Key words: Osteoarthritis, High Intensity Laser Therapy, Low Level Laser Therapy, Ultrasound.

Clinical experience using Hilterapia® in "knee arthrosis".

Sabbahi S.
King Faisal Specialist Hospital& Research Center, Riyadh, KSA

ABSTRACT

The aim of this study is to compare the efficacy of High Intensity Laser Therapy "HILT" against Low Level Laser Therapy "LLLT" and therapeutic ultrasound "US", in combination with exercises, in relieving knee pain, increasing walking distance without pain and squatting in patients with knee early osteoarthritis (OA).

Thirty subjects with knee early OA, males and females, age between 40 and 72 years, were enrolled. Participants were randomly and equally classified into three groups. All participants received exercise program for knee in combination with one of the therapeutic modalities compared (HILT, LLLT, US). All participants received six treatments for three weeks (two-sessions/week).

The results show that HILT is significantly more effective than LLLT and therapeutic US in inhibiting pain, increasing walking distance without pain and improving the ability to squat in people with knee early OA. No differences between LLLT and therapeutic US effectiveness in the treatment of early OA have been found.

INTRODUCTION

Knee osteoarthritis (OA) is a complex disease whose pathogenesis includes the contribution of biomechanical and metabolic factors which gradually lead to articular joint tissue destruction [1,2]. Knee OA is a common musculoskeletal disorder in the Saudi population and is a leading cause of physical disability. Pain and functional disability "like walking and squatting", are considered the most common complaints by OA patients. Knee OA affects both males and females and is one of the two major skeletal disorders (OA and osteoporosis) with strong social impact. It has been reported on 1999, that about 50% of adults with knee OA were "unable" or had "much difficulty" in crouching, stooping, or kneeling [3]. More than 30% of adults with knee OA were "unable" or had "much difficulty" in walking a quarter of a mile; more than one-fourth was unable to take 10 steps without resting. More than 25% were "unable" or had "much difficulty" in lifting or carrying 10 lbs [3].

In addition to NSAIDs (nonsteroidal anti-inflammatory drugs), routine therapy may use instrumental therapeutic modalities such as ultrasound or low level laser for their analgesic effects in combination with daily exercise. Regular exercise is recommended for middle-aged and older people, but the effect of exercise on the development of OA in older people is unclear, especially if they are overweight. Some studies have suggested that exercise has a protective effect [4,5]. The efficacy of weight bearing exercises on increasing the thickness of normal knee cartilage has been assessed using MRI (la prima volta scrivere per esteso) [6]. It has been reported that exercises were associated with an increase in tibial cartilage volume, free from cartilage defects. Also, moderate physical activity, including regular walking, was associated with a lower incidence of bone marrow lesions [6].

Controlled clinical studies of LLLT effectiveness in knee OA showed different and sometime contradictory results [7] . In a double blind, placebo-controlled study, no difference was found between the LLLT and placebo groups in relieving knee pain [8].

The results of clinical trials on the effectiveness of ultrasound in OA treatment were also controversial. In clinical trials carried out on 294 patients no difference between US and placebo were found for the outcomes of pain and patient-assessed improvement [9]. On the other hand, some studies suggest that therapeutic US is a safe and effective treatment modality in pain relief and improvement of functions in patients with knee OA [10].

High intensity laser therapy (HILT-or Hilterapia) is an advanced therapeutic approach of Orthopedic Physical Therapy. Its characteristic is a high peak power laser pulse, featuring peculiar frequencies and pulse width. As reported by some research, HILT has the capability to induce indirect photomechanical effects, which can act on the lymph drainage pump, performing their action on the inflammatory process and on cells of the connective tissues, stimulating the production of matrix molecules, like collagen and proteoglycans [11].

The aim of the study is to compare the efficacy of HILT against LLLT and US in

combination with exercises in relieving knee pain, walking distance without pain and squatting in patients affected by knee early OA.
The comparison between High Power- and Low Level - Laser Therapies (very different as regards the energy release into the tissue) is, in our opinion, particularly interesting because of the different mechanisms at the basis of the two therapeutic strategies: mostly phototermical-photomechanical in the former case and mostly phototermical-photochemical in the latter one.

MATERIALS AND METHODS

Patients suffering for knee OA were recruited for this trial from Physical Therapy Department, King Faisal Specialist Hospital & Research Center at Riyadh, Kingdom of Saudi Arabia. Thirty subjects with knee early OA, aged 40-72 years, were included. Informed consenst was obtained. Inclusion criteria required the presence of knee/s pain no more than two years, with clinical and radiological confirmation of the diagnosis of OA. Exclusion criteria were: knee joint disease other than OA, OA of the hip joint or of the foot joints, presence of knee varus or valgus deformities, knee surgery.
Patients were randomly and equally classified into three groups. All participants received exercises program for knee in combination with one of the therapeutic modalities compared (HILT, LLLT, US). Patients of group (1) were treated with HILT, group (2) with LLLT, and group (3) with US therapy. No control group was included for ethical reasons. All participants received six treatments for three weeks (two treatments/week). Equipments used were 3.0 HIRO (Pulsed high power Nd:YAG laser, λ 1064 nm) (ASA S.r.l., Vicenza, Italy), IDEA PULSED (IR laser, λ 905 nm), (ASA S.r.l., Vicenza, Italy), Ultrasound Unit (Zimmer Medizin System). Measurement parameters were perceptive pain using VAS, walking distance without pain (in meters), and squatting with/without pain. Measurements were taken pre-treatment and after completion of six sessions.

Therapeutic Protocol:

Hilterapia protocol	6 treatments, two treatment/week. Total energy of treatment 3000 Joule (J) (500 J. antero-lateral window; 500 J. antero-medial window; 500 J postero-lateral window, and 500 J postero-medial window; 500 J medial patella; 500 J lateral patella, according to the individual optical windows). Surface area: 24 cm^2 for all anterior and posterior windows. The total treatment duration is 15-20 min.
Low level laser therapy	6 treatments, two treatment/week. Surface area: 7-9 cm^2 for each compartment, 20 cm^2 for popliteal fossa. The session duration is 13 min. Energy 1,365 J.
Ultrasound therapy	6 treatments, two treatment/week. (Patella, medial and lateral compartments). Pus 8.1 W, era 4.1 cm. Power 1.7 w/cm^2. Dimensions of the treated surface: 12 cm^2. The treatment duration is 7.5 min.
Exercise program (for all patients)	Quadriceps muscle strengthening and hamstrings'stretch. Three sessions/day.

STATISTICAL ANALYSIS

Data obtained from the three groups have been compared using ANOVA test.

RESULTS

Comparing the baseline and after-treatment data, results showed the following:
HILT had a more significant analgesic effect than LLLT and therapeutic US in inhibiting pain ($p<0.0001$)
HILT was more effective in increasing walking distance without pain and improvement of the ability to squat without pain than LLLT/US in people with early OA ($p<0.0001$).
No difference were found between LLLT and therapeutic US in inhibiting pain, increasing walking distance without pain and improving of the ability to squat in people with early OA

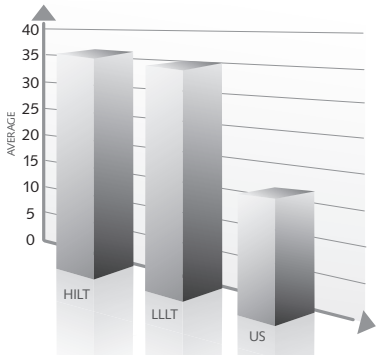

Figure 1. Effect of HILT, LLLT, and US on VAS. HILT shows the greatest effectiveness in pain inhibition in comparison with the other modalities: LLLT and US.

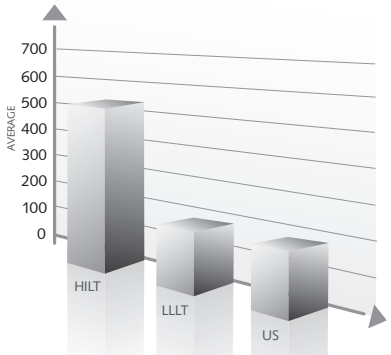

Figure 2. The effect of HILT, LLLT and US on walk. HILT had a significant effect in increasing walking distance without pain. No differences between LLLT and US were found.

Finally, the patients' satisfaction index is shown in Figure 5. Better results were achieved in group H, compared to group C also for this parameter. In group H, 9 patients were very satisfied (60%) and 6 satisfied (40%). In group C, 6 patients were very satisfied (40%), 7 satisfied (46%), 1 a little satisfied (7%) and 1 not satisfied (7%).

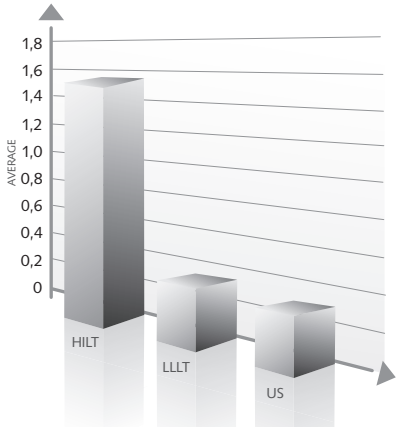

Figure 3. The effect of HILT, LLL and US on squat. As shown, HILT is more effective that LLLT and US (at p<0.0001).

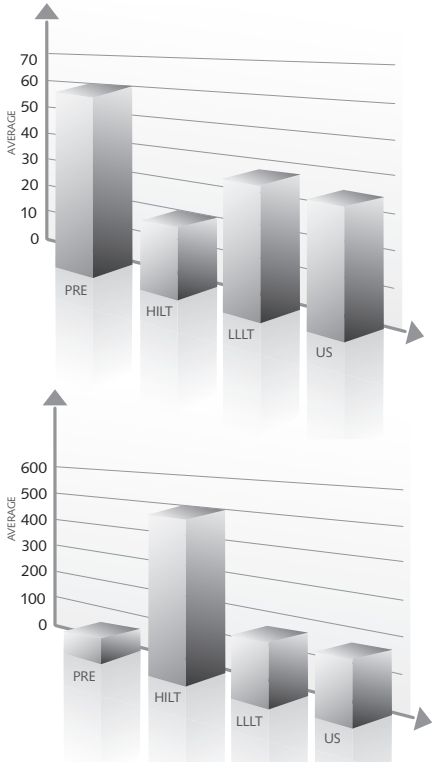

Figure 4-5. The effect of HILT, LLLT and US on VAS and walk. HILT had a very significant effect on pain reduction and improved the ability of knee OA patients to walk for longer distance whitout pain. No significant differences between LLLT and US on pain inhibition or function improvement in people whit kneeOA was found.

DISCUSSIONS

The results from our study may support the importance of HILT application for analgesic and anti-inflammatory effects in patients with symptomatic knee OA, over other therapeutic modalities as LLL and US. In general, in patients with knee OA, an association between pain severity and physical disabilities "as walk and squat" is observed. With the significant effect of Hilterapia on pain inhibition, the patient's ability to walk and squat without pain is improved.

In knee OA, pain control represents one of the principal tasks in order to get over acute phases. In this study, patients enrolled in the in Hilterapia group reported very early (often after the first treatment) a significant pain reduction. In patients who received other physical Therapies "LLLT or US", in combination with exercises, little or no significant pain reduction was observed. The effectiveness of LLL and US has been often investigated with different results. LLLT showed some limits in the treatment of knee OA, possibly due to low penetration and a low intensity of the light radiation [12]. A recent Cochrane review [13] didn't succeed in demonstrating a sure effect of laser therapy, mainly due to methodological problems in the studies, as doses and wavelength of laser.

In the current study, US therapy appears to have no benefit over placebo for people with knee OA. In a Cochrane review of three studies with a total of 147 participants assigned to compare US to placebo, there was no benefit of US therapy for pain relief, range of motion or functional status. These conclusions are limited by overall poor methodological quality of the comparative trials [14].

Hilterapia has proved his efficacy in the treatment of early knee OA, as shown in figures (1,2,3), in pain inhibition and improvement of knee functions. This data may come along with other studies which support its efficacy in different musculoskeletal diseases and it is believed to have anti-inflammatory, anti-edema and analgesic effects [15]. It seems that Hilterapia laser may overcome difficulties and limitations in LLLT, and prove its efficacy over LLLT.

For the effects of exercises on pain and disabilities of patients with early OA, it seems that quadriceps muscle strengthening may be attributed to pain inhibition and improved function. Research work suggested that quadriceps strength is strongly associated with knee pain and physical disability, even when activation and psychological factors are taken into account [16,17]. These deficits in physical capacity may be corrected with exercise training. By decreasing pain and increasing joint movement, knee exercises for strengthening quadriceps muscles and stretching hamstrings muscles may help patients to maximize their ability to overcome their physical disabilities as walk and squat.

From our data, Hilterapia appears to be the an elective treatment tool for pain reduction and improvement in functional disabilities in people with knee OA.. This study may come along with other preliminary studies indicating that Hilterapia can be more effective than LLLT in pain and flogosis control, due to its more intense and deeper effects [18,19,20].

CONCLUSIONS

Because of its efficacy in relieving pain and improving function, Hilterapia in combination with exercises can be considered a very suitable therapeutic tool in treatment of early knee OA.

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