



Luisenkrankenhaus
Düsseldorf
Europäisches Brustzentrum Dr. Rezai

HILOTHERM®

Hilotherapy in chemotherapy - reduction / prevention of hand-foot syndrome and neuropathy

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What is Hilotherapy?

HILOTHERAPY is a thermo-healing process

- it acts locally on damaged body parts with cold or heat
- Thus oxygen demand of the tissue, the metabolism as well as the blood circulation and pain receptors are positively influenced
- This leads to pain relief and / or faster healing

Hilotherapy and its application



Medical sectors

Trauma / Joint

Mouth, jaw, and facial surgery

Otorhinolaryngology

Plastic / Aesthetic Surgery

implantology

rheumatology

Oncology

Vascular and microsurgery

dermatology

urology

sports medicine

emergency medicine

General postoperative wound healing

Physiotherapy / Rehabilitative Medicine

Therapy areas

edema

hematomas

pain relief

Sprains, muscle strains, muscle tears,

dislocations, tendonitis

Inflammatory rheumatism

Hand-foot syndrome

sciatica

rheumatism

Chemotherapy

fever

migraine

Functional rehabilitation, such as
improvement of mobility and muscle
relaxation

NEW: use in oncology

HILOTHERAPY in hand-foot syndrome



The hand-foot syndrome and the development of polyneuropathies -
a big problem in oncology.

What is the hand-foot syndrome

Grade 1



Tingling, painless swelling or
Erythema of the hands and / or feet or
discomfort that does not affect everyday life
affect.

Grade 2



Painful erythema and swelling of the
hands
and / or feet and / or discomfort
affecting the patient's activities in
daily life.

Grade 3



Moist desquamation, ulceration, blistering and severe pain on the hands and / or feet and / or severe discomfort to the patient impossible to work or activities of the to carry out daily life

What is polyneuropathy?

Neuropathy: the damage of one or more nerves

- affected nerves are significantly limited in their function - or even completely functionless.
- **a possible side effect after special chemotherapy substances (platinum derivatives, taxanes, 5-FU ...) - up to 10% of the patients.**
- Polyneuropathy caused by chemotherapy is particularly noticeable on the hands and feet

Hilotherapy in use - the pilot project

Acquisition of a total of 140 patient data in two practices / clinics:

European Breast Center Rezai at Luisenkrankenhaus in Düsseldorf (n=60)

➤ Formation of three observation groups

Specialist practice in gynecological oncology Dipl. med. Rene Schubert (n=80)

➤ Comparison of conventional cooling with ice gloves / feet
with Hilotherapy at 12°C



Luisenkrankenhaus
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Gynecological Oncology Scheibenberg

Evaluation of 60 patients at Luisenkrankenhaus

Three observation groups were formed:

1. Observation: the patients received their chemo without cooling
2. Primary cooling: the patients cooled their hands / feet for prophylaxis with the first chemotherapy
3. Secondary cooling: Patients only started to cool the hands / feet, with the appearance of the first symptoms / complaints.

Chemotherapy regimen: Taxane-containing therapy

Nebenwirkungen während Chemotherapie

ID / Name: _____

Datum der Chemotherapie: _____

Regime: _____ Zyklus: _____

Kühlung mit Hilotherm: Hände Füße keine Kühlung

Kühldauer in Min: _____ Vorkühlung _____ während der Therapie _____ Nachkühlung _____

Kühltemperatur: _____ 10°C (falls abweichend, die Temperatur bitte hier _____ eintragen)

Grund der Kühlung: vorbeugend nach Auftreten von Symptomen

Zutreffendes bitte rückwirkend ankreuzen:

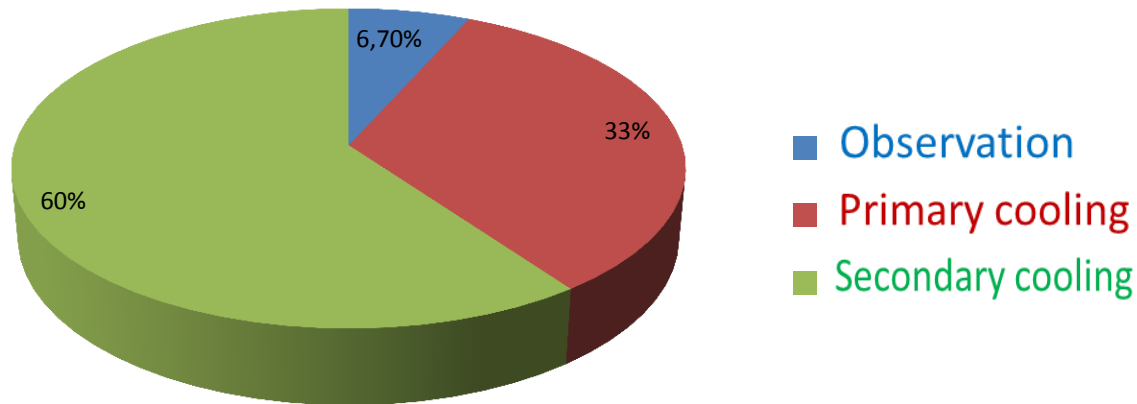
Grad	CTC
0	<input type="checkbox"/> Keine Symptome
1	<p><u>keine bis leichte Beschwerden</u> (keine Einschränkungen im Alltag)</p> <input type="checkbox"/> Taubheitsgefühl, Brennen, Gefühlslosigkeit, Kribbeln an Händen / Füßen (sensorische Neuropathie) <input type="checkbox"/> Minimale, schmerzlose Rötung (Veränderungen) an Händen / Füßen (HFS) <input type="checkbox"/> Nagelverfärbung
2	<p><u>mittel starke bis starke Beschwerden mit Schmerzen</u>, (Einschränkungen im Alltag)</p> <input type="checkbox"/> Taubheitsgefühl, Gefühlslosigkeit, Kribbeln an Händen / Füßen <input type="checkbox"/> Schmerzhaftes Rötung, Ablösen der Haut, Blasen an Händen / Füßen <input type="checkbox"/> Nagelriss
3	<p><u>sehr starke Beschwerden</u> (Starke Einschränkungen im Alltag und Einschränkungen in der Selbstversorgung)</p> <input type="checkbox"/> Taubheitsgefühl, Gefühlslosigkeit, Kribbeln an Händen / Füßen <input type="checkbox"/> Hautschuppungen, Blasenbildung, Brennen, Blutungen an Händen / Füßen <input type="checkbox"/> Nagelablösung

weitere Beschwerden:

To record the side effects:

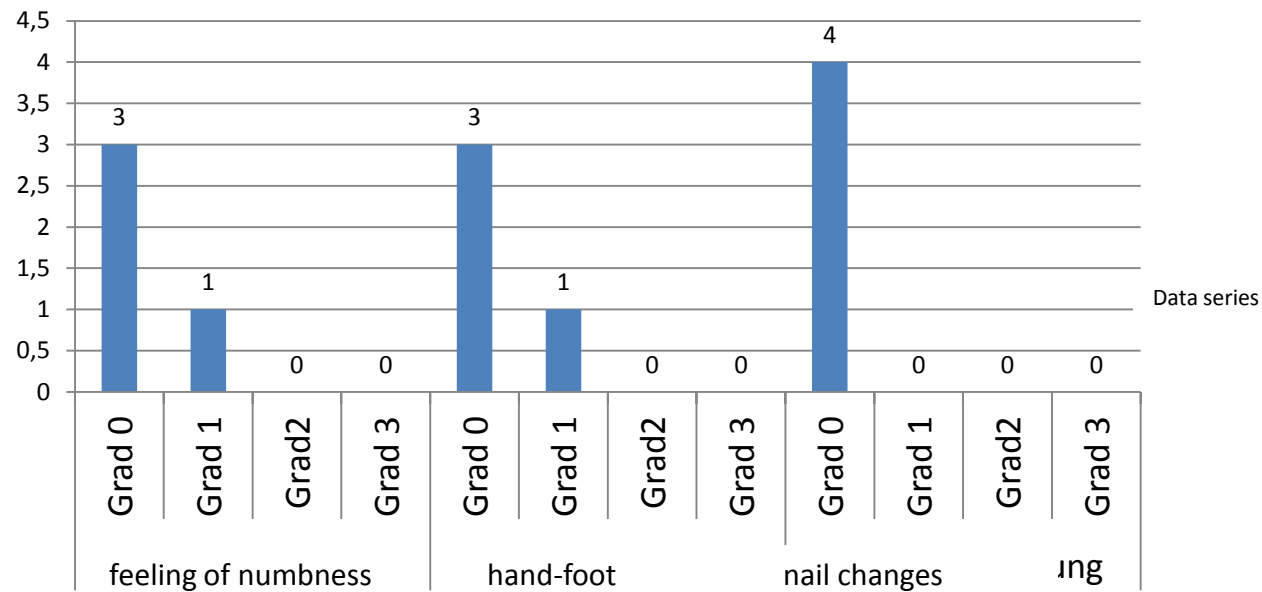
- Hand-foot-syndrome
- Polyneuropathy
- (Nail changes)

Patient population – Luisenkrankenhaus n = 60		
Observation	Primary cooling	Secondary cooling
4	20	36



- Only 6.7% of patients (n = 4) do not develop appreciable NW and remain in the observation - they do not cool.
- 33% of patients (n = 20) opt for primary, preventive Hilotherapy
- 60% of patients (n=36) develop without preventive Hilotherapie symptoms in HFS / Polyneuropathy - they switch to the secondary group – opt for the secondary Hilotherapy

Observation group (n= 4)

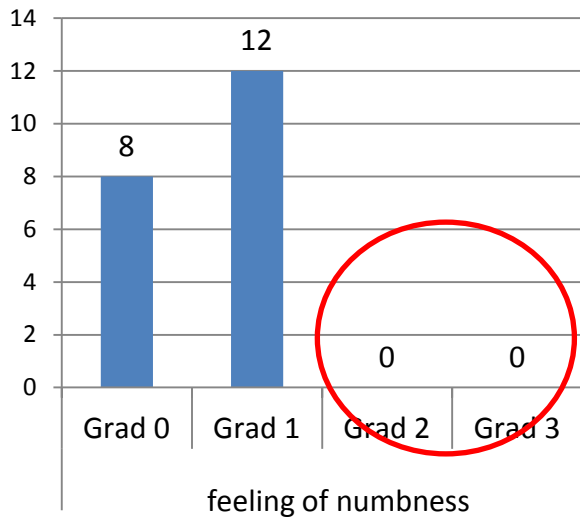


4 patients (6.7%) remain in the observation group
- they do not develop NW or only grade 1 symptoms -
without impairments in everyday life

Results of primary cooling 20 patients

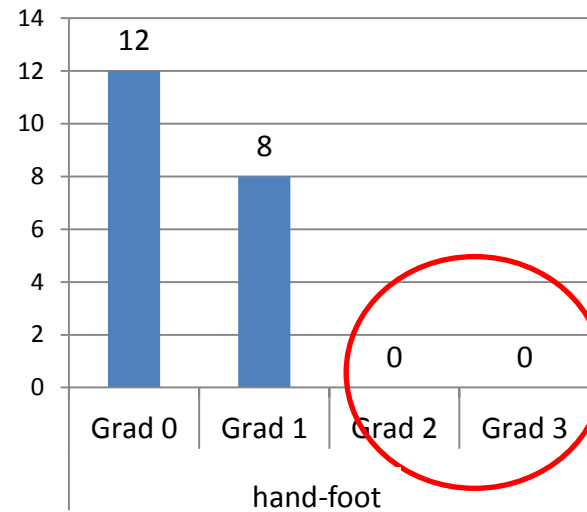
Patients begin cooling in the first taxane-based chemotherapy

Polyneuropathy



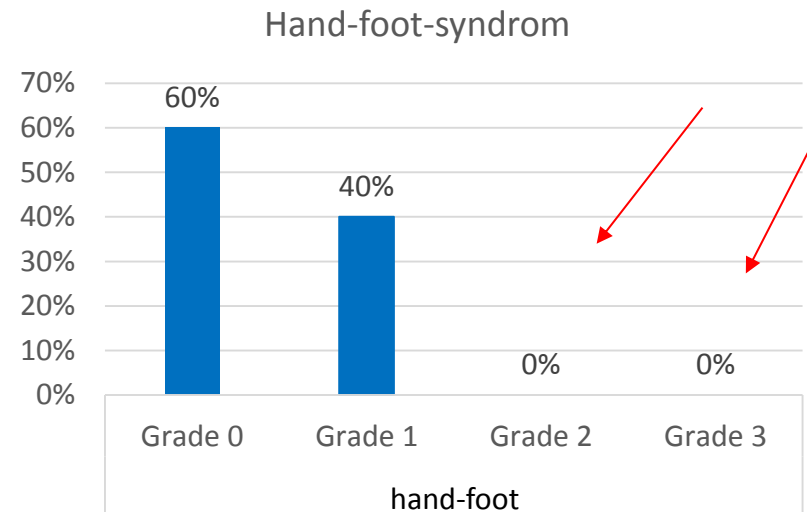
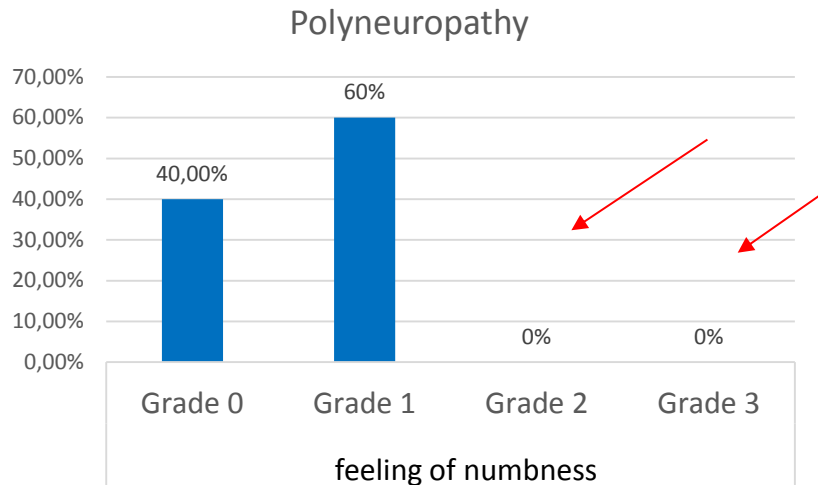
■ Number of patients

Hand-Foot



■ Number of patients

Primärgruppe – prophylaktische Hilotherapie bei 10° C



Results of Prophylactic Hilotherapy:

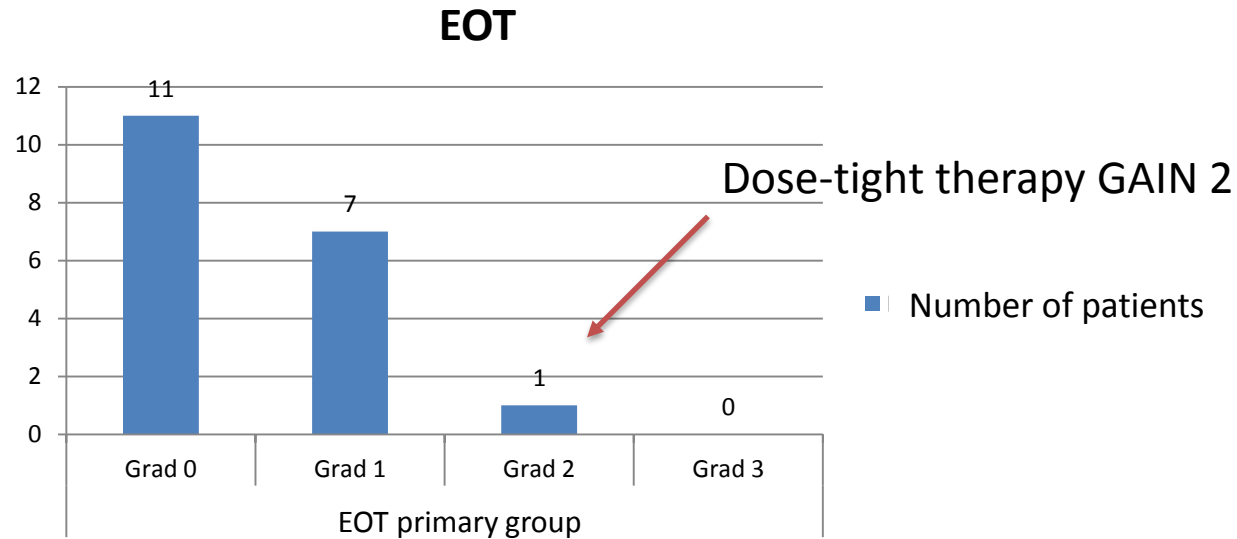
no occurrence of grade 2 and grade 3 toxicities (impairments in everyday life)

- 40% Patients (n = 8) **do not develop polyneuropathy**
- 60% Patients (n = 12) develop mild symptoms of polyneuropathy (grade 1 = no impairment in everyday life)

- 60% Patients (n = 12) **do not develop HFS**
- 40% Patients (n = 8) **develop mild symptoms of HFS (grade 1)**

Only grade 1 toxicities occur - these do not affect everyday life.

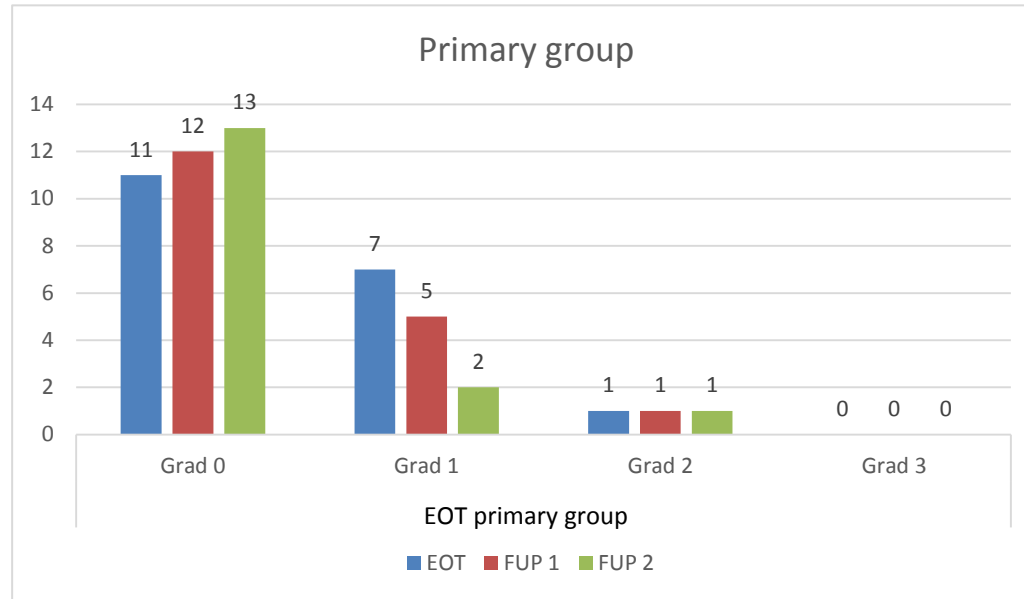
EOT bei prophylaktischer Hilotherapie bei 10°C (19 Patienten)



4 weeks after last therapy (EOT) the symptoms improve:
1 Patient still has symptoms that easily affect everyday life

- 58% have no symptoms anymore,
- 37% show still mild symptoms without impairments in everyday life (Grad1)
- 5% have symptoms with mild limitation

Follow Up course after primary Hilotherapy



EOT : 4 weeks after last chemotherapy (n = 19)

FUP 1: 4 months after last chemotherapy (n = 18)

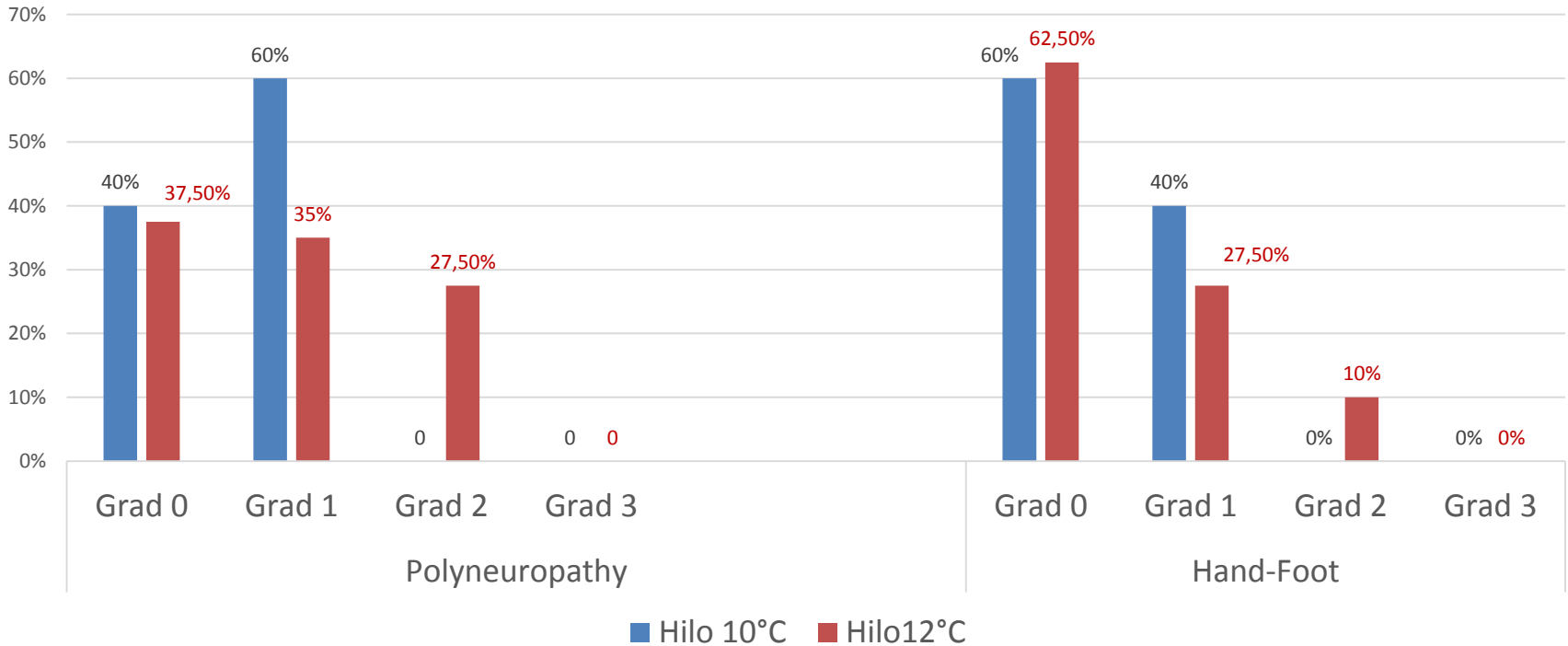
FUP 2: 7 months after last chemotherapy (n = 16)



Results as a function of the cooling temperature -
are there any differences?

Hilotherapie with 10°C (n=20) - vs – Hilotherapie with 12°C (n=40)

Comparison Hilotherapy 10 ° C vs Hilotherapy 12 ° C



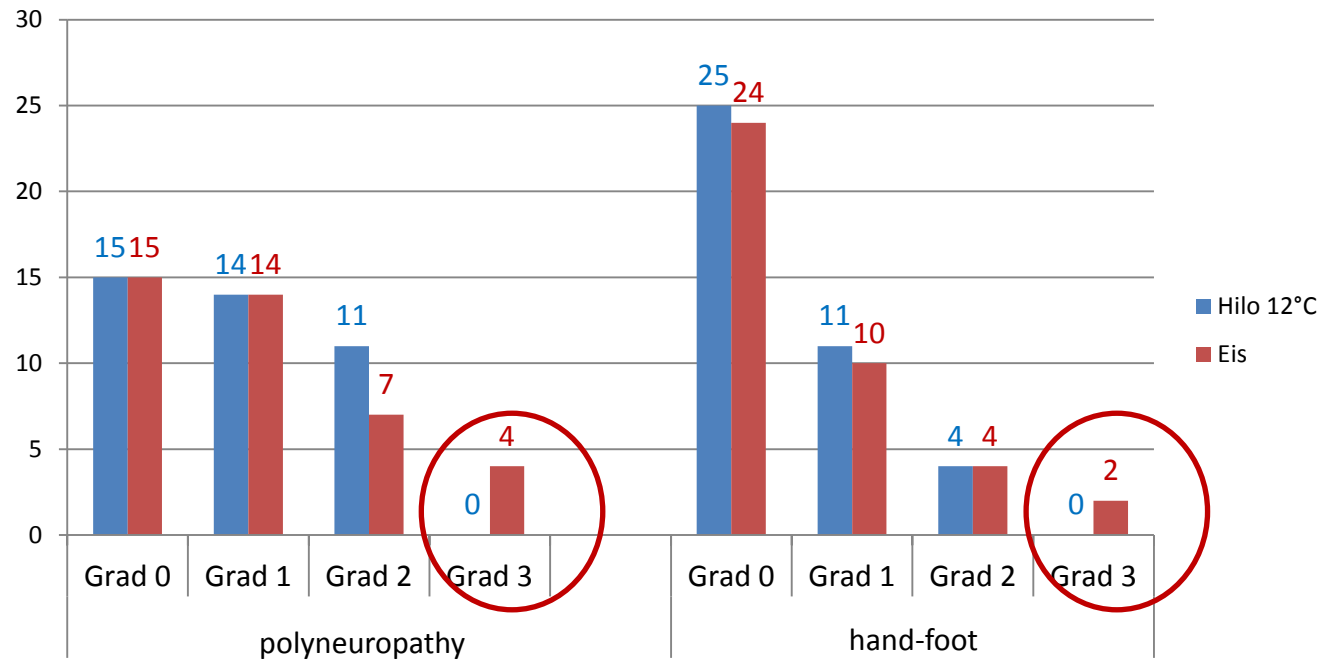
- developing severe grade 3 pathologies remains off in both temperature approaches
- Hilotherapy at 10 ° C tends to show better results
- Hilotherapy at 10 ° C does not result in grade 2/3 toxicities
- Hilotherapy at 12 ° C leads to grade 2 toxicities (27.5% and 10%)



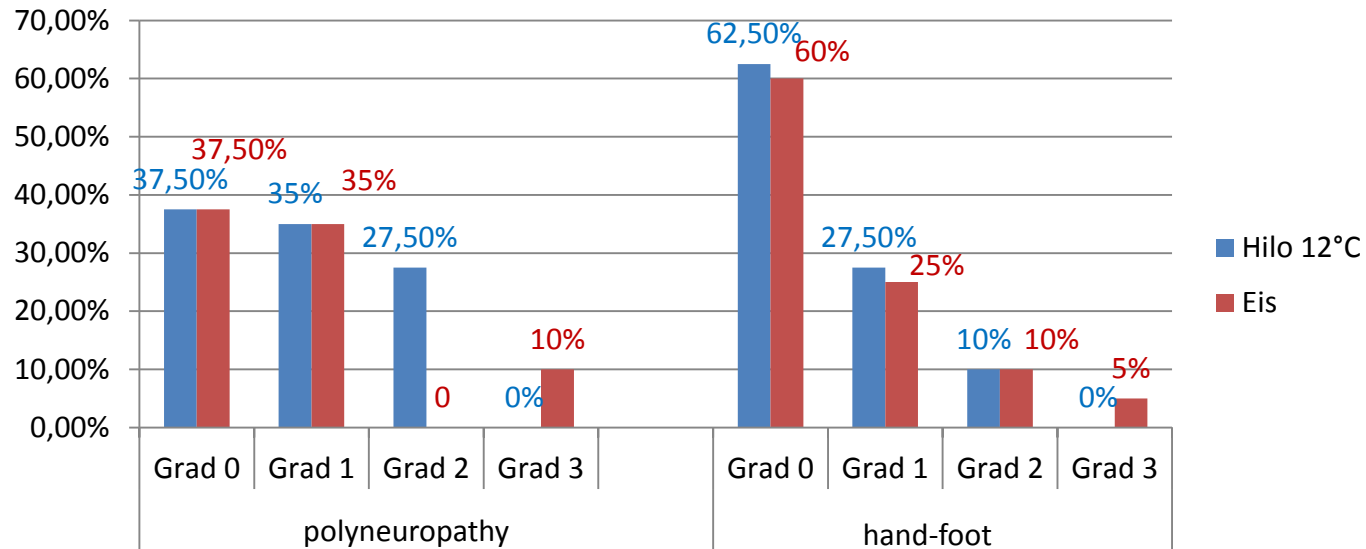
Preventive cooling in comparison
Ice gloves / booties - vs Hilotherapy 12 ° C
(N = 80)

Comparison: Hilotherapy 12 ° C vs Ice Gloves / Booties

N = 80



Vergleich: Hilotherapie 12°C vs Eishandschuhe / Füßlinge N=80

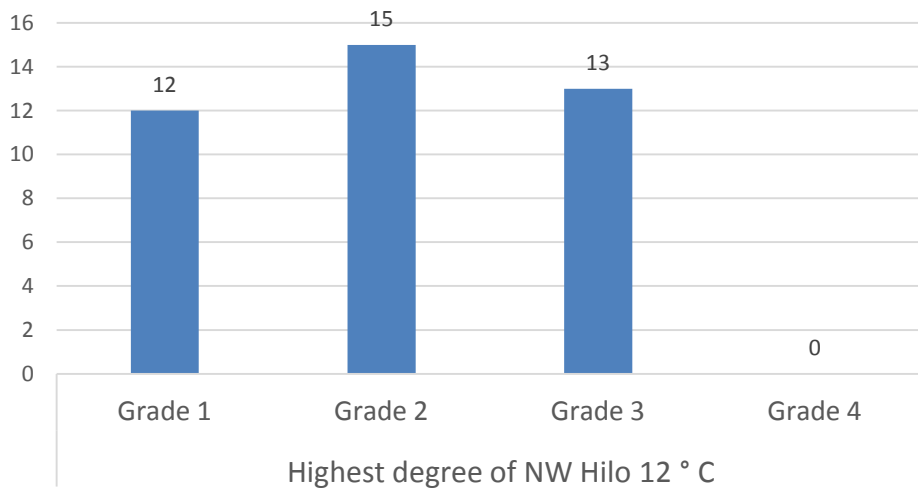


Results:

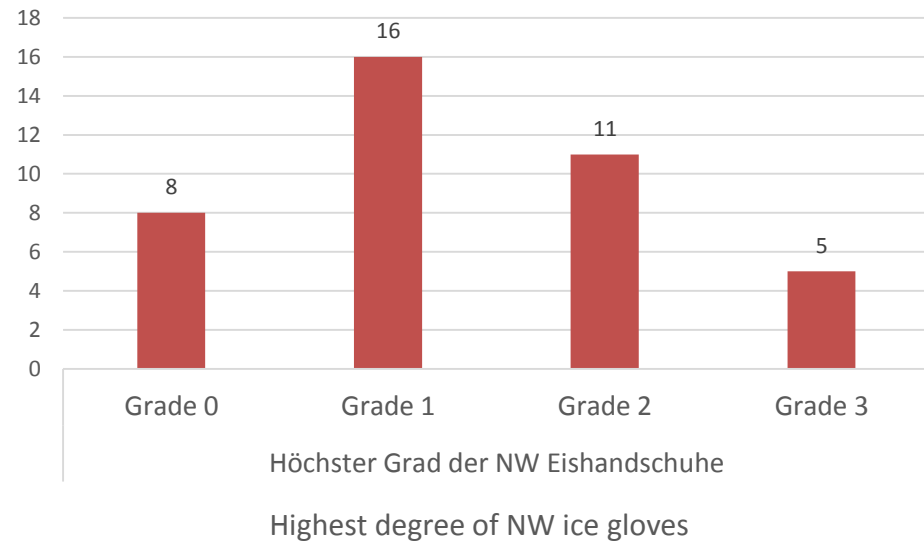
- die Hilotherapie zeigt die besseren Behandlungserfolge
- mit der Hilotherapie entwickeln sich keine Grad 3 Toxizitäten
- mit der herkömmlichen Methode (Eis) entwickeln auch Grad 3 Symptomatiken (Polyneuropathien und HFS)

Comparison Hilotherapy 12 ° C vs. ice gloves

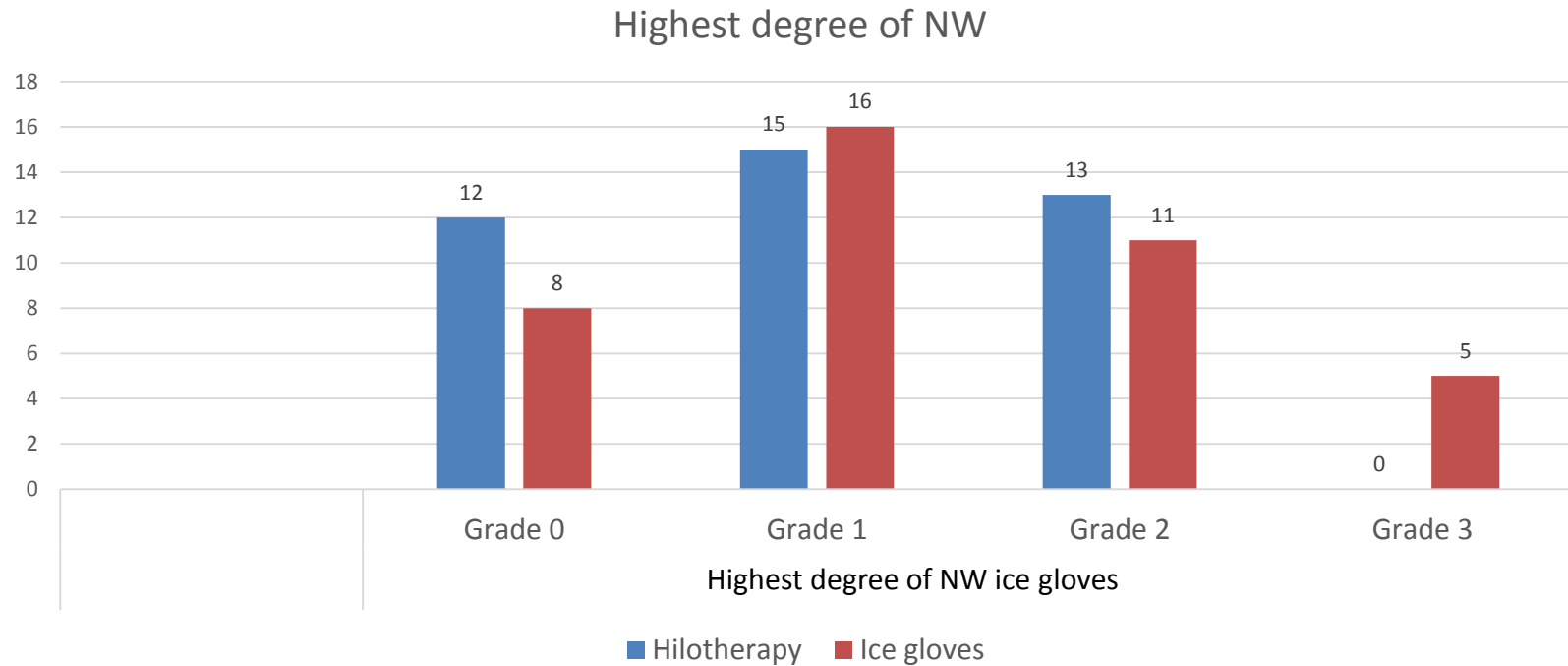
Highest degree of NW Hilo 12 ° C



Highest degree of NW ice gloves



Comparison Hilotherapy 12 ° C vs. Ice gloves



Results:

- Hilotherapy shows better treatment success
- with Hilotherapy, grade 3 toxicity does not develop
- with the conventional method (ice) also develop grade 3 symptoms (polyneuropathies and HFS)

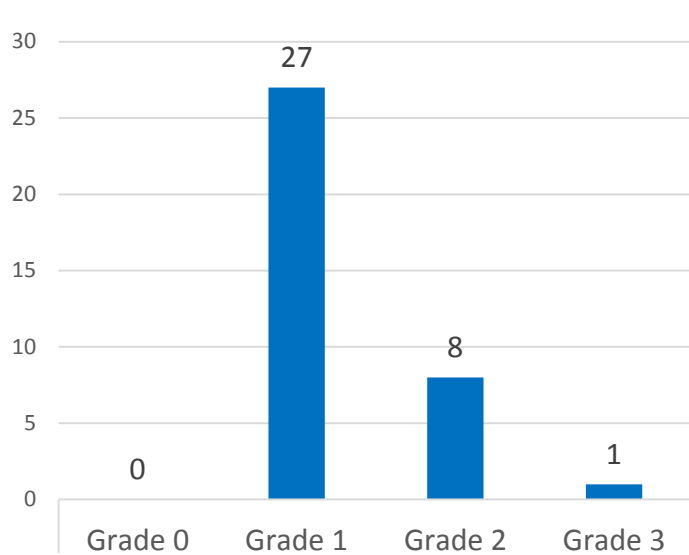
Secondary Hilotherapy 10 ° C

Secondary cooling - beginning of Hilotherapy after the onset of symptoms

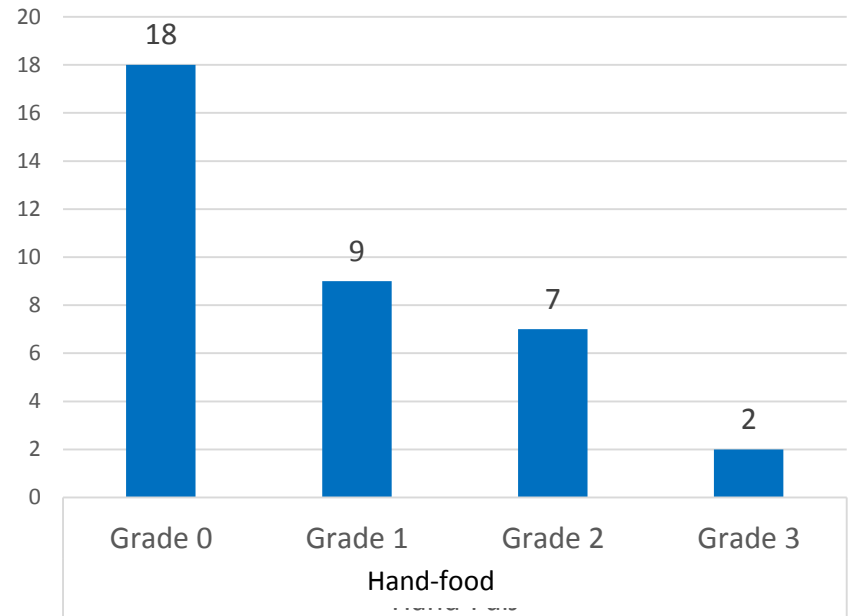
Secondary group n= 36

60% of our patients develop symptoms of HFS and polyneuropathy during chemotherapy without Hilotherapy - they opt for secondary cooling.

Polyneuropathy



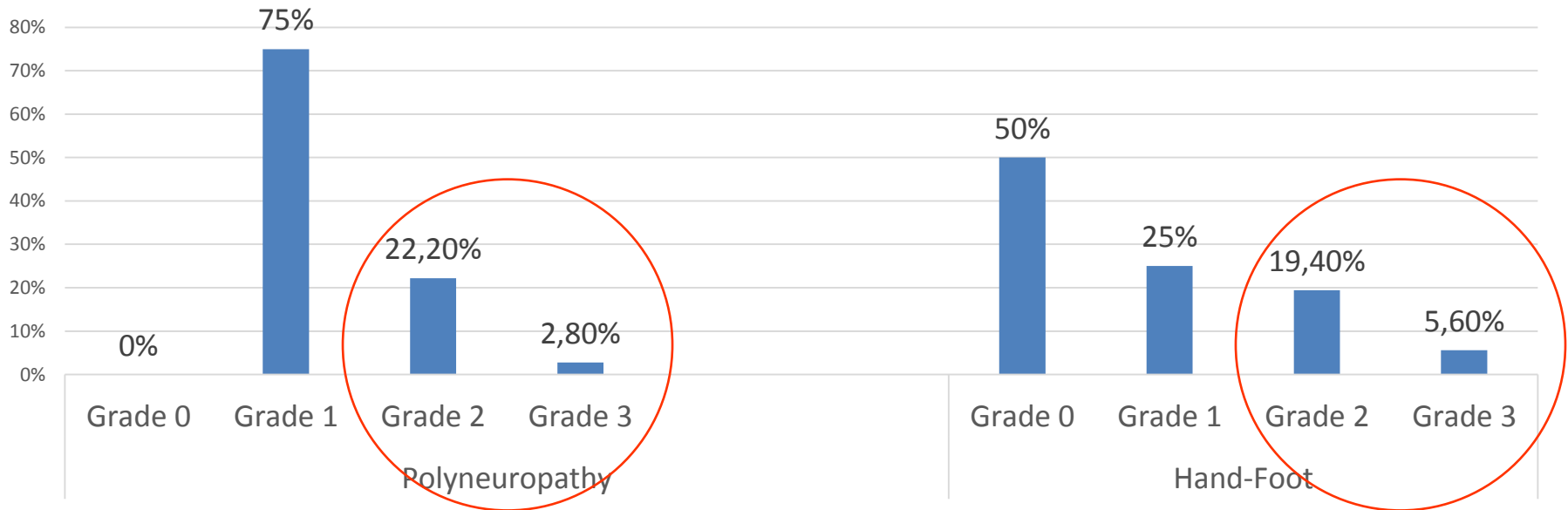
Hand-foot-syndrom



Secondary cooling - beginning of Hilotherapie after the onset of symptoms

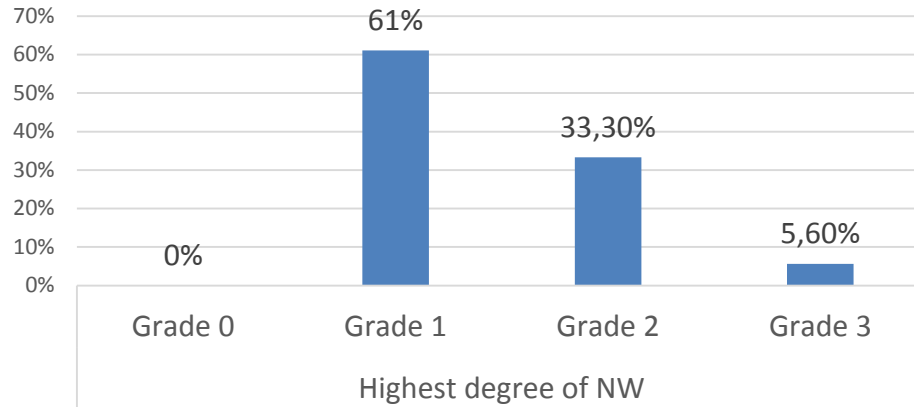
Secondary group n= 36

Secondary Hilotherapie

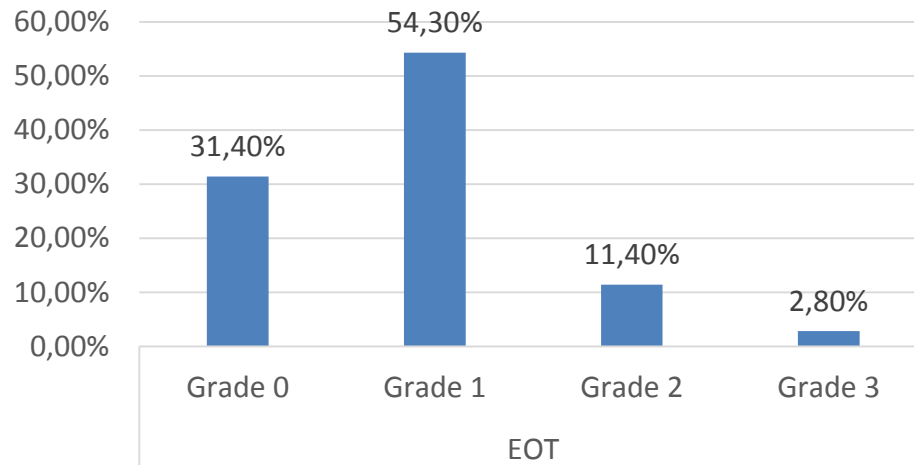


- there are Grade 2 and 3 symptoms
- After all, 75% of patients only develop grade 0-1 symptoms

Highest degree of NW secondary cooling



EOT - secondary cooling

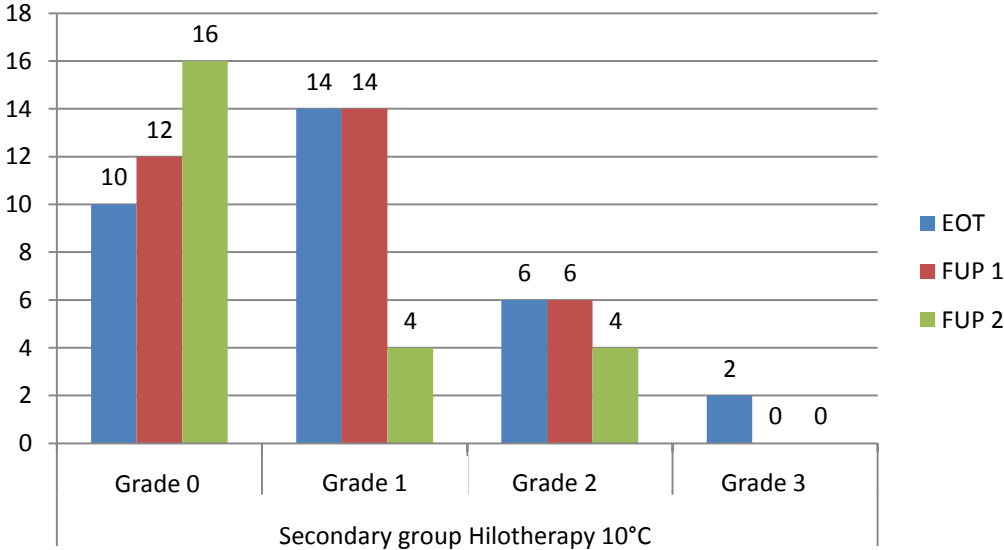


Improvement of the symptoms 4 weeks after the last therapy

Follow UP Elevation in the secondary group

Secondary group Hilotherapy 10°C

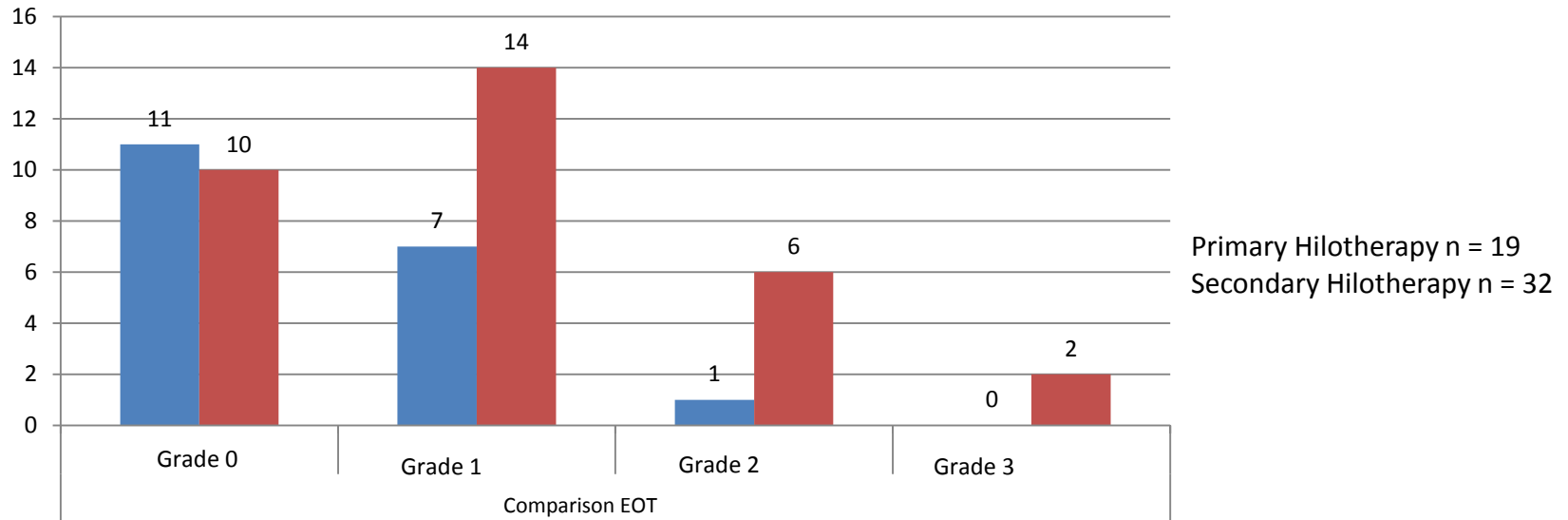
	Grade 0	Grade 1	Grade 2	Grad 3
EOT	10	14	6	2
FUP 1	12	14	6	0
FUP 2	16	4	4	0



EOT : 4 weeks after the last chemotherapy
FUP 1: 4 months after the last chemotherapy
FUP 2: 7 months after the last chemotherapy

Symptoms 4 weeks after last therapy EOT

Comparison Primary Hilotherapy vs. secondary Hilotherapy



Primary Group: n=19

Grade 0 / 1 : 95%

Grade 2 : 5%

Grade 3: 0%

Secondary Group: n = 32

Grade 0 / 1 : 75%

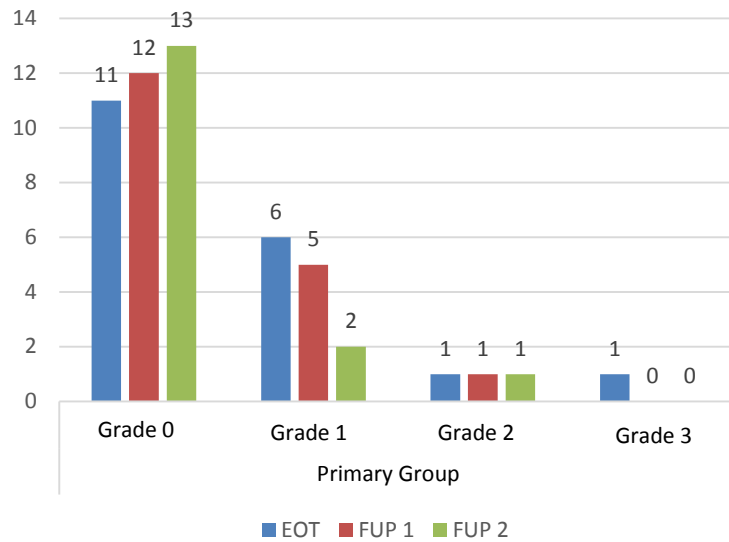
Grade 2: 18,75%

Grade 3: 6,25%

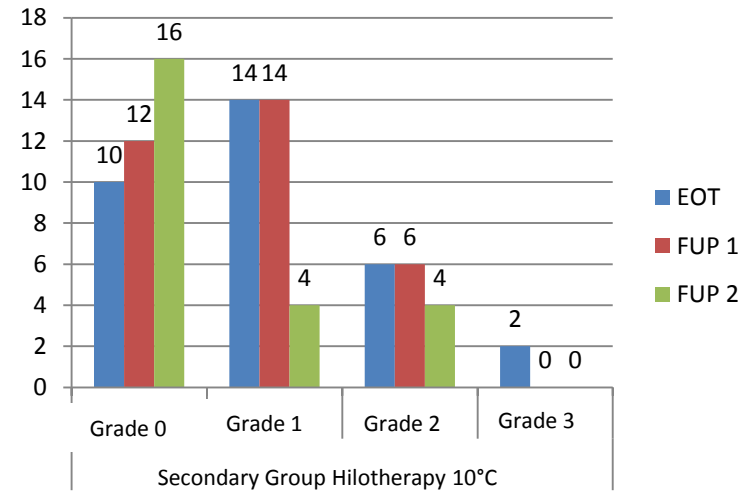
Symptoms recover faster the sooner they are cooled (primary group and secondary group)

Comparison Follow UP Primary - vs. Secondary Hilotherapy

Primary Group



Secondary Group

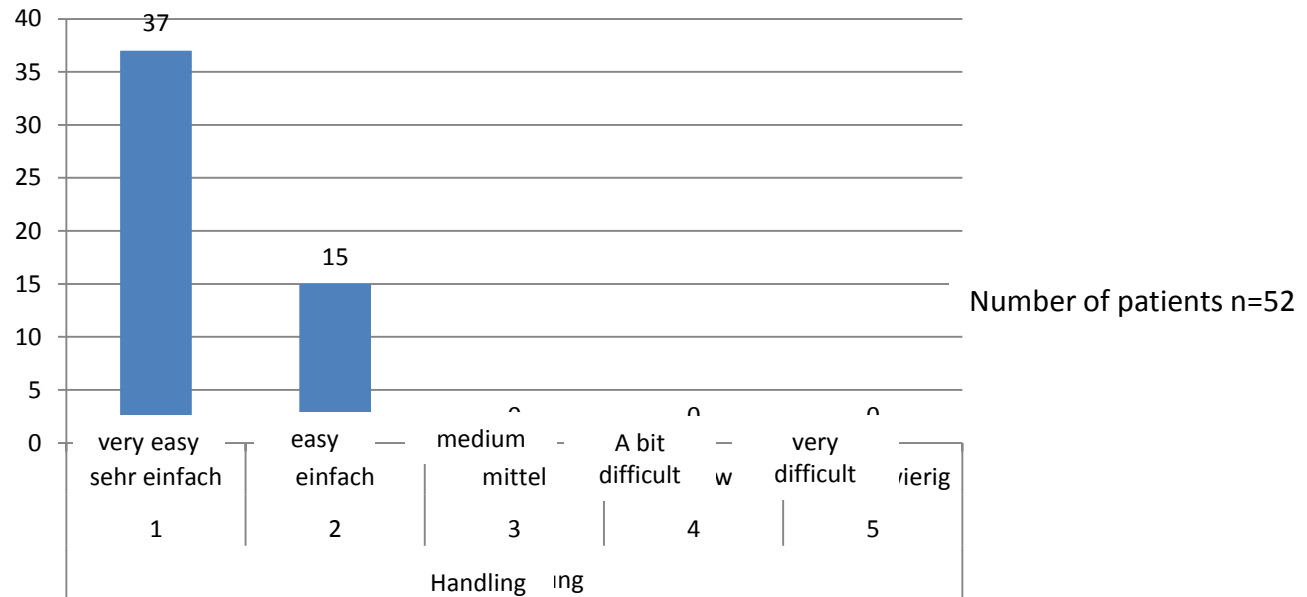


How do patients feel about the handling of Hilotherapy 10 ° C

Handling: How did you feel about the handling? School grading scale 1-5

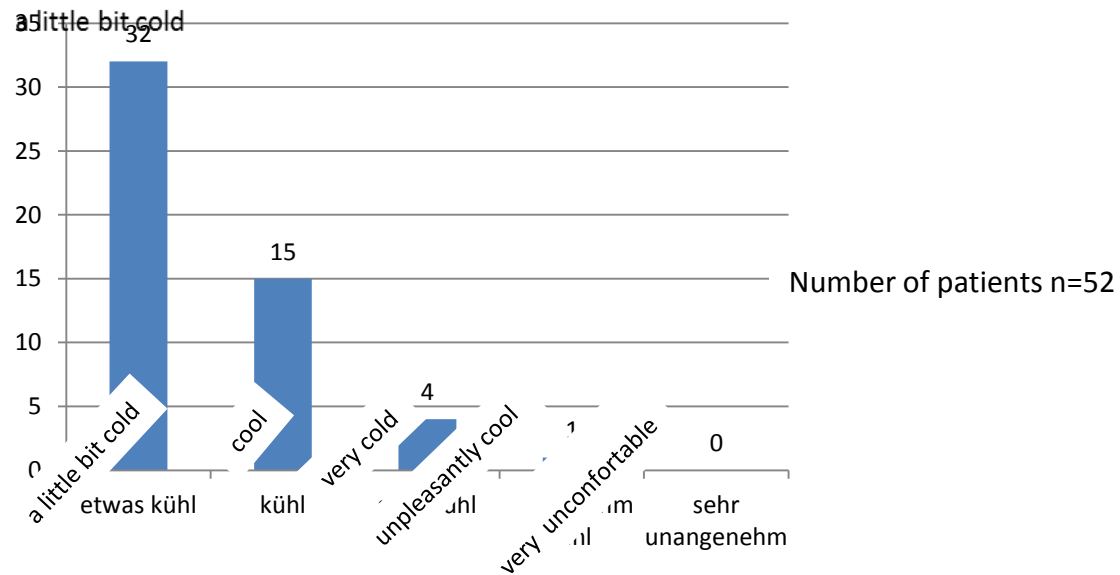
Handling

1	2	3	4	5
very easy	easy	medium	a bit difficult	very difficult
37	15	0	0	0



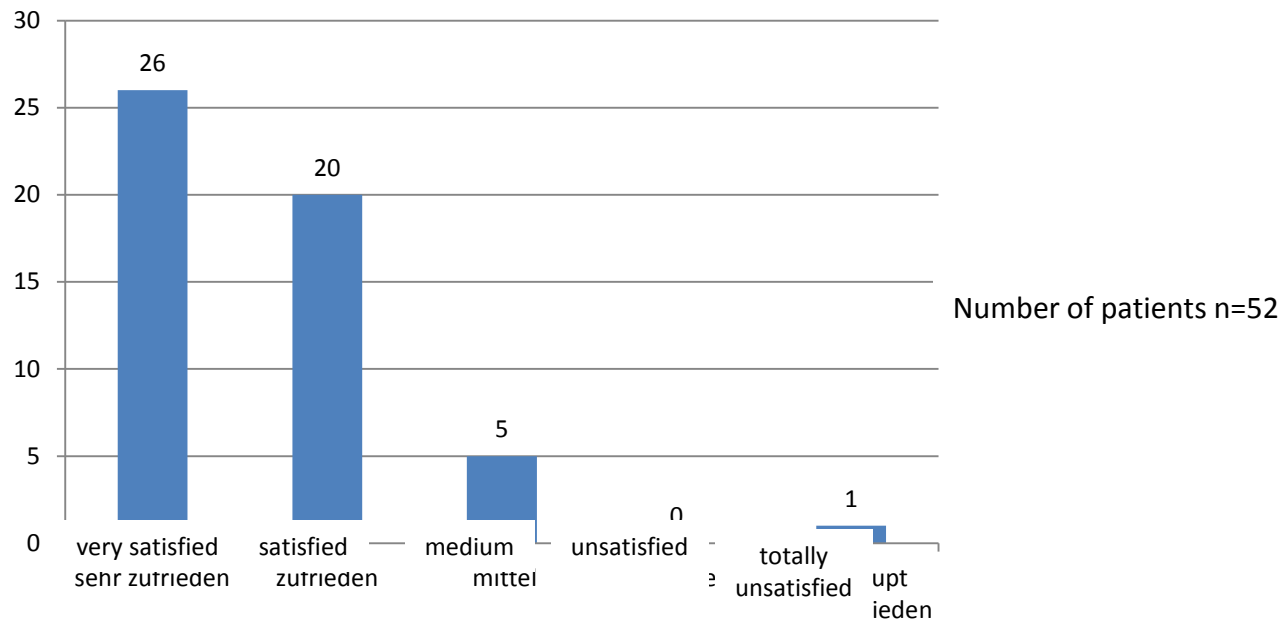
Subjective feeling: How did you feel about the cooling?

Subjective feeling				
1	2	3	4	5
a little bit cold	cool	very cold	unpleasantly cool	very uncomfortable
32	15	4	1	0



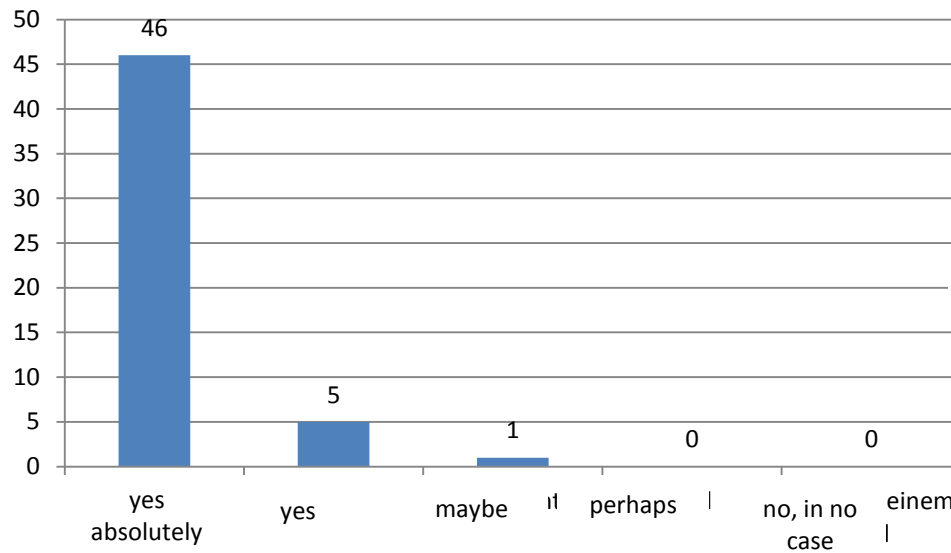
Satisfaction: How satisfied are you with the result?

Satisfaction / result				
1	2	3	4	5
very satisfied	satisfied	medium	unsatisfied	totally unsatisfied
26	20	5	0	1



Recommendation: Would you recommend Hilotherapy to your friend?

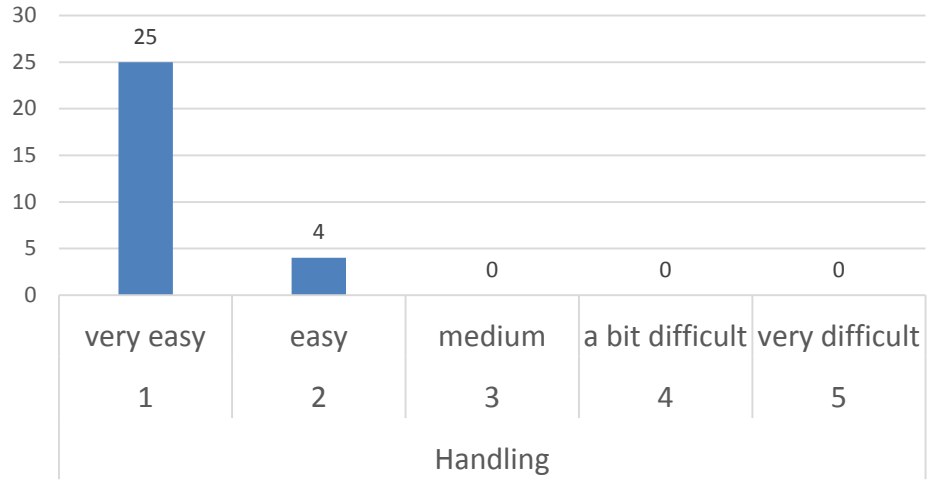
Recommendation				
1	2	3	4	5
yes absolutely	yes	maybe	perhaps	no, in no case
46	5	1	0	0



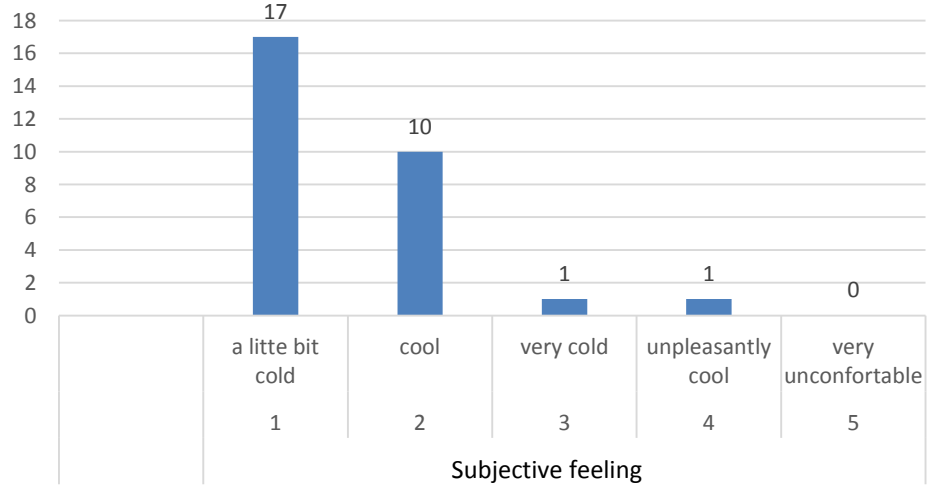
Number of patients n=52

Handling Hilootherapy 12 ° C Schubert n = 29

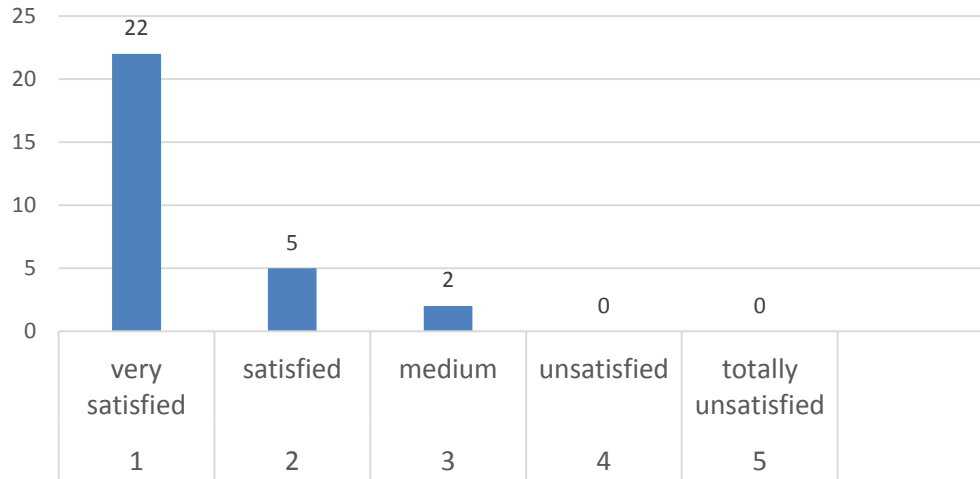
Handling Hilotherapy 12°C



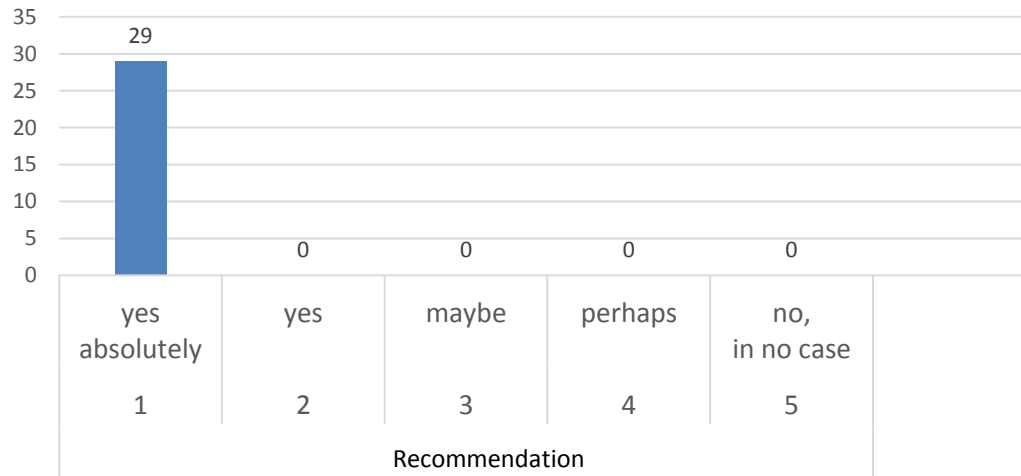
Subjective feeling Hilotherapy 12°C



Satisfaction / outcome Hilotherapy 12°C



Recommendation Hilotherapy 12°C



Summary

Results from a total of 120 patients

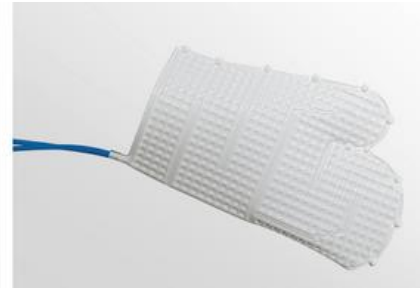


Luisenkrankenhaus (n = 60) - Hilotherapy at 10 ° C

- without prophylactic hilotherapy, only about 7% of patients remain without symptoms of HFS / polyneuropathy
- Prophylactic use of Hilotherapy resulted in only mild HFS and polyneuropathy (no grade 2 and 3 toxicity)
- Only Grade 1 toxicities developed, but by definition they do not affect everyday life
- 4 weeks after the last chemotherapy 70% of the patients in the primary group no longer show any symptoms;
- 30% only grade 1 toxicities - without stress in everyday life / no pain
Secondary cooling is also successful and can avoid or reduce the severity of severe symptoms
- the sooner the cooling starts the better: grade 2 and 3 toxicities can be greatly reduced (polyneuropathy grade 0-1: 75%, HFS grade 0-1: 75%),
- 4 weeks after the last therapy there are fewer symptoms in the primary group than in the secondary group

Gynecological Oncology Scheibenberg (n=80)

- Hilotherapy was applied at 12 ° C
 - the results of Hilotherapy at 10 ° C are better than those at 12 ° C; at 10 ° C there is no level 2 toxicity
 - conventional cooling with ice gloves or footlets is inferior to Hilotherapy; in the group of ice gloves also grade 3 toxicities are formed
-
- the use of Hilotherapy is comfortable for both patients and caregivers
 - Hilotherapy in oncology shows promising results
 - The quality of life of severely damaging symptoms of HFS and polyneuropathy are prevented or reduced



Statement:

Hilotherapy in oncology is a promising one
Thermo-healing that greatly reduces or prevents the
development of HFS and polneuropathy and should be
offered to as many patients as possible.