatisfied' (NS - little or no pain removal), and 'Exacerbation' (E - worsening of pain). All raw data from the six trial centers were sent to the author for compilation and consolidation. Table 2 sum-marizes the handling protocol for the data sheets.

After the tenth session, PRS and VAS scores were compared and charted for each pain type, as was the SI. The PRS and SI averaged results were then compared for each individual pain type and overall, rounded up or down to the nearest whole point.

1999 Results

Figure 2 and Table 3 show the 10th session PRS and VAS values (mean ± SD) compared for each pain type and overall. The PRS tended to show a more accurate value for the actual pain relief, as it always started at the maximum pretreatment score of 10. The four-grade SI values for each pain type and overall are seen in Table 4. The SI scores for VS, S, NS and E for each respective pain type were as follows: Shoulder pain (n=53), 6 (11.3%), 38 (71.7%), 7 (13.2%) and 2 (3.8%), respectively; Lum-bar pain (n=93), 16 (17.2%), 63 (67.7%), 12 (12.9%) and 2 (2.2%), respectively; Knee pain (n=59), 7 (11.9%), 39 (66.1%), 12 (20.3%) and 1 (1.7%) respectively; and PHN pain (n=51), 7 (13.7%), 24 (47.0%), 19 (37.3%) and 1 (2.0%), respectively. The average overall SI values for VS, S, NS and E in the total population were (n=256) 36 (14.0%), 164 (64.1%), 50 (19.5%) and 6 (2.3%), respectively. Figure 3 examines the correlation of the averaged overall values for the PRS and SI in a area graph where the PRS score is along the horizontal axis, and the patient number on the vertical axis, with the areas on the bars representing the distribution of the four grades of the PRS. The greatest number of patients fell into the S (satisfied) group and a wide range of PRS scores in the S group of from 8 to 0 points. In other words, even though the pain relief score was excellent, some patients still only expressed themselves as 'satisfied'.

1999 Conclusions

For the 2000 trial the following points should be observed:

• The VAS should be used only for the pretreatment pain score at the first treatment session, and the PRS used thereafter, as the latter appeared to give a more realistic assessment of actual pain relief for each session, with the start-ing score standardized at 10.

• In the SI data for each pain type and overall, the range of patients in the 'satisfied' (S) group was disproportionate when compared with the very satisfac-tory PRS scores, therefore a five-item SI scale should replace the existing 4 item scale, namely VS (very satisfactory), S (satisfactory), F (fair), NS (not satisfactory) and E (exacerbation). It was believed that this would encourage patients to give a level of their satisfaction level more commensurate with their actual pain relief scores.

• Concomitant with this, the PRS values should also be assigned grades as follows: Excellent, final score of 0-1; Good, 2-5; Fair, 6-8; Little or no change, 9-10; and Poor (= exacerbation, >10). Using these grades, the efficacy ratio for pain relief (ERPR) could then be calculated, using the formula

$$ERPR = \frac{A + B}{N} \times 100(\%)$$

where A and B are the combined excellent and good scores, and N is the total number of patients.

• More centers should be recruited to increase the patient base

B: 2000 Criteria

2000 Patients and Methods

In addition to the original six institutes, a further two institutes were recruited, making a total of eight institutes for the 2000 study (Table 1). A total of 477 patients were enrolled in the study who met the enrollment criteria as detailed below and just under double the population of the 1999 study, consisting of 106 shoulder pain, 130 lumbar pain, 85 knee pain and 156 PHN pain patients. The same infrared diode laser therapy system (OhLase-3D1) was used in the same manner as in the 1999 study in all institutions, i.e. in the contact pressure technique. Table 5 compares the 1999 and 2000 base data sets.

Table 5:
1999 and 2000 patient data sets compared for each pain type.

Pain type	11th JaLTA meeting (1999)	12th JaLTA meeting (2000)	
		Total Patient No.	[f]PRS/SI Correlation Subjects
Shoulder pain	53	106	95
Lumbar pain	93	130	115
Knee pain	59	85	71
PHN	51	156	111
Total	256	477	392

[f] Total of 85 nonresponders

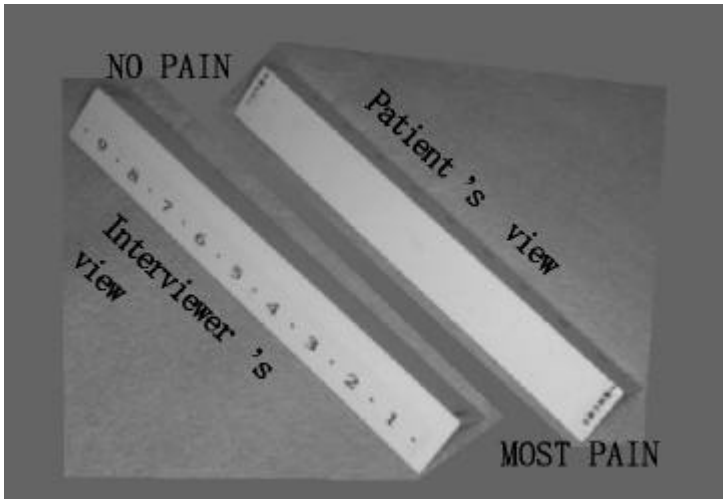

Fig. 1:
Rigid plastic VAS scale used in all institutes for the trial. The side facing the patient is labeled 'Worst Pain' on the right and 'No Pain' on the left. The patient indicates their level of pain by placing their finger on the top edge of the scale at the point corresponding to their level of pain. On the interviewer's side there is a scale from 0 to 10 ('No Pain and Worst Pain' respectively), from which the patient's pain score is read off, and rounded up or down to the nearest half-point.

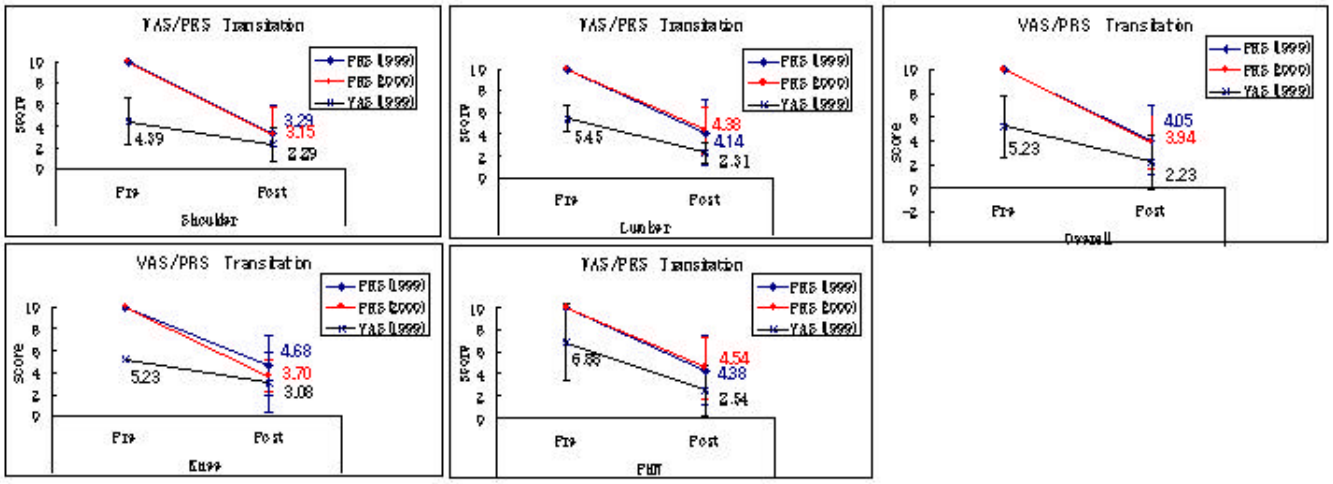

Fig 2:
VAS and PRS transitions for each pain type and overall in the 1999 (VAS and PRS) and 2000 (PRS only) data sets. Values are given as the means ± standard deviation (SD). PRS initial value is always 10.

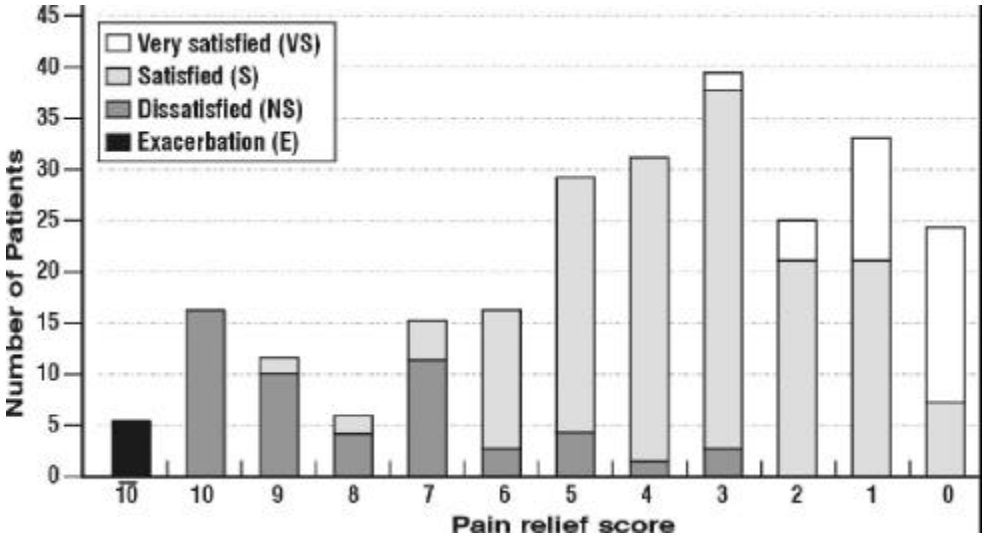

Fig 3:
Correlation shown in a area chart between the overall four-grade SI distribution (bars, shaded and labeled as shown) the overall PRS (horizontal axis) and patient numbers (verical axis) in the 1999 group. There is a poor correlation between the numbers of patients with a high PRS and the SI VS and NS scores.

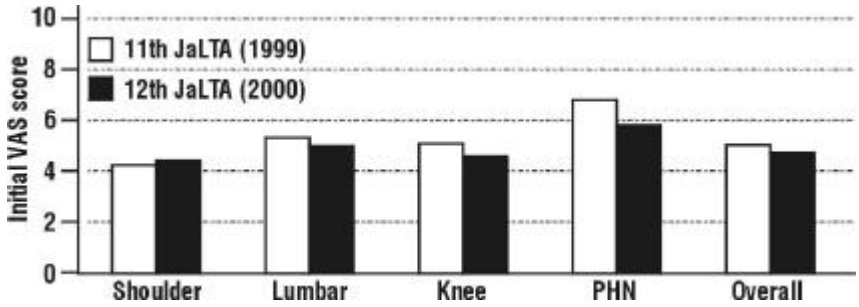

Fig 4:
Initial VAS scores for each pain type and overall, compared for the 1999 and 2000 patient groups. There was no statistically significant difference between the initial VAS values, despite the larger patient population and increased number of recording institutes, indicating that the initial VAS is a reasonably accurate and relevant value.

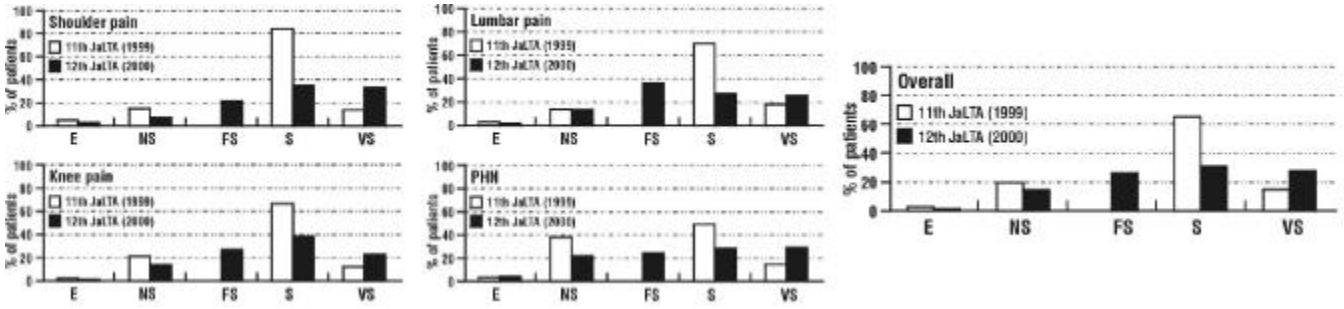

Fig. 5:
SI values shown individually for each pain type and overall for the 1999 (4 grade rating) and the 2000 (5 grade rating) groups. E=- exacerbation, NS = dissatisfied, FS = somewhat satisfied (2000 group only), S = satisfied and VS = very satisfied.

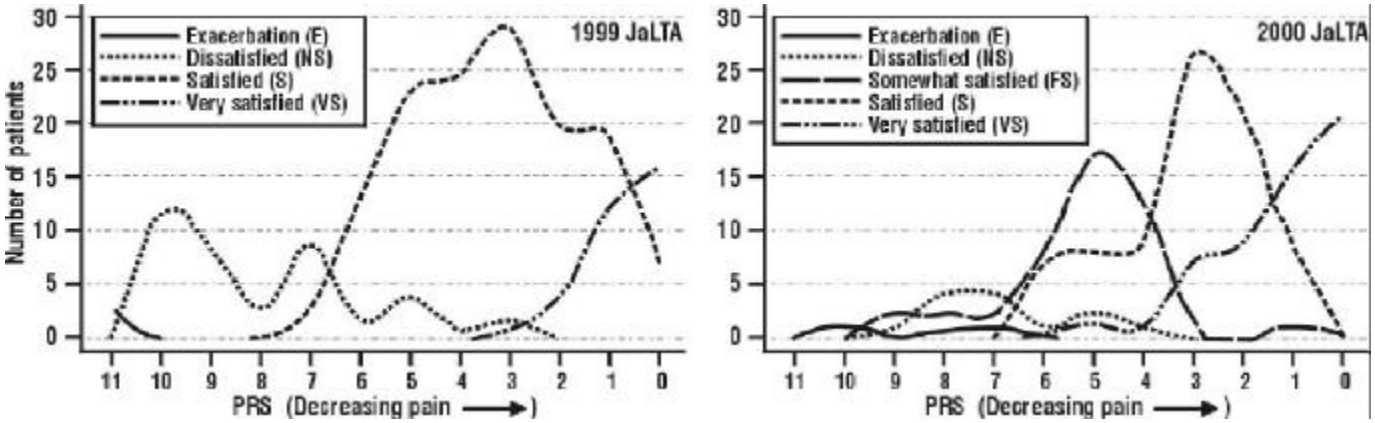

Fig 6:
Correlation between the PRS and SI scores graphically compared for the 1999 (left) and 2000 (right) trials. A much better correlation between the satisfactory and very satisfactory SI grades on the one hand and the PRS scores on the horizontal axis (0 = pain free) is seen for the 2000 trial, due to the five grade SI.

Enrollment criteria

Harada's Criteria for Admission (Toho University School of Medicine, Depart-ment of Rehabilitation) were applied to study participants to ensure uniformity in each pain type over all institutes, and are as follows:

Shoulder pain: Periarthritis only admitted; patients must be over 40 y.o.; atraumatic or traumarelated pain both acceptable; pain on movement, resting and nocturnal pain all acceptable; limitation on extension and abduction range of movement (ROM) required; and no swelling or inflammation detected in the joint at the time of enrollment.

Lumbago: Only chronic lumbar pain; patients over 20 y.o.; lumbar pain of any etiology acceptable; musculofascial pain, disc damage and a history of osteoporosis all acceptable; neurogenic pain a contraindication; presence or absence of trigger points both acceptable; any change in the pain site and characteristics once the subject is in the trial are allowed.

Knee pain: Osteoarthritis only; patients must be over 50 y.o.; atraumatic or trauma-related pain both acceptable; pain on standing and general fatigue-related pain which can be easily removed by heat treatment are acceptable; inability to kneel and hydroarthrosis acceptable; slightly restricted ROM required.

PHN: At least one month postonset required; no age limitations; no limitation on de-gree of motoparesis associated with neuralgic symptoms.

Data recording and comparison

The data items recorded and their method of comparison were basically the same as in the 1999 trial, with the exception that the VAS was only recorded before the first treatment and the PRS was used thereafter. Although the same 10 treatments reference point was used as for the 1999 data to cross-relate the VAS, PRS and SI, the 2000 group of patients were treated until pain was totally removed. As per the conclusions of the 1999 data, the SI was changed to include five instead of four grading values (very satisfied, VS; satisfied, S; fairly satisfied, FS; dissatisfied, NS; and ex-acerbation of the pain, E), and the PRS was assigned a 5 scale set of efficacy rates from 'Excellent' to 'Poor' (see 1999 Conclusions above for details).

2000 Results

Figure 4 shows the initial VAS scores for each pain type and the overall score, compared with the 1999 values. There was no statistically significant difference between the two sets of scores. Table 3 and Figure 2 show the averaged VAS and PRS scores (mean ± SD) for 2000, compared with those of 1999, with the exception of the VAS which was only used as an initial pretherapy value in the 2000 group. The SI values for each pain type and overall are compared between the 1999 (4 grade) and 2000 (5 grade) groups in Table 4 and illustrated in Figure 5. In all groups except lumbar pain, there were lower ratings for the dissatisfied grade (NS). In all groups, a higher SI rating in the very satisfied (VS) grade can be seen. There was of course no fairly satis-fied group in the 1999 SI grades. Finally, Figure 6 graphically illustrates the correlated differences between the PRS and SI scores for the 1999 and 2000 groups. The five-grade scale for the 2000 group allows a much more accurate correlation between the SI values and the PRS than the four-grade scale used in 1999, with the VS, S and F values corresponding much better to the lower (= less pain) PRS scores.

Discussion

Although the VAS is a very subjective assessment of pain and its relief, the use of VAS scores for the initial pretreatment pain levels provides a quick guide to the pa-tients' conception of their pain levels before receiving any laser therapy, and the similarity of the VAS scores in Figure 4 shows that this is a fairly accurate assessment, even though the patient population was almost doubled in the 2000 data set and there were eight institutes involved instead of six.

The use of the PRS with an initial base value of 10 for every treatment session gave a more accurate view of actual pain relief per session. When correlated with the SI value it showed a good spread matching the good PRS with the actual level of satisfac-tion felt by the patients with their laser therapy. This can be clearly seen in Figures 5 and 6, where comparisons between the 1999 and 2000 trial findings are illustrated. It is recommended that the five-grade scale should be adopted as a matter of course rather than the original four-grade scale used in the 1999 study. All JaLTA members now use this stan-dardized reporting system.

The 2000 results only report the findings at the 10 treatments point. The study is continuing, and a future article will tie in the longer-term (3-5 year) findings with the efficacy grades assigned to the PRS and the SI values. From these data it should therefore be possible to formulate guidelines for the most effective laser therapy regimens for specific disease entities.

Professor Chukuka S. Enwemeka meets and greets Dr. Toshio Ohshiro at the Opening Ceremony of the 2000 meeting of the Japanese Soceity for Lasers in Medicine and Surgery.

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A cross-section of the high table during the Opening Ceremony of the third Congress of WALT held at Athens, Greece, May 10-13, 2000