

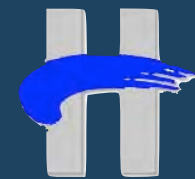


Niigata National Hospital
& College of Nursing



DEUTSCHES
INSTITUT FÜR
JAPANSTUDIEN

Workshop Thursday November
10th 2011
Care Robotics in the Aging
Society: Integrating Users,
Developers and Technology



National Hospital Organization

Issues in Testing Care Robotic Devices in the Field: Using HAL in a Japanese Hospital

Clinical trial of Orphan medical device for intractable neuromuscular rare diseases

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Wearable robot HAL : Hybrid Assistive Limb

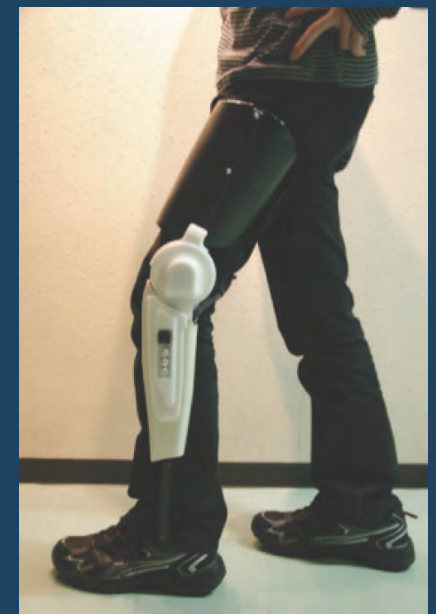
- HAL technology can be divided to two parts:
 1. Estimating wearer's motion intention at real time using measuring bioelectrical signals such as wearer's surface EMG, joint angles, and acceleration and force plate signals
 2. Enhancing the wearer's limbs movement with appropriate motor torque=Human enhancement technology
 - Prototype HAL-1 (Prof.Sankai, Tsukuba Univ. 1997)
- HAL has hybrid control mechanism
 1. Cybernic voluntary control, based on wearer's intention
 2. Cybernic autonomous control, based on machine internal estimation
- HAL may have protective effect for human muscles



Cybernetics was coined from cybernetics, robotics, and informatics by Prof. Sankai.

Perspectives of medical applications of HAL

- Four medical application areas
 1. Single leg HAL model can be utilized for **stroke rehabilitation in acute phase**=Possible reduction of time for recovery of walking
 2. Prevention and **improvement of secondary disused limb functions**. Re-education of limb function including incomplete hemiplegia and paraplegia
 3. New intelligent **orthosis**
 4. **This study: Reduction of disease progression speed=declining muscle weakness and atrophy in neuromuscular diseases**
- HAL combination therapy with other translational therapies including enzyme replacement therapy and gene therapy
 - Exon skipping and HAL combination therapy in Duchene muscular dystrophy
 - ERT and HAL combination therapy in Pompe disease



In the present study we are focusing on the below rare disorders

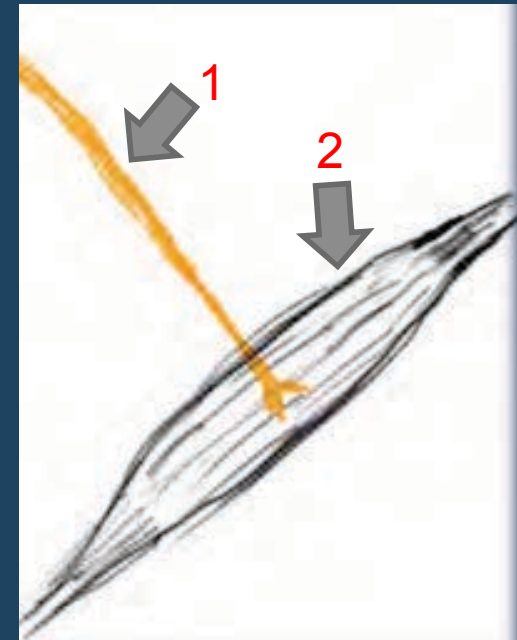
Neuromuscular intractable rare diseases develop irreversible progression of muscle weakness and atrophy in natural course. There are two groups including neurogenic muscular atrophy and myogenic muscular atrophy. Relatively slowly progressed type including the below could be chosen in this clinical trial at first.

1. Neurogenic muscular atrophy

- ▶ **SMA: Spinal muscular atrophy**
- ▶ SBMA: Spino-bulbar muscular atrophy
- ▶ **ALS: Amyotrophic lateral sclerosis**
- ▶ Post-Polio syndrome
- ▶ **CMT: Charcot-Marie-Tooth disease**
- ▶ Axonal-GBS : Guillain-Barre synd.
- ▶ Intractable CIDP

2. Myogenic muscular atrophy

- ▶ DMD: Duchenne muscular dystrophy with exon-skipping
- ▶ BMD: Becker muscular dystrophy
- ▶ LMD: Limb girdle type muscular dystrophy
- ▶ Pompe disease with ERT
- ▶ **DMRV : Distal myopathy with rimmed vacuole**



Targets of this trial

- **HAL-welfare lower limb model** : designed for people with normal muscle is now in market from CYBERDYNE Inc. in Tsukuba, Japan.
<http://www.cyberdyne.jp/english/index.html>
- **HAL-neuromuscular lower limb model** : that is able to sense and assist damaged muscles, has been redeveloped. Clinical trial for efficacy and safety of this model will be necessary.
- **Target in this clinical trial of HAL-neuromuscular lower limb model**
 - **Main target** : Modifying natural disease progression such as protective effects of muscle atrophy and weakness, using HAL intermittently
 - **We hypothesize** : “Appropriate muscle assistance is able to protect degenerative muscles, to keep muscle function longer and to prevent disused phenomena in healthier muscles”

Intermittent usage of ventilator slows down the decline speed of forced vital capacity or pulmonary function

**Appropriate
muscle assist
protects muscle
and prolongs its
function:
Disease modifying
effects**

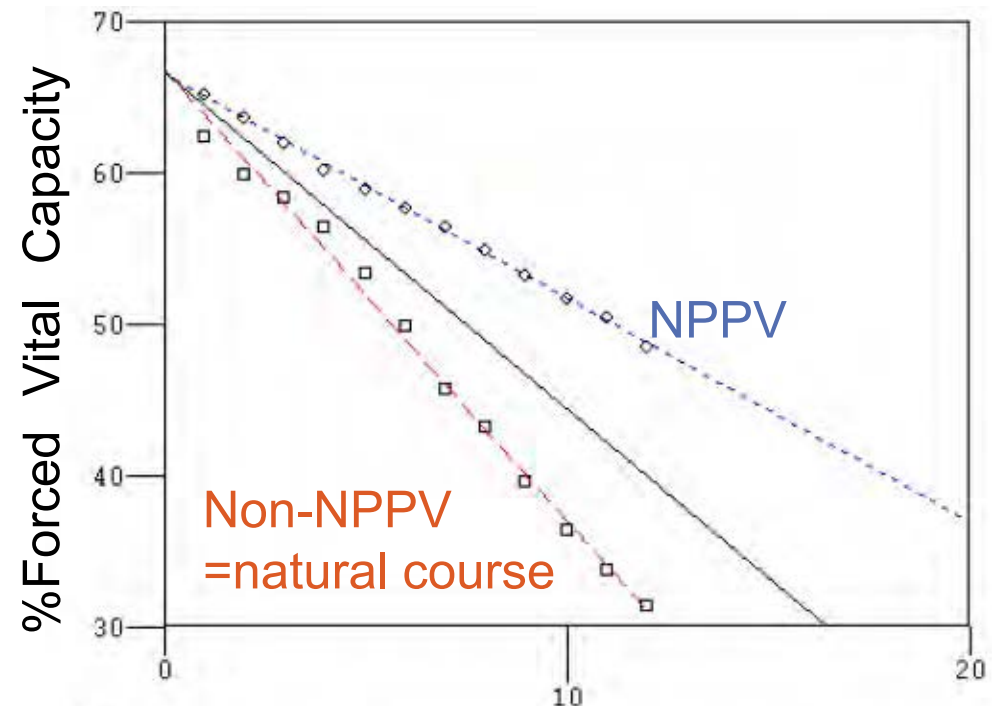


Figure 2
Slope of FVC% in 1 year between survivors of the groups 2 and 3. Blue line: Group 2 (12) (NPPV); Red line: Group 3 (4) (no NPPV). X axis: months; Y axis: FVC%. FVC% slope change per month in group 2 (1.52 ± 0.3) and group 3 (2.81 ± 0.8); $p < 0.0001$.

Orphanet Journal of Rare Diseases 2009,4:10

Early treatment with noninvasive positive pressure ventilation prolongs survival in Amyotrophic Lateral Sclerosis patients with nocturnal respiratory insufficiency

Pierluigi Carratù^{*1}, Lucia Spicuzza², Anna Cassano¹, Mauro Maniscalco³, Felice Gadaleta¹, Donato Lacedonia¹, Cristina Scoditti¹, Ester Boniello¹, Giuseppe Di Maria² and Onofrio Resta¹



52 year old man with SMA3

Spinal muscular atrophy type 3

- ⌚• He became unable to run at the age of 15.
- ⌚• After he graduated from high school, he got a job of professional driver in City Hall.
- ⌚• He gradually became unable to stand and walk independently. He always use a electric wheel chair.
- ⌚• Although he has not been able to flex and extend his knee joint since 10 years ago, he can still walk with support.

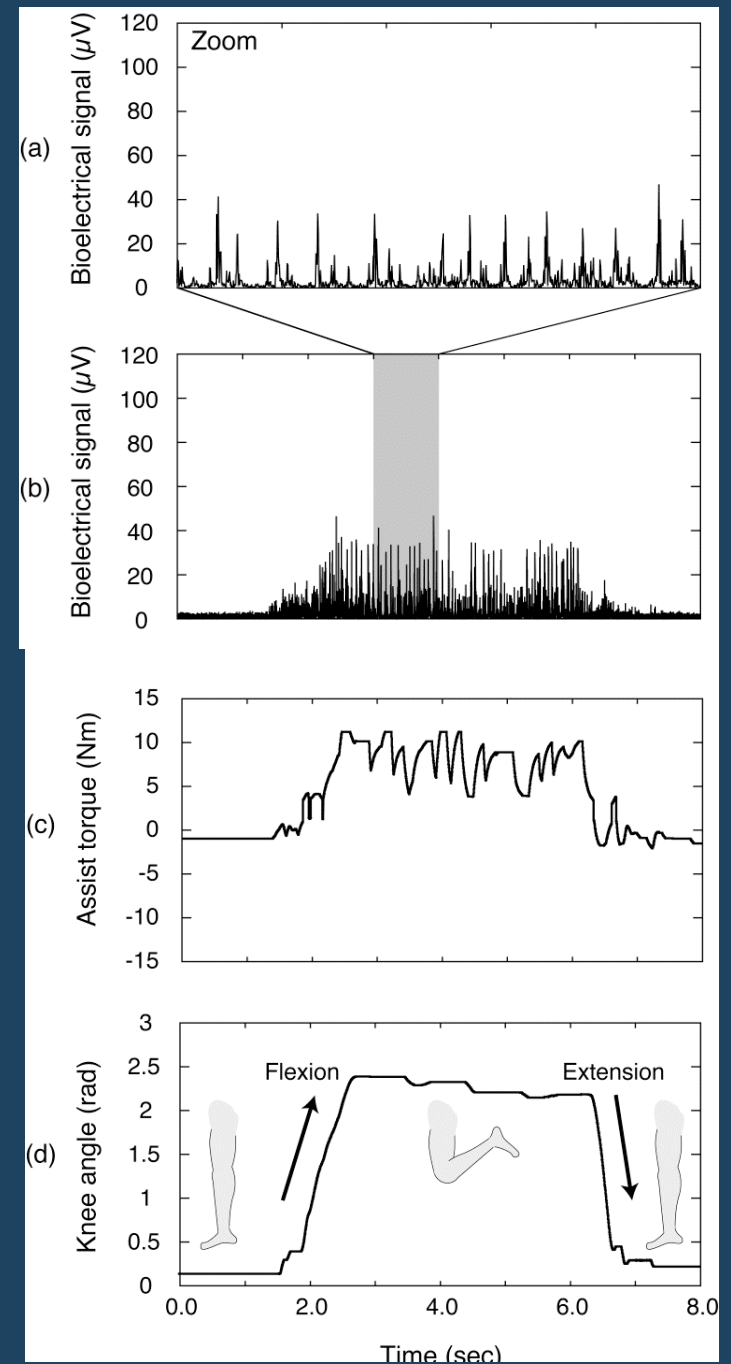
New signal processing method for neuromuscular diseases

- Surface EMG of neuromuscular disease patients shows
 - Low voltage surface EMG
 - Sparse frequency of firing of motor unit potential
- How can HAL translate such signals into motor torque as the patient's motion intention?
- Shingu's method (2009) is useful for signal processing of surface EMG from neuromuscular disease patients.

Proceedings of the 2009 IEEE
International Conference on Robotics and Biomimetics
December 19 -23, 2009, Guilin, China

Substitution of motor function of polio survivors who have Permanent Paralysis of Limbs by using Cybernic Voluntary Control

SHINGU Masahiro, EGUCHI Kiyoshi and SANKAI Yoshiyuki



Wearer's intention based HAL-assist using the similar signal processing method

With HAL

Both patient and researchers were surprised. The patient said "I have almost forgotten how to use knee joints. But I remember".



Before

Original movement:
he is not able to
extend and flex knee
joint against gravity



The first day

Walking with hoist and HAL for 40 minutes



The 5th day

Walking with hoist and HAL for 40 minutes



**Pre-test:
Walking with hoist**



**Post-test:
Walking with hoist
after 4 times
walking with HAL**

Leg-swings and walking speed are apparently improved compared with the pre-test walking.

Preliminary result(-2011) and Ongoing Clinical trial(2011-)

• **Completing development of HAL-neuromuscular model (-2011)**

- Standardizing method of evaluation of damaged muscle using X-ray CT
- Standardizing method of electrodes selection using HAL internal function
- HAL tuning: improving signal processing method of surface EMG
- Standardizing safety control and safety evaluation
- Demonstrable data showed that intermittent usage of HAL improves walking function without HAL

• **Making a final protocol of the clinical trial (2011-)**

- Making standard user's manual, including method of electrodes selection and wearing HAL, safety, training clinical staff etc
- Completing clinical evaluation method and end point analysis method
- Completing inclusion criteria and exclusion criteria
- Determining clinical sites and sample size in Japan
- Meeting PMDA(Pharmaceutical and Medical Device agency, Japan)

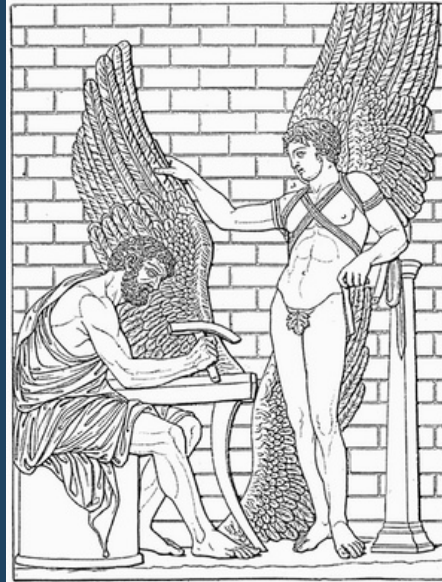
Hybrid (human and others) and Enhancement

Historical perspective



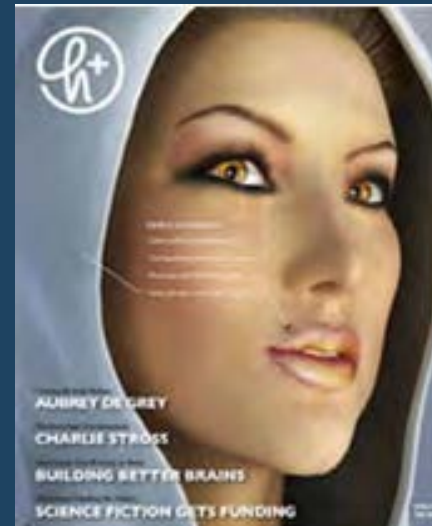
Assyrian Shedû

A protective goddess.
Human head, eagle wings, bull's legs, and lion body. (the late 8th century BC)



Daedalus and Icarus

Greek myths



Euphenics

Transhumanism
Cover page of
H+ magazine



HAL

Wearable robot
for medical and
welfare (1999-)

Is HAL[®] enhancement technology?



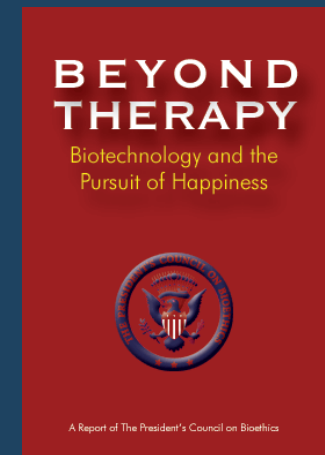
Target of HAL is to improve human life, especially in medical and welfare fields. Our team strongly think that medical and welfare technology should be more superior to military technology, because patients are more vulnerable than soldiers. Patients have weaker signals and more fragile physical structure. HAL researchers willingly overcome these points.

Using HAL is Beyond therapy?

Biotechnology and the Pursuit of Happiness American President's Council Report on Bioethics in 2003

<http://bioethics.georgetown.edu/pcbe/reports/beyondtherapy/index.html>

- Therapy=restoration to normal
- Beyond therapy= therapy beyond normal
=Enhancement, Desire driven therapy
- Neuromuscular patients as well as aged handicapped patients are unable to become normal as strict meaning. In this area HAL may not be enhancement technology. HAL can change dynamically ourselves, help us and rehabilitate us in the community again.



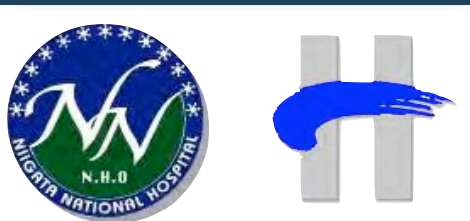
Team member on this project



Mr. Tomohiro Hayashi
HAL researcher



Prof. Yoshiuki Sankai
and his laboratory
member



HAL workgroup in
the department of
Neurology and
rehabilitation of Niigata
National Hospital



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Welfare