A NEW HOME PROTOCOL OF LLLT IN PATIENTS AFFECTED BY TMJD RELATED PAIN. RESULTS OF A RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED CLINICAL TRIAL.

Del Vecchio A.[A]*, Fioravanti M.[A], Boccassini A.[B], Di Paolo C.[B], Romeo U.[A]

Department of Oral and Maxillo Facial Sciences

***A**: Unit of Dental Clinic, Director: Prof U. Romeo*

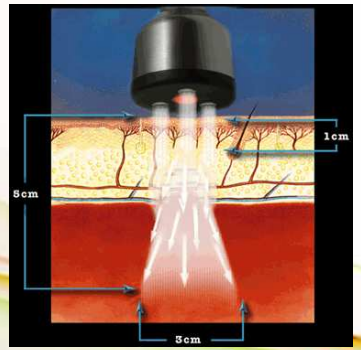
***B**: Unit of Temporo Mandibular Joint Pathology, Director: Prof C. Di Paolo*

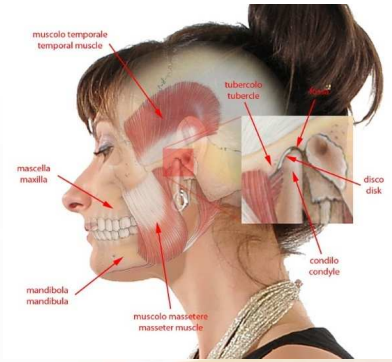
"Sapienza" University of Rome, Italy

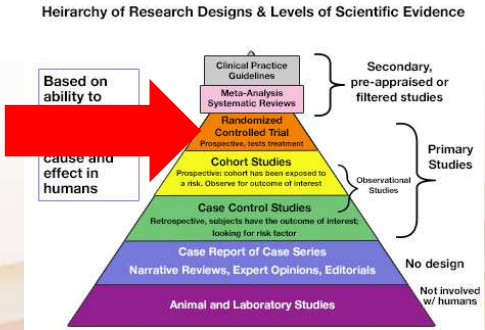
INTRODUCTION & BACKGROUND

Starting from the widely accepted and clinically demonstrated efficacy of the Low Level Laser Therapy in the management o the pain related to TMJDs, this study investigated about the possibility to obtain the same positive results with a **new home LLLT protocol**, based on the self administration of the therapy.

It was designed at a high level in the pyramid of evidence: ***Randomized, Double blind, Placebo controlled Clinical trial***







SAPIENZA
UNIVERSITÀ DI ROMA

INTRODUCTION & BACKGROUND

If demonstrated efficient, the protocol could permit to overcome the main bias of the conventional LLLT

Need of repeated presence of patients at dental clinics

Waste of time for both patients and clinicians

MATERIALS & METHODS

Patients cohort: 90 consecutive patients affected by TMJD referring at the Department of Oral and Maxillo-Facial Sciences of Sapienza, University of Rome randomly sub-divided into 3 groups.

Study Group (SG) patients (n=30) effective LLLT

- B-cure Dental Pro, 808nm low level diode laser, (Good Energies, Haifa Israel), applied over the painful area ***twice a day, for 1 week***. Each application was performed at 5 J/min, 250 mW and 15 KHz for ***8 mins***, for a total of 40 J each. A LLLT skilled operator performed the first application, while patients themselves performed the remnants at home.

Placebo Group (PG) patients (n=30)

- Same protocol than SG, with a ***sham device,*** devoid of the main laser source and with the sole indicator light, furnished by the same manifacturer.

Drug Group (DG) patients (n=30)

- Conventional drug therapy adopted at the Department for the TMJD related pain:
- 2 non consecutive cycles of 5 days of ***Nimesulide (100mg/day***), interspersed with one 5 days cycle of ***cyclobenzaprine hydrochloride (10 mg/day***).

SAPIENZA UNIVERSITÀ DI ROMA

MATERIALS & METHODS

INCLUSION CRITERIA

- Male and female adult patients (>18 y.o.) affected by pain related to TMJDs.
- The pathology was diagnosed through clinical and radiologic exam.
- History of at least 3 mths of pain
- All the patients signed an informed consent to the participation to the study.

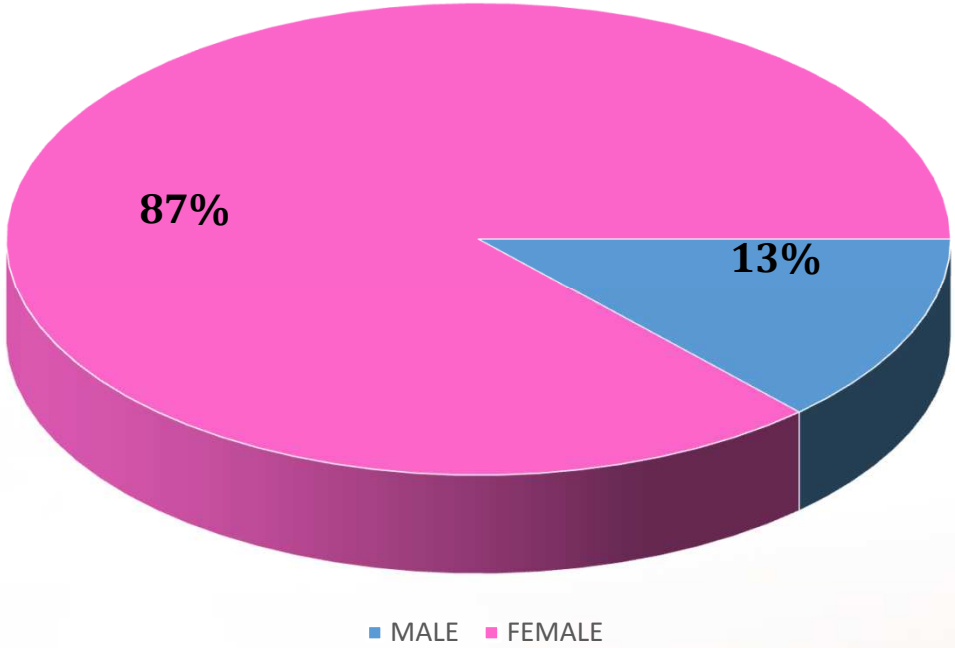
MATERIALS & METHODS

EXCLUSION CRITERIA

- Patients with cancer in ear area or neoplasms that affect the area of LLLT irradiation;
- Patients who received analgesic therapy within 2-3 weeks before the start of the treatment;
- Patients that assume long lasting analgesics or non-steroidal anti-inflammatories for systemic diseases, such as rheumatoid arthritis;
- Patients who have already made previous therapies for the TMJD related pain, both of the conventional type, or laser;
- Pregnant women
- Patients affected by epilepsy, coagulative disorders and/or connective tissue diseases.

MATERIALS & METHODS

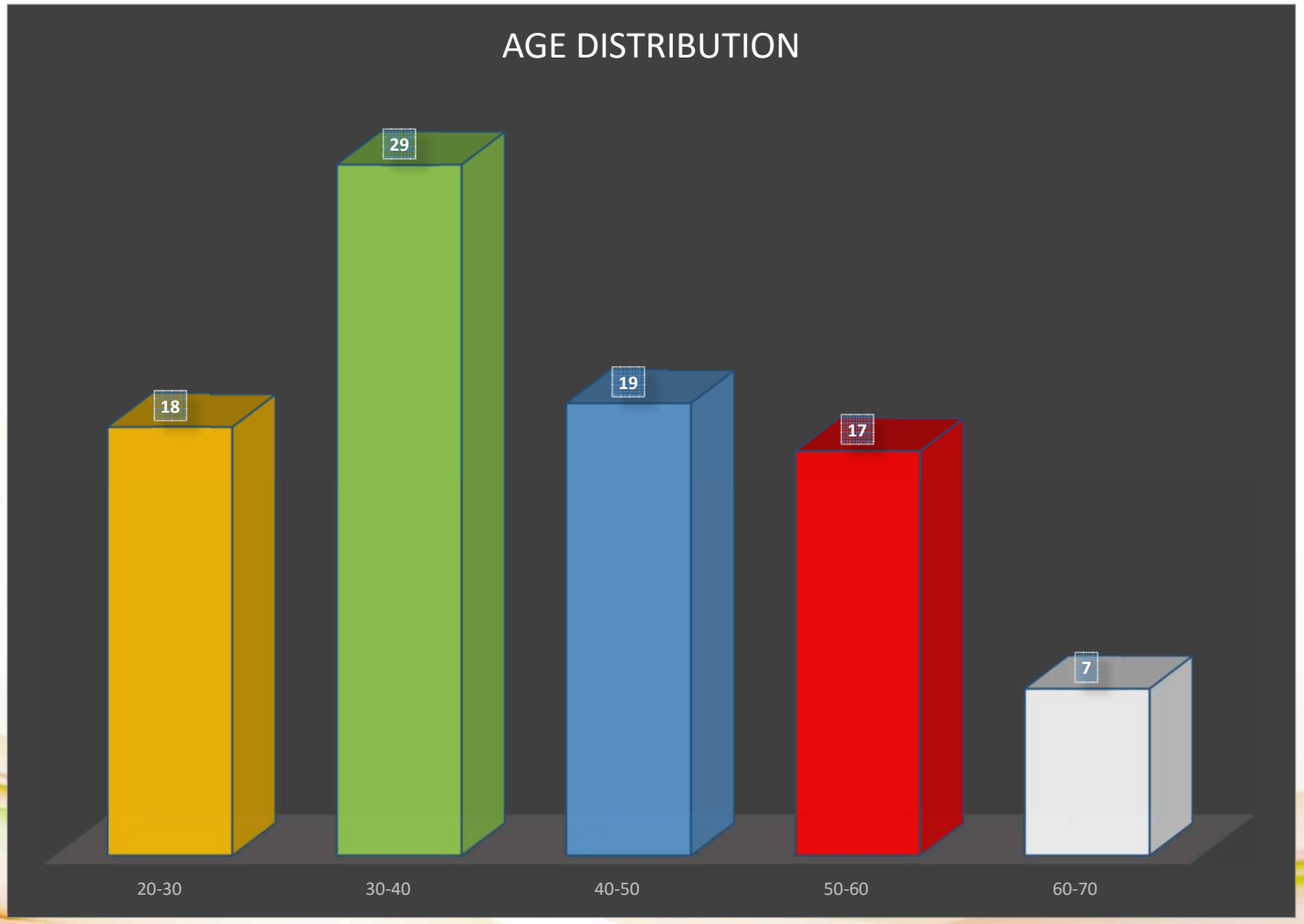
PATIENT GENDER



GENDER	
FEMALE	87%
MALE	13%

SAPIENZA
UNIVERSITÀ DI ROMA

MATERIALS & METHODS



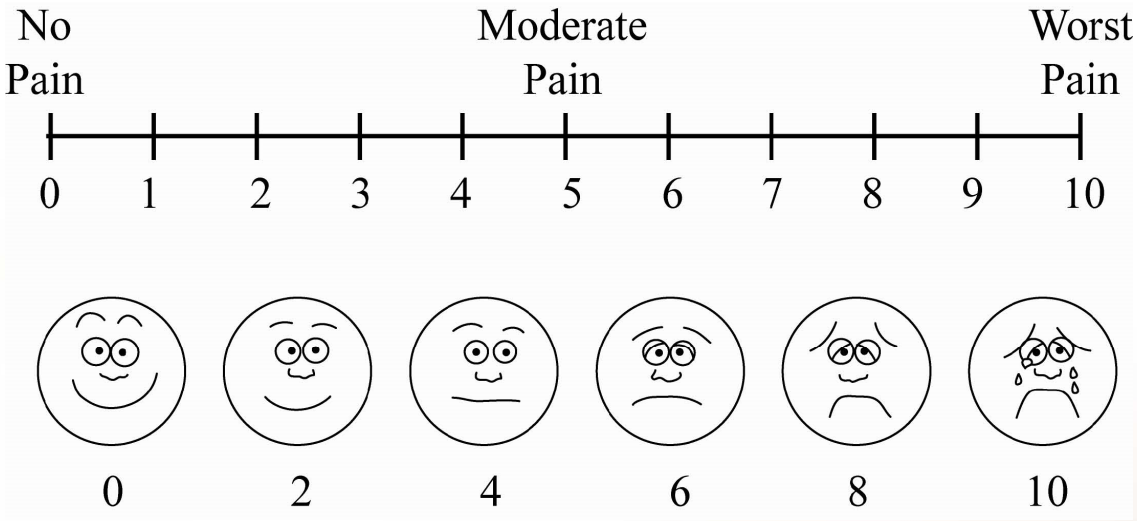
Decade	Patients
20-30	18
30-40	29
40-50	19
50-60	17
60-70	7

SAPIENZA
UNIVERSITÀ DI ROMA

MATERIALS & METHODS

A pain evaluation was requested by the examiner immediately before the laser treatment (T0), and at the end of the laser treatment (T1).

For the **pain evaluation** was adopted the ***Verbal Numeric Scale (VNS).***

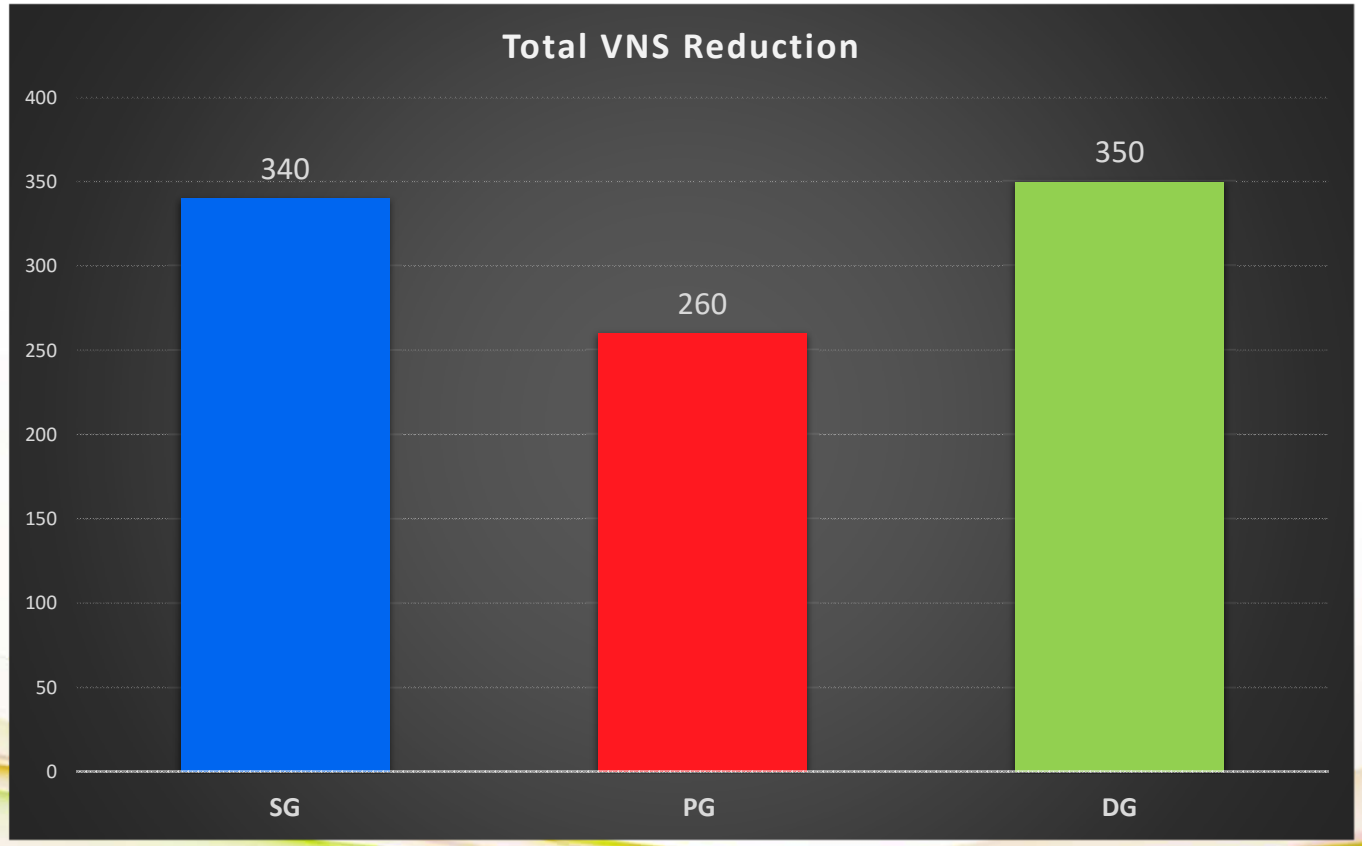


After the treatment all the patients received the conventional therapy for the resolution of the TMJD.

LASER APPLICATION

- Emitting 808nm 5 Joules / min, 4.5 cm^2 consistent therapy, 250 mW of power and full coherence for effective laser deep penetration in tissues
- Frequency of 15 KHz, the actual duration of the laser diode 3000-4000 hours
- 8 minutes per day to 2 times per day for 7 days
- Laser Class I Medical device Class IIa

RESULTS



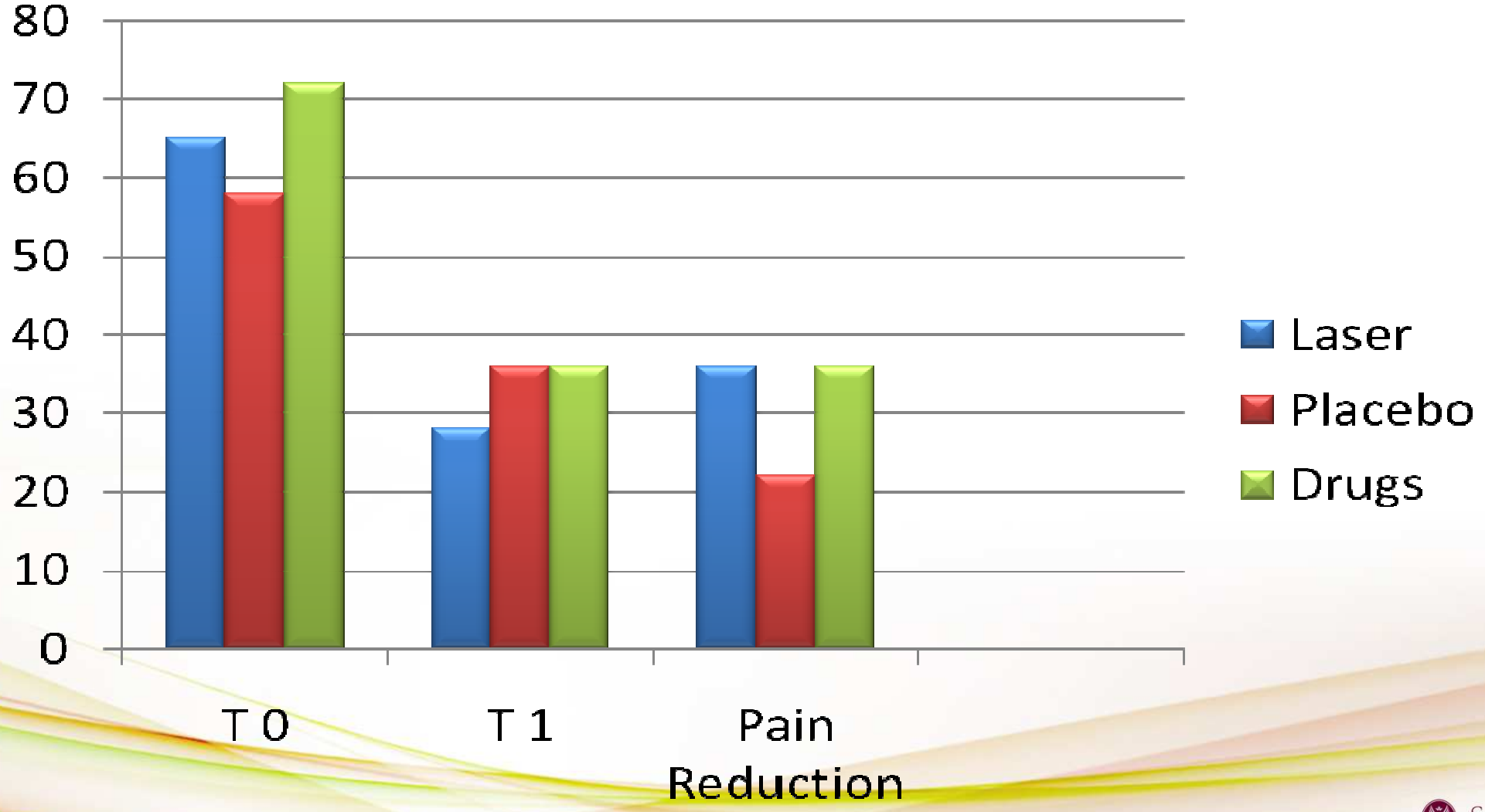
Total VNS reduction

DG = 350

SG = 340

PG = 260

RESULTS



SAPIENZA
UNIVERSITÀ DI ROMA

DISCUSSION

Two main considerations emerge from the study

This at home LLLT protocol is effective in treatment of TMJDs related pain, as confirmed by the **equivalence of pain reduction** registered in SG and DG.

The high value of the pain reduction in PG

DISCUSSION

Even though with the caution that is mandatory due to the little number of patients

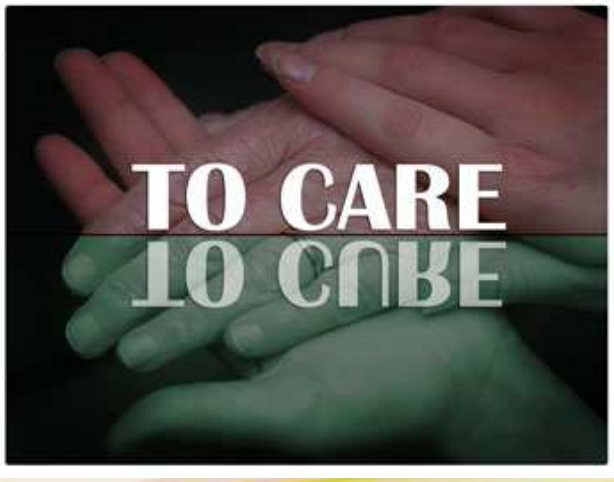
The at home protocol confirms the efficacy of LLLT treatment in the management of TMJDs related pain

High relevance must be assigned to the equivalence of results between LLLT and conventional drug therapy

DISCUSSION

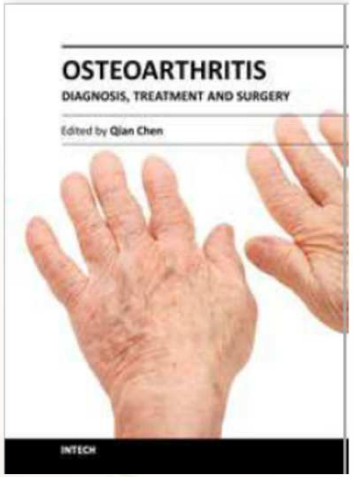
In every case, both in SG and PG patients completed the whole cycle of applications

No worsening of symptoms was registered



DISCUSSION

In some cases of the SG an early increase of pain was registered, probably due to an initial local hyperemia, but after few hours pain reduced to the definitive values



Low Level Laser Therapy in the Treatment of Temporomandibular Joint Arthritis: Questions and Answers

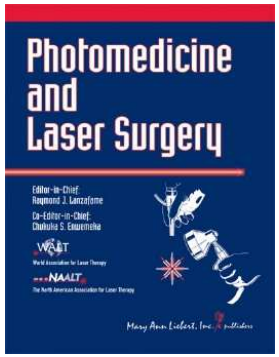
Marini Ida and Gatto Maria Rosaria
Department of Oral Sciences, School of Dentistry, "Alma Mater Studiorum", University of Bologna Italy

Marini Ida and Gatto Maria Rosaria (2012). Low Level Laser Therapy in the Treatment of Temporomandibular Joint Arthritis: Questions and Answers, Osteoarthritis - Diagnosis, Treatment and Surgery, Prof. Qian Chen (Ed.), ISBN: 978-953-51-0168-0, InTech, Available from: http://www.intechopen.com/books/osteoarthritis-diagnosis-treatment-and-surgery/low-level-laser-therapy-in-the-treatment-of-temporomandibular-joint-osteoarthritis-questions-and-rep

The laser group showed an increase in pain, which then disappeared for a long time; the increased pain could be explained with an increased local hyperemia.

SAPIENZA UNIVERSITÀ DI ROMA

DISCUSSION



The Relevance of Accurate Comprehensive Treatment Parameters in Photobiomodulation

Chukuka S. Enwemeka, Ph.D., FACSM

Photomed Laser Surg. 2011 Dec;29(12):783-4. doi: 10.1089/pho.2011.9896. Epub 2011 Nov 9.

of the real treatment applicator was kept at 100 mW/cm^2. As expected, treatment with the real applicator prompted faster healing of treated ulcers from the very beginning of therapy. Overall, it gave better results than the "placebo" treatment. However, the small amount of light emitted by the placebo applicator was not totally ineffective as was anticipated. Indeed, after the initial 45 days of treatment during which placebo-treated ulcers worsened, the ulcers began to heal virtually as nicely as those in the real treatment group did from the very beginning. This finding suggests that once the total amount of energy, that is, energy delivered at each treatment session multiplied by the total number of treatments, reached a certain threshold, the so-called "placebo" treatment began to engender positive healing.

cers." The lesson here is that there may be no such thing as "placebo" phototherapy; <1 mW/cm^2 irradiance is not so minute that it could not possibly stimulate healing of ulcers—in this case, ulcers that failed to respond to any other form of treatment. Had the treatment been stopped within 45

The Placebo

DILEMMA

SAPIENZA UNIVERSITÀ DI ROMA

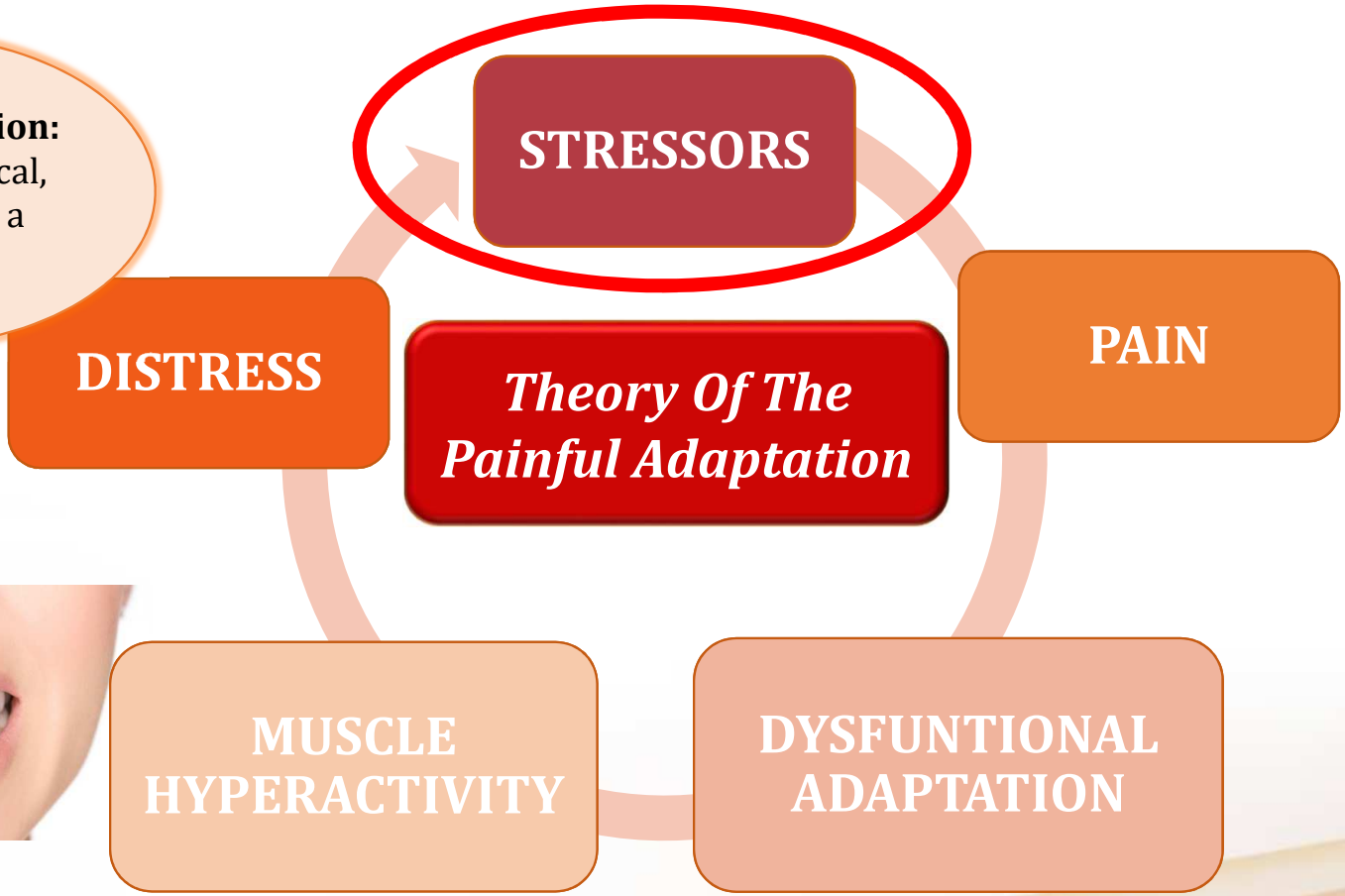
DISCUSSION

The significant value registered in PB could be explained through the light irradiation released by the **520nm** indicating LED, that even poor, can be still considered as a

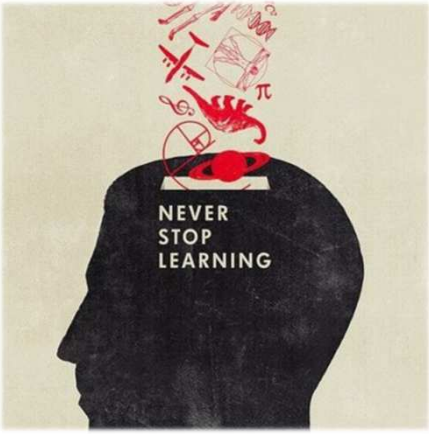
THERAPEUTIC LIGHT SUBMINISTRATION

DISCUSSION

Oral Parafunction: paraphysiological, not finalize to a purpose



Even a placebo application may be expected as a potential positive outcome



CONCLUSION

- The LLLT home protocol can be considered an effective and safe method to manage the pain related to TMJDs
- Its efficacy is almost equivalent to the conventional drugs therapy
- The LLLT has no adverse local or systemic effects
- The real extent of the placebo effects need further investigations with larger cohorts of patients and lower number of laser applications

A NEW HOME PROTOCOL OF LLLT IN PATIENTS AFFECTED BY TMJD RELATED PAIN. RESULTS OF A RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED CLINICAL TRIAL.

Del Vecchio A.[A]*, Fioravanti M.[A], Boccassini A.[B], Di Paolo C.[B], Romeo U.[A]

Department of Oral and Maxillo Facial Sciences

***A**: Unit of Dental Clinic, Director.: Prof U. Romeo*

***B**: Unit of Temporo Mandibular Joint Pathology, Director..: Prof C. Di Paolo*

"Sapienza" University of Rome, Italy