Observational study with cryotherapy Hilotherm  
(Preliminary results)

Introduction
The cold therapy cryotherapy plays an integral role in orthopedics, traumatology and Rheumatology, particularly in the postoperative period after joint surgery but may be considered for patients with rheumatoid arthritis to provide pain relief and reduce swelling.

Especially in older patients, severe pain syndromes, or polyneuropathy and other nerve disorders are the typically treated Ice packs or Cold packs. This approach can often be problematic, since it may lead to uncontrolled application with cold damage, such as necrosis. Also the use of leaking ice water bags and displaced cold packs is often problematic.

The cold treatment in this study is provided using the Hilotherm device. The objective was to identify its capabilities to reduce pain, improve patient comfort and practicality of application.

Method
Within an observational study in the Rehabilitation Clinic for Orthopedics and Rheumatology at Rheumatology Center Oberammergau, Medical Director Dr. Peter Keysser applied Hilotherapy to a total of 192 patients using Hilotherm device and collecting results by means of issuing standardized questionnaires to patients. The data was collected on age, gender, affected Joints, number of applications and pain intensity on visual analogue scale (VAS 0-10) before and after each use.

The applications have been standardized on 20 minutes at a temperature of 10 ° C. The most common indications were Knee replacement surgery with a total of 132 applications, of which 55 applications with rheumatics. 18 applications were for post-traumatic conditions (patella fracture and complex internal knee trauma) in non-rheumatic patients performed, 11 applications after shoulder surgery, and 30 applications in patients who had not undergone surgery but suffer from rheumatoid of hands, 1 application for a total hip replacement patient.

71.4% of respondents were female, male 28.6%, 38.5% of patients had a inflammatory rheumatic underlying disease.

Results
192 treatments have been carried out. 164 cases after lower pain intensity than before the treatment given, 26 cases pain intensity was stated to be equal and in 2 treatments were evaluated after treatment slightly more symptoms than previously stated.

Overall, all patients have at the end of the treatment with the device Hilotherm demonstrated lower pain intensity than indicated at the beginning. The only exception was a total hip replacement patient, but before the 1 Therapy analgesia started, just after therapy and no other cold therapies conducted. The average pain intensity on visual analogue scale before the 1st Therapy was 4.9, the average pain intensity after the last treatment was 1.6. On average 13.7 applications were performed per patient and joint.
Complications and incompatibilities
During the entire period of observation there were no complications or Intolerance observed. No patient interrupted the cold therapy with Hilotherm due to disorders. In all cases the treatment ended with resolution of symptoms or discharge from clinical treatment.

Excerpt from personal observations of the patient:

- "Very pleasant, do not need any more pain killers."
- "Redness and warmth on the left of decline, decreasing pain."
- "Redness decreased, yet knee too warm."
- "The cold is very pleasant to the remaining swelling."
- "Don’t need any more pain drop."
- "With continuous passive motion splint and Hilotherm the bruising is diminished more quickly."
- "Pain relief approximately 20 minutes after cold application."
- "First cold experienced as unpleasant, later improvement."

Overall assessment
The results of the standardized patient survey confirm our clinical impression from several hundred applications of cryotherapy with Hilotherm. All patients have demonstrated after the treatment, significantly less pain intensity than prior to using the treatment. 2 of 192 treatment sessions only demonstrated slightly greater pain levels than prior to treatment. This was only for the first two sessions, after the following 12 applications the same patient stated an equal pain level before and after treatment.

In particular patients with inflammatory rheumatic diseases, including patients who did not undergo surgery, with application to the hands also benefitted from the therapy. Hilotherm should consider developing a special hand cuff for use in rheumatoid arthritis patients.

In summary, in our view, the application of cold therapy Hilotherm both in rheumatoid arthritis patients and in orthopedic trauma patients is recommended. In general, the application is perceived as pleasant, the pain intensity decreases. Applications showed no signs of problems or complications.

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