としたトレーニングの実施により，常時有用な運動学習と回復効果をもたらすことが可能と考えている．既存研究において視覚情報と体性感覚の組み合わせにより身体イメージが拡張されることも示唆[26]されており，本研究の目的であるセンサスーツからの視覚による運動情報により運動機能を支援・拡張することは十分に可能性を有していると考えられる．

5.3 システム改善

提案するシステムの計測対象である筋活動は股関節，膝関節角度に加え，大腿部における筋電位であり，表層筋の提示に限られている．しかし，表層筋の活動に加え深部筋における活動も身体動作に大きく関係しており，特に腸腰筋のような股関節部における深部筋は歩行安定性やバランス維持等の基本的な動作に寄与している．これら深部筋の筋活動推定および提示は，現在のセンサスーツへ膝下における筋活動や床反力計測を組み込むことで，着用型のインタフェースとして実現可能である．一般的に，これら深部筋の活動推定はモーションキャプチャや高度な筋骨格シミュレーションを用いた大掛かりなシステムに限られているが[8)–10)]，このようなシステムをセンサスーツにより実現することができれば，高度な筋活動解析を容易に日々のトレーニングへ適用することが可能となる．これにより，一般的に行われているトレッドミル上での歩行リハビリテーションと平地における歩行との筋活動の違い[27]の比較検証やそれに伴うリハビリテーション効率の再検討など，日常現場において高度な解析と効果的トレーニングへとつながる可能性がある．

一方，既存機器との併用によるセンサスーツの応用も考えられる．実証実験においてはモーションキャプチャシステムの課題点を解決する役割としてセンサスーツの代替使用を提案したが，高精度な動作計測はモーションキャプチャに優位性があり，その運動データからは各筋の詳細な働きや関節動作との関わりなど多様な情報を算出することが可能である[8)–10)]．これらの情報を提示するインタフェースとして，センサスーツを併用する形での利用が考えられる．体表上提示を活かし高精度なデータから算出した情報を身体に重畳して観察することで，リアルタイムでの動作理解の促進やコーチングへの場へと拡張することが期待される．

5.4 実用面における展望

提案するセンサスーツは，今後継続的に実応用場面における長期的効果の検証をおこなう予定である．センサスーツにより生じる自身の生体とのインタラクションおよび他者とのインタラクションによる効果は，特に指導者と運動者のやりとりが交わされる機会の多いリハビリテーションや体育コーチングの場面において有用と考えられる．従来のディスプレイによるフィードバックを用いたトレーニング手法では，運動者とディスプレイ間での頻繁な視線の移動が必要となり，筋活動と身体動作のどちらか一方の情報取得に限定されるといった問題がある．また指導者と運動者間で，訓練対象部位や筋活動への認識が正確に共有されない状況も考えられる．リハビリテーションでは特に運動者の状態に常時注意を向けることが必要であり，患者と医師との近い距離感での指導も求められる．体育コーチングにおいても同様の場面が多く見られ，これらの点において，センサスーツは体表上への筋活動提示手法により，指導部位に対しての正確な注意の共有や常時運動者へ着目した指導，さらには運動における主観的，客観的動作の差を埋めるトレーニングへの貢献が可能と考える．

6. おわりに

本研究では，下肢運動状態の計測および身体動作と複数筋動員様式の直感的な知覚を実現する着用型発光センサスーツの開発を行った．知覚特性実験により，センサスーツ上で知覚可能な分解能を検証するとともに，動的な運動観察時における筋活動知覚にも有用であることを示した．さらには，外骨格型脚部支援機器との併用実験，体育トレーニングにおける実証実験を行い，センサスーツにより生み出されるインタラクションを活かした次世代リハビリテーションおよび体育教育の両分野における応用の展望を示した．

本稿により提案した，生体の動作や表現を情報技術により拡張し，自身の生体そのものをメディアとして利用する技術は「拡張生体技術」といえる．センサスーツは，筋活動を体表上で可視化する拡張生体技術であり，提示情報をより自身の情報であることを容易に知覚させるための手法として体表上における筋活動の面発光提示を提案している．本技術は，認知的支援としてモチベーション向上や運動理解の促進，さらにはより高度な身体制御や脳の可塑性の促進を実現する可能性があり，最終的には物理的能力の支援，拡張へとつなげることを試みる．

今後は，システムの実応用を考慮した改善を行うとともに，上肢および下肢リハビリテーションやスポーツでのさらなる検証により長期的なセンサスーツの使用における認知的・物理的両側面への効果を検証する予定である．

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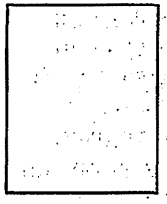

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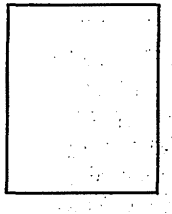

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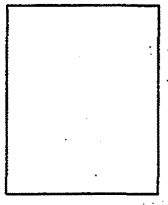

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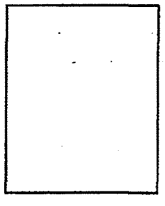

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研　究

3次元骨格系モデルによる腰部支援用HALの動作支援評価

原　大雅*・山海　嘉之*

Evaluation of HAL for Lumbar Support by 3D Skeletal Model

Hiromasa HARA,* Yoshiyuki SANKAI*

Abstract Low back pain (LBP) is one of severe diseases due to an overload onto lumbar area such as vertebrae, disks and nerves. The pathogenesis of LBP are caused by the physical load on the lumbar during the task of keeping a static posture, lifting a weight, spinning a lower back. To reduce the physical load, exoskeletal robots are researched and developed. However, it is difficult to verify non-invasively the load reduction of wearer's endoskeletal by motion assist. The load reduction of endoskeletal such as lumbar disks of area of injury can not be verified. The purpose of this paper is to propose and develop 3D skeletal model and the method that verify load reduction of wearer's endoskeletal, and to verify the effectiveness of HAL for lumbar support on lumbar load reduction. 3D skeletal model that consists of vertebrae and disks was developed based on anatomical insight and the radiograph of ordinary person. Finite element method (FEM) by using this model was proposed as the evaluation method of motion assist of exoskeletal robots. We simulated this model of wearer holding a weight, and analyzed the lumbar stress, without or with HAL support. The wearer held weights of 5-20 kg in a flexed posture. The effectiveness of this model was confirmed, because the stress concentrates on lumbar disks in a flexed posture. The analysis results showed that motion assist by using HAL decreases lumbar stress when it is compared to without HAL support. We proposed and developed the method that verify load reduction of wearer's endoskeletal, and verified the effectiveness of HAL on lumbar load reduction. The evaluation method of motion assist of exoskeletal robots was developed by this study. The proposed method can be applied to upper and lower body. It is expected as new index of motion assist.

Keywords: motor function support, biomechanics, lumbar load, robot suit.

1. はじめに

腰痛は，現代病のひとつに挙げられ，骨，椎間板，神経の損傷により腰部に痛みを発症する疾患である．損傷部位や脊髄の圧迫の程度によって，痛みだけでなくしびれや麻痺を伴う下肢機能障害に悪化するケースもある．そのため腰痛患者は，ADL（Activities of Daily Living）の制限やQOL（Quality of Life）の低下を強いられる．腰痛の物理的要因は，腰部への過度な身体的負荷であり，発症要因として長時間の静的作業姿勢維持，重量物挙上動作，捻転動作，反復同一動作が挙げられる[1]．これらの動作を頻繁に行うことで腰痛発症リスクの上昇，腰痛の悪化が懸念される．しかし，姿勢維持や重量物挙上動作などは，日常生活において頻繁に行われる動作であるため，これらの動作に対する腰部負荷軽減の重要性が指摘されている[2-3]．

身体的負荷を軽減するために，外骨格型ロボットの研究開発が行われている[4-6]．外骨格型ロボットは，装着者の内骨格に加え，ロボットによる外骨格で重量物などの負荷を支え，アクチュエータによって動作支援を行うことで身体的負荷を軽減することが可能である．外骨格型ロボットの動作支援の評価は，筋電位を用いた評価方法があり，筋電位の減少から計測対象の筋群の負荷軽減を示している．しかし，動作支援による装着者の内骨格系の負荷軽減を非侵襲的に検証することは困難であるため，損傷部位でもある椎間板などの内骨格系の負荷軽減の評価には至っていない．

本研究室で開発が行われてきたロボットスーツHAL（Hybrid Assistive Limbs）は，人間と一体化し装着者の運動機能を強化及び補助することで日常動作や重作業の支援を行うことを目的とした装着型ロボットである．先行研究では，健常者における立ち上がりや歩行などの下肢動作に適用され，身体的負荷の軽減に対する有効性が実証されてきた[7, 8]．その技術を応用して，図1に示すように全身型，下半身型や単関節型など様々なタイプを開発しており，健常者から障害者まで様々な対象者における適用が期待されている[9, 10]．

本研究は，解剖学の観点から腰痛の発症原因を追及し，工学技術による腰痛の予防・緩和を目指している．これまでに，HALの技術を応用して腰部負荷軽減に特化した腰部支援用HALの開発を行ってきた．本稿の目的は，外骨格型ロボットの動作支援による装着者の内骨格系の負荷軽減を検証可能な3次元骨格系モデルの開発と検証手法の提案，3次元骨格系モデルを用いた動作支援評価による腰部支援用HALの腰部負荷軽減に対する有効性の確認である．

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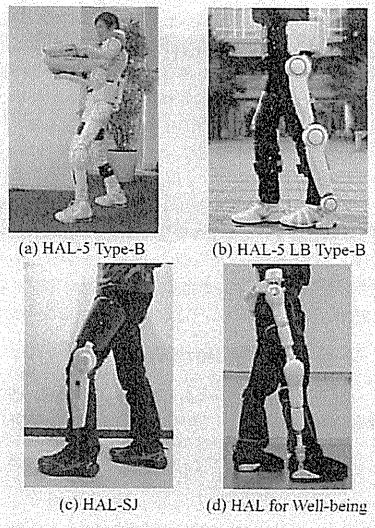


図1　ロボットスーツHAL
Fig. 1　Robot suit HAL.

2. 3次元モデル

2·1　腰部支援用HAL

介護分野をはじめ，重量物の運搬や，挙上を行うことは，身体的負荷の大きい仕事である．重量物把持時には，腰部に重量物増加分のモーメントが発生し，筋骨格系に負荷がかかり腰痛症や椎間板ヘルニア症等の障害が発生する危険性がある．それらを防止するためには，腰部負荷を軽減することが重要である．腰部負荷の軽減は図1(a)に示す全身型でも可能であるが，本研究では図2に示す腰部負荷の軽減に特化した腰部支援用HALを開発している．HALは，人間が関節筋を動かす際に発生する生体電位信号から装着者の動作意思を推定し，動作意思に応じたトルクを支援する．そのため，装着者の筋肉の動きと一体的に関節を動作支援することが可能である．

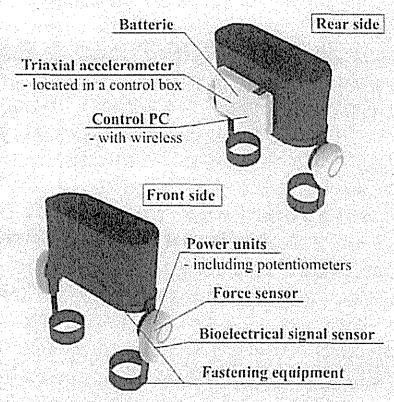


図2　腰部支援用HAL
Fig. 2　HAL for lumbar support.

腰部支援用HALが支援対象とする動作は，腰部負荷の大きい体幹の屈曲・伸展動作である．体幹屈曲・伸展動作は，腰椎の屈曲・伸展動作と両股関節を中心とした骨盤の回旋運動による股関節の屈曲・伸展動作から成り立っている．腰椎の可動域は回旋，側屈はほとんどなく，屈曲・伸展のみであるため，腰椎の屈曲・伸展動作を制動することで，体幹の屈曲・伸展動作を股関節の屈曲・伸展動作とみなすことができる．そのため，体幹屈曲・伸展動作における腰部モーメントは，股関節まわりに作用するモーメントとなる．従って，体幹屈曲・伸展動作を股関節の屈曲・伸展動作に代替し，腰部支援用HALによって股関節の動作支援を行うことで腰部負荷を軽減することができると考えられる．腰部支援用HALは，背面にコントロールユニット，股関節にパワーユニットを有している．腰部支援用HALは，腰部と大腿部に取り付けられたモールドと呼ばれる固定具により装着が可能である．両モールドを介してパワーユニットから発生されるトルクを体幹及び下肢に伝達する．腰部モールドは，腰椎を制動する役割を担っており，腰椎のみを制動するため体幹の回旋，側屈は阻害されない．

2·2　3次元骨格系モデル

外骨格型ロボットの動作支援による装着者の内骨格系の負荷軽減を検証するために，人体モデルの開発を行う．人

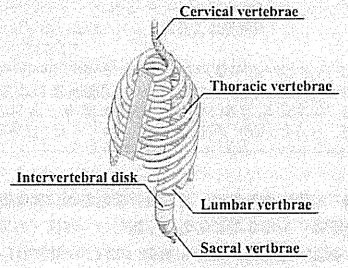


図3　3次元骨格系モデル
Fig. 3　3D skeletal model.

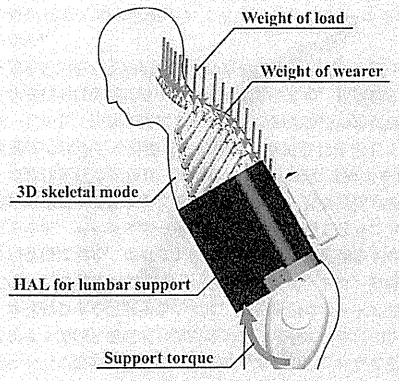


図4　動作支援評価モデル
Fig. 4　Evaluation method of motion assist.

間の脊柱は，33個の椎骨で形成されている．椎骨は上から順に，7個の頸椎（Cervical vertebrae：C1-C7），12個の胸椎（Thoracic vertebrae：T1-T12），5個の腰椎（Lumbar vertebrae：L1-L5）の合計24個の可動椎と不動椎である5個の仙椎（Sacrum：Sacral vertebrae 1-5）と4個の尾椎（Coccyx：Coccygeal vertebrae 1-4）があり，各椎骨間には椎間板が存在する．椎骨は，椎体と椎弓から成り，椎体と椎間板を前部脊柱と呼び，脊柱支持の役割を担っており，椎弓を後部脊柱と呼び，運動の調整機能を担っている．これらの解剖学的知見及び健常者のレントゲン写真をもとに開発した3次元骨格系モデルを**図3**に示す[11]．本研究は重量物把持時の脊柱支持における解析を対象としているため，椎骨は椎弓及びそれに伴う関節，筋，靱帯等を省略してモデルを簡単化し，3次元骨格系モデルは椎骨と椎間板，体組織により構成している．モデル要素である椎体，椎間板，体組織の機械的性質は，Tanakaらが解析で使用したデータを参考にした[12]．

3．動作支援評価方法

外骨格型ロボットの動作支援評価の検証方法として，3次元骨格系モデルを用いた有限要素法応力解析を提案する．本研究では，腰部支援用HALの腰部負荷軽減に対する有効性を確認するために，腰部支援用HALの3次元モデルと3次元骨格系モデルを用いた動作支援評価を行う．

評価対象は，動作支援の有無によって比較評価を行うために，体幹屈曲角度30 degの同姿勢における重量物なしと，重量物ありについて解析を行う．

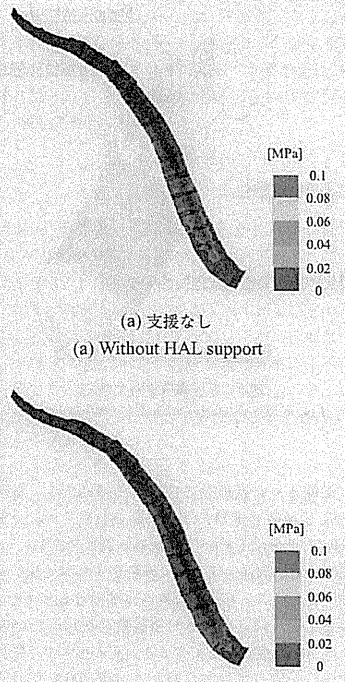
本モデルは，任意の体幹屈曲角度における解析が可能であるが，比較評価の際の実験条件の統一のために体幹屈曲角度を30 degとした．体幹屈曲角度とは，肩-大転子と鉛直線のなす角度である．重量物なしは，重量物を把持していない状態を表し，重量物ありは，重量物を把持している状態を表し，把持する重量物の重さは5，10，15，20 kgとする．本解析では，腰部の応力分布の定性的傾向と支援なしと支援ありの相対的比較により評価する．支援なしは，HALを装着せず動作支援がない状態を表し，支援ありは，HALを装着し動作支援がある状態を表す．

本解析では，拘束条件として脊柱が生体内で受ける拘束を模擬するために，不動椎である仙椎を完全拘束する．荷重条件は，図4に示すように重量物を把持していない場合には，上半身部分の自重による負荷を頭椎から腰椎までの各椎体にかかる等分布荷重とし計約700 Nを鉛直下向き方向に与える．重量物を把持している場合には，上半身の自重による負荷に加え，把持する重量物による負荷は腕を介して脊柱に作用するため胸椎上部への集中荷重として計約50～200 Nを鉛直下向き方向に与える．重量物なしとそれぞれの重量物ありに対して，支援なしと支援ありについて上記の条件で解析を行う．支援ありでは，上半身の自重と把持する重量物に応じたモーメントの50%を重力方向と拮抗した方向に股関節を中心とした支援トルクとして加える．支援トルクはフレーム及びモールドを介して，体組織，内骨格に伝達され，実際の静的作業姿勢における力の伝達を再現しており，本解析条件は妥当であると考えられる．支援トルクは，装着者の身長，体重から次式により推定する．

$$\tau_{HAL}=(0.475W_B\cdot g\cdot 0.17L_B+W_H\cdot g\cdot L_S)\cdot\sin\theta_t \qquad (1)$$

ただし，τ_{HAL} Nmはの支援トルク，W_B kgは装着者の体重，g Nm/s^{2}は重力加速度，L_B mは装着者の身長，W_H kgは把持している重量物の重さ，L_S mは股関節から肩までの距離，θ_t degは体幹屈曲角度とする．

解析条件は，全ての要素を線形等方性弾性として静解析を行う．要素サイズを15 mm，許容誤差サイズを0.75 mmでメッシュを作成する．支援なしでの要素数は110496，節点数は156165とし，支援ありでの要素数は124560，節点数は180917とする．



(a) 支援なし
(a) Without HAL support

(b) 支援あり
(b) With HAL support

図5　脊柱にかかる応力
Fig. 5　Stress of spine.

4．動作支援評価結果

本解析で得られた重量物なしでの体幹屈曲姿勢維持における脊柱全体の応力分布を**図5**に示す．支援なしの脊柱全体の応力分布を(a)，支援ありの脊柱全体の応力分布を(b)に示している．体幹屈曲姿勢では，脊柱の中でも腰部に大きな負荷がかかり，本解析結果においても腰部に高い応力値を観測することができた．腰部の中でも第5腰椎(L5)と仙椎（S1）の間のL5-S1椎間板に応力集中が発生した．図5に示すようにHALによって動作支援を行うことで腰部にかかる応力の減少が確認できた．腰部モールドの制動による胸部への応力集中が予想されたが，解析結果が示すように腰部にかかる応力が減少するだけでなく，脊柱全体においての応力の減少が確認できた．

重量物なしと重量物ありにおける本解析で得られた腰部椎間板の応力分布を**図6**に示す．支援なしの腰部椎間板の応力分布を(a)，支援ありの腰部椎間板の応力分布を(b)に示している．図6(a)において重量物なしと比較すると，重量物ありでは重量物の重さの増加に伴って各椎間板にかかる応力の増加が観測された．図6(a)と比較して，図6(b)では重量物なしと各重量物ありのすべてにおいて各椎間板にかかる応力が減少した．更に，図6(b)の20[kg]の重量物ありでは，図6(a)の支援なし時の重量物なしで作用する応力よりも減少した．

支援なしと支援ありの腰部椎間板にかかる最大応力を図7に示す．最大応力はすべての条件においてL5-S1椎間板にかかっていることを確認した．図7から応力分布だけでなく，すべての条件において最大応力の減少も確認できた．これらの結果は，把持した重量物の重量に関係なく支援なしと支援ありを比較して，椎間板の応力分布と最大応力からHALによる動作支援が腰部負荷軽減に有効であることを示している．

5．考　　察

従来製造業で多く見られた腰痛は，機械化や自動化などにより減少しているが，非製造業における腰痛が増加する傾向にある．介護の現場では，腰部負荷の大きい挙上動作，体幹屈曲姿勢などを頻繁に行うため介護者の腰痛発症リスクが高い．介護作業に伴う腰痛は，介護施設の職員に留まらず，在宅介護に携わる家族の健康障害の発生という深刻な事態を招いている[13]．そこで本研究では，腰痛の予防・緩和を目指して，腰部支援用HALを開発している．本稿では，腰部支援用HALの動作支援による内骨格系の負荷軽減を検証可能な3次元骨格系モデルの開発と3次元骨格系モデルを用いた動作支援評価による腰部支援用HALの腰部負荷軽減に対する有効性の確認を行った．

外骨格型ロボットの動作支援による内骨格系の負荷軽減を検証するために3次元骨格系モデルを開発した．3次元骨格系モデルの妥当性を確認するために，体幹屈曲姿勢維持における有限要素法応力解析を行った．体幹屈曲姿勢は，腰部に大きな負荷がかかる姿勢のひとつである．図5(a)，図6(a)に示す重量物なしの解析結果から腰部に高い応力値を観測できた．腰部の中でも第5腰椎（L5）と仙椎（S1）の間に存在するL5-S1椎間板に応力集中が発生した．L5-S1椎間板は，可動椎と不動椎の移行部にあたるため，体幹の屈曲に際して大きな負荷がかかり損傷を受けやすい部位である．それを反映するモデルであることから，3次元骨格系モデルの妥当性を確認できた．

開発した3次元骨格系モデルを用いて腰部支援用HALの動作支援評価を行った．図6，図7に示す解析結果から支援なしと比較して，支援ありでは腰部椎間板に作用する応力が減少した．支援なしでは，重量物の重さの増加に伴って腰部に作用する応力も増加する．それに対して，支

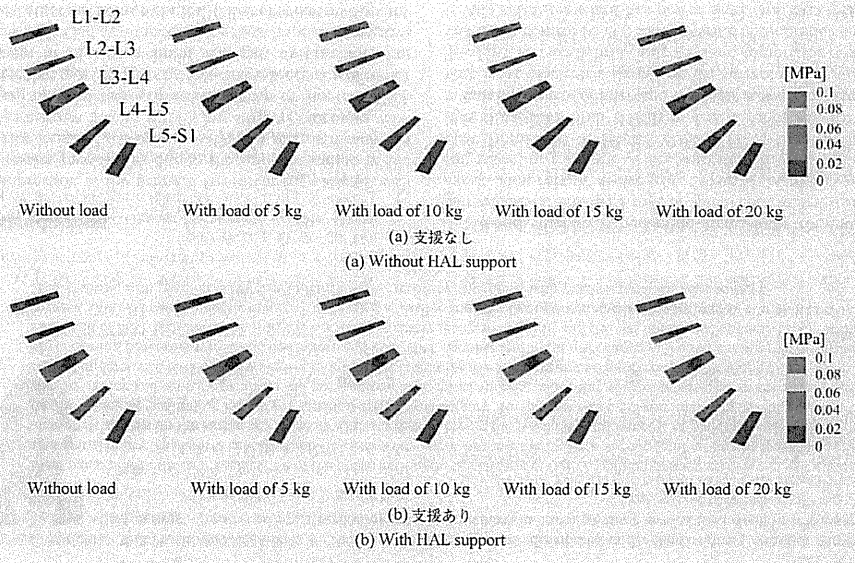


図6　腰部椎間板にかかる応力
Fig. 6　Stress of lumbar disk.

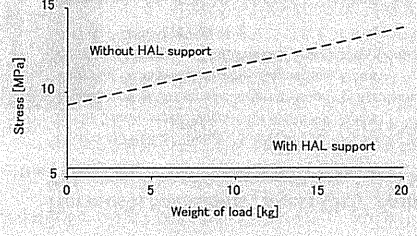


図7　腰部椎間板にかかる最大応力
Fig. 7　Maximum stress of lumbar disk.

援ありでは重量物の重量の増加による影響はほとんどない．これは，腰部支援用HALが式(1)によって推定される支援トルクに応じて動作支援を行うことで，上半身の自重や把持している重量物によって生じる腰部モーメントを減少させた結果である．

本研究で開発した3次元骨格系モデルを用いた有限要素法応力解析により，腰部椎間板に作用する応力の減少の定性的傾向を示すことができた．支援なしと支援ありの相対的比較によって腰部支援用HALの腰部負荷軽減に対する有効性を示した．本稿では，静的作業姿勢維持について解析を行った．しかし，重量物挙上動作などの動的動作においても重量物を挙上する際には，静止した姿勢をとり，その姿勢が最も体幹屈曲角度が大きく腰部負荷の大きい姿勢となる．そのため，本手法は，動的動作において負荷の大きい姿勢で解析することで，対象動作として動的動作を含めた動作支援評価を行うことが可能である．また，解析による定量的評価を行うためには，モデルの複雑化及び骨格系だけでなく筋肉の影響を考慮した3次元筋骨格系モデルを開発することが有効であると考えられる．筋骨格系モデルを構築することができれば，筋肉の損傷を考慮した動作支援評価を行うことが可能となり，本研究で提案する動作支援評価がより有益な指標になると期待されるため，今後の研究課題とする．

6. ま　と　め

本研究では腰痛の予防・緩和を目指して，外骨格型ロボットの動作支援による内骨格系の負荷軽減を検証可能な3次元骨格系モデルの開発と検証手法の提案，3次元骨格系モデルを用いた動作支援評価による腰部支援用HALの有効性の確認を行った．重量物なしで解析を行った結果，体幹屈曲姿勢で最も負荷がかかる腰部に応力集中が生じたことから3次元骨格系モデルの妥当性を確認した．開発した3次元骨格系モデルを用いて腰部支援用HALの動作支援評価を行った結果，支援なしと比較して，支援ありでは腰部椎間板に作用する応力が減少した．これらの結果から，外骨格型ロボットの動作支援による内骨格系の負荷軽減を検証可能な3次元骨格系モデルを開発し，3次元骨格系モデルを用いた動作支援評価により，腰部支援用HALの腰部負荷軽減に対する有効性を確認することができた．

本研究により従来困難であった動作支援による内骨格系の負荷軽減を評価する手法が構築された．本研究で用いた検証手法は，上肢や下肢動作などにも適応することが可能であり，動作支援評価の新たな指標として期待される．

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原　大雅（ハラ　ヒロマサ）

2011年筑波大学大学院博士前期課程修了．修士（工学）．現在，同大学院博士後期課程に在学し，2011年文部科学省グローバルCOEプログラム「サイバニクス：人・機械・情報系の融合複合」SRA研究員．「内閣府最先端研究開発支援プログラム」（健康長寿社会を支える最先端人支援技術研究）に従事．特に，腰部負荷軽減のための腰部支援用HALに関する研究開発を行う．

山海　嘉之（サンカイ　ヨシユキ）

1987年筑波大学大学院工学研究科修了．工学博士．筑波大学機能工学系助教授，米国Baylor医科大学客員教授を経て，現在，筑波大学大学院システム情報系教授，サイバニクス研究センター長，内閣府最先端研究開発支援プログラム「健康長寿社会を支える最先端人支援技術研究プログラム」研究統括，サイバニクス国際教育拠点リーダ．人・機械・情報系の融合複合新領域「サイバニクス」を開拓し，ロボットスーツHAL，生理・運動・神経系のセンシング技術・研究を推進．

日本ロボット学会理事，日本栓子検出と治療学会学会長などを歴任．

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Case Report

A Newly Developed Robot Suit Hybrid Assistive Limb Facilitated Walking Rehabilitation after Spinal Surgery for Thoracic Ossification of the Posterior Longitudinal Ligament: A Case Report

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Most patients with thoracic ossification of the posterior longitudinal ligament (OPLL) exhibit delayed recovery of gait dysfunction after spinal injury. The hybrid assistive limb (HAL) is a new robot suit controlling knee and hip joint motion by detecting very weak bioelectric signals on the surface of the skin. This study is to report the feasibility and benefits of patient-assistive HAL walking rehabilitation for facilitating locomotor function after spinal surgery. The patient was a 60-year-old woman with thoracic OPLL, and her motor and sensory paralyses did not improve after spinal surgery, indicating severe impairment in the paretic legs. The subject underwent 6 HAL sessions per week for 8 weeks, consisting of a standing and sitting exercise and walking on the ground with HAL. Clinical outcomes were evaluated before and after HAL training and 1 year after surgery. The subject improved considerably as a result of HAL training. Subsequently, her walking ability recovered rapidly, and she was able to walk unaided six months after surgery. This case study suggests that HAL training is a feasible and effective option to facilitating locomotor function and the early HAL training with physiotherapy may enhance motor recovery of patients with residual paralysis after surgery.

1. Introduction

Decompression is the primary treatment for patients with compressive myelopathy due to thoracic ossification of the posterior longitudinal ligament (OPLL) and ossification of the ligamentum flavum (OLF), but surgical outcomes vary. Studies of postoperative clinical outcomes of thoracic OPLL indicate that most patients exhibit delayed recovery of motor weakness in the lower limbs and gait dysfunction after surgery [1, 2]. Gait dysfunction is the most important negative surgical outcome, being a clinical deficit of spinal myelopathy [3].

Robotic therapy is becoming increasingly common for gait rehabilitation after stroke or spinal cord injury, using an exoskeleton robotic device (e.g., Lokomat, LOPES exoskeleton robot) or a robotic device with foot-driven plates (e.g., Gait Trainer GT I, Haptic Walker) [4–6].Th e robot suit hybrid assistive limb (HAL) is a new robot suit to assist voluntary control of knee and hip joint motion by detecting very weak bioelectric signals on the surface of the skin [7]. The HAL suit is a hybrid control system comprising cybernic voluntary control (CVC) and cybernic autonomous control (CAC) subsystems and has power units and force-pressure sensors in the shoes [8, 9]. The power units consist of angular sensors and actuators on the bilateral hip and knee joints (Figure1). The HAL suit can support the wearer's motion by adjusting the level and timing of assistance [7]. HAL training, using muscle activity, has the potential to intensify the feedback by evoking by an appropriate motion more strongly than standard robot training [9]. HAL training has been shown to improve gait speed or cadence for chronic stroke and incomplete spinal cord injury [8, 9]. However, no studies have attempted to clarify the feasibility of rehabilitation with HAL for patients with residual paralysis after spinal decompression for thoracic OPLL or OLF.

This case was markedly improved locomotor function by training with HAL, although recovery did not start until 7 weeks after spinal decompression of thoracic OPLL. Therefore, we report a case of patient-assistive HAL walking rehabilitation from an early stage for facilitating locomotor functions for patients with severe residual paralysis.

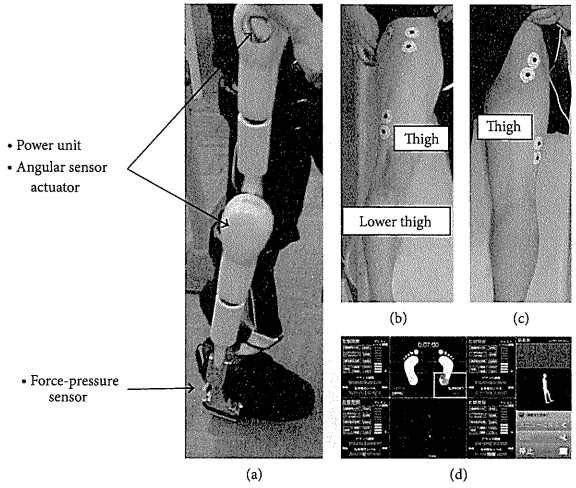

FIGURE 1: Newly-developed wearable robot suit, hybrid assistive limb (HAL). The HAL suit has power units and force-pressure sensors in the shoes. The power units consist of angular sensors and actuators on bilateral hip and knee joints (a). Muscle action potentials are detected through the electrodes on the anterior and posterior surface of the thigh ((b), (c)). Assist levels and force-pressure are shown on a computer monitor (d).

2. Case Presentation

A 60-year-old woman (body mass index: 31.1 kg/m^2) presented with onset of pain and numbness in her right lower limb and gait disturbance. The diagnosis was cervico-thoracic OPLL. After 15 months, her symptoms had gradually progressed, showing motor and sensory paresis of the lower limb and urinary disturbance. Magnetic resonance imaging showed areas of OPLL extending from T2 to T8 and T9/T10 OYL (Figure2). Because of progressive myelopathy, she underwent posterior decompression surgery two times. However, she showed aggravation of myelopathy after the second surgery, complete motor and sensory paralysis below T4, and urinary retention. She then underwent anterior decompression surgery to remove the OPLL. Active movement of her toes was weak at 1 day after surgery. She underwent physical therapy (PT) with pharmacological and high atmospheric pressure oxygen inhalation therapy. However, her motor and

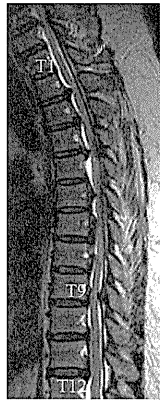

FIGURE 2: T1-weighted magnetic resonance imaging showed areas of OPLL extending from T2 to T8 and T9/T10 OYL.

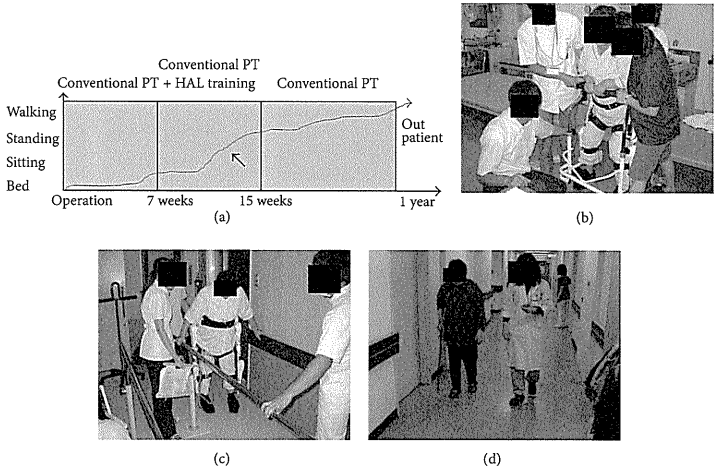

FIGURE 3: Improvement time course of activity of the patient in a schematic view (a). Although she underwent conventional physical therapy (PT), she was still bedridden 7 weeks after surgery. Locomotor functions of the patient improved considerably by intervention of the robot suit hybrid assistive limb (HAL) training. Subsequently, the walking ability recovered rapidly (arrow). When she put on the HAL at baseline, she could stand for only few seconds with assistance from three tree therapists (b). However, she could walk in the parallel bars at 12 weeks after surgery (c) and could walk independently 1 year after surgery (d).

sensory paralyses did not improve. She was still bedridden 7 weeks after surgery and at risk of disuse syndrome. We decided to use HAL in addition to the conventional PT such as muscle strength exercises and range of motion exercises. Before participating in walking exercise using HAL, the subject provided informed consent, and the study was approved by the Ethics Committee of the Kagoshima University Faculty of Medicine.

Clinical assessments were carried out at the initial evaluation (at 7 weeks after final surgery) and 8 weeks and8 months after HAL intervention (15 weeks and 1 year after surgery, resp., Table1). After the initial evaluation, the subject underwent 6 HAL sessions of 70 minutes per week for 8 weeks. Sessions consisted of a standing and sitting exercise, and walking on the ground with HAL. Standing and walking training started in parallel bars with HAL. A typical 70-minute HAL training session proceeded as follows: preparation of electrodes, putting on the HAL suit, and computer setup (15 min); HAL training (40 min, including rest time); taking off the HAL suit and electrodes (15 min). Three therapists implemented the training. The HAL suit has a hybrid control system comprising the CVC and CAC. The CVC mode of the HAL suit can support the patient's voluntary motion according to the voluntary muscle activity and the assistive torque provided to each joint [9].Th is study used the CVC mode, which allows the operator to adjust the degree of physical support to the patient's comfort and gradually reduce support as training progresses. After the end of HAL intervention, the patient underwent conventional PT without HAL in another hospital, and she was discharged 10 months after surgery.

TABLE 1: Baseline and clinical assessment during follow-up period.

	7 weeks (baseline)	15 weeks (end of HAL)	After 1 year
MMT (U/L)5/	1-2	5/3-4	5/4^{+}-5
JOA score	8	11	13
ASIA classification	C	D	D
ASIA score (lower limbs)	23	34	42
WISCI II	0	8	20
FIM motor score	22	40	83

MMT: Manual muscle testing. JOA: Japan orthopedic association (maximum score: 17). ASIA: American spinal injury association. WISCI: Walking index for spinal cord injury (score range 0 to 20). FIM: Functional independence measure (maximum score: 91).

Locomotor functions of the patient improved considerably by the intervention of HAL training. Subsequently, her walking ability recovered rapidly and she was able to walk independently six months after surgery. Figure3 shows the improvement time course of activity of the patient in a schematic view. At 15 weeks after surgery, she was able to sit without back support and transfer to a wheelchair independently. She could walk in parallel bars without HAL, although rocking of the knee was observed while standing. At 1 year after surgery, she was able to walk independently with a T-cane.

3. Discussion

This case report describes the feasibility of facilitating locomotor functions with HAL training for patients with residual paralysis after spinal surgery. Matsumoto et al. [10] reported improvement in 36.8% of patients but deterioration in8.4% after spinal surgery for thoracic OPLL in a retrospective multicenter study of 154 Japanese hospitals. The present patient was operated on 3 times and showed aggravation of her lower limb myelopathy after surgery. Although recovery did not start until 7 weeks after surgery, her locomotor function markedly improved by combining training with HAL, suggesting that HAL training facilitated recovery of locomotor functions. The HAL may facilitate rehabilitation by providing postural support and assisted voluntary muscle activity during ambulation.

HAL is a robotic device with potential rehabilitation applications that are dependent on the physical support it can provide [9]. A patient's recovery of locomotor functions may be due to changes in plasticity of the spinal cord and supraspinal centers. Appropriate sensory inputs, such as maximum weight loading, facilitating proper trunk posture, and hip extension, are essential for maximizing functional recovery [11]. Sensory input evoked HAL-induced motion may affect the central nervous system, resulting in recovery of locomotor functions. Furthermore, the visual feedback of watching a display indicating the center of gravity and range of motion of the lower limbs may also affect the central nervous system. HAL rehabilitation can be implemented safely and effectively for early mobilization and gait training for patients with residual paralysis after spinal surgery.

This study had a clear limitation in that the HAL training was started relatively soon after surgery. However, even if this patient was still in the recovery period, her locomotor function markedly improved by combining training with HAL. HAL training at an early stage may be necessary to prevent disuse syndrome such as muscle weakness in the lower limbs or joint contracture. The subject may also have experienced improved motivation for rehabilitation by HAL training use from an early stage, because she had been bedridden for 7 weeks after surgery. The findings from this case report suggest that HAL training for voluntary control of leg joint motion from an early phase is a safe and effective option for restoring locomotor functions in patients with residual paralysis after spinal surgery.

4. Conclusion

We concluded that for patients of thoracic OPLL, the early HAL training with physiotherapy may enhance motor recovery after surgery. Early mobilization using HAL may be also advocated to prevent post surgery complications, such as contractures and deep vein thrombosis.

Conflict of Interests

The authors have no competing financial interest to declare.

Acknowledgments

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Development of Noise Resistant Hybrid Capacitive-Resistive Electrodes for Wearable Robotics, Computing and Welfare*

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and Yoshiyuki Sankai, *Member, IEEE*

***Abstract*—Myoelectrical signals have many applications in medical, sports, wearable robotics and computing fields. Wet electrodes are widely used to acquire these signals. In contrast, dry contact electrodes and noncontact capacitive coupling electrodes have been developed. However, their use has several limitations. In this research, we developed a hybrid electrode that is capable of both capacitive and resistive recordings by optimizing the sensor input impedance value using a new electrode noise model that contained noise sources. We extend this design so that noise originated during real usage, such as motion artifacts and noise from electric motors is also measured and removed from the sensor output. In experiments, noise analysis and experiments were performed by measuring myoelectrical signals from both upper and lower limbs in realistic situations, including weight lifting, robot arm control, and walking on a treadmill. As the results, we verified that our electrodes were capable of bioelectrical measurements at noise levels comparable to wet electrodes in realistic situations and with high correlation coefficients between both types of sensors.**

I. Introduction

Bioelectrical signals generated by muscle activity, known as myoelectricity, have become an important source of information about movement intention. Myoelectrical signals have been useful for interfacing with physically assistive devices, such as the Robot Suit HAL [1-3], and prosthetic limbs [4-5]. Applications on other areas of human life, such as entertainment industry and virtual reality are also gathering attention [6-7]. However, for such fields, high usability is a requirement alongside high performance.

Traditionally, wet electrodes have been widely used to perform myoelectrical measurements. Because the measurements rely on a passive and resistive electrical contact point, using wet electrodes has major drawbacks such as the requirement for skin preparation and the use of conductive gels [8]. Dry resistive electrodes have been developed to increase sensor performance and usability [9-10]. The dry electrodes rely on active resistive contact with the user's skin surface. Active sensing eliminates the need to use the conductive gels and the problems associated with its use. However, skin preparations such as body hair removal and cleaning may be required because constant electromechanical skin contact is still required for bioelectrical sensing. In order to eliminate this requirement, noncontact electrodes that are capable of achieving capacitive coupling between the electrode lead and the user's skin have been proposed [11-15]. However, ultra-high input impedance is required. Ultra-high impedance input is highly susceptible to any electrostatic noise that originates from the surroundings. Therefore, robust shielding, isolation, and current leakage prevention techniques are mandatory to reduce the noise. Furthermore, complex low noise bootstrapping techniques are necessary to avoid drift due to the bias current from the input. These disadvantages make capacitive electrodes larger, noisier, and more expensive than conventional electrodes.

In order to solve the problems of the previous bioelectrical measurement technologies, we focused in combining the properties of both dry and noncontact electrodes in to a new hybrid resistive-capacitive electrode by optimizing its input impedance so that it is sufficiently high to record bioelectrical signals but low enough to reject external electrostatic noise [16]. However, previous studies consisted of only proof-of-concept basic experiments performed at ideal conditions. Noise from real life situations such as motion artifacts or near high-power devices such as electrical motors are still an issue [13]. In order to solve these problems, the sensor must be designed not only to sensitively measure bioelectrical signals but also to sense and subtract external electrostatic noise from the sensor output.

The aim of this study is to develop a novel hybrid resistive-capacitive electrode using an original sensor based on a circuit model using optimized input impedance for bioelectrical signals while also measuring high frequency noise and removing it from the sensor output. In this study, we focused on a novel extension to our bioelectrical measurement model [16] by actively measuring electrostatic noise and canceling it. This new model allowed us to develop a new electrode design with two inputs, one for electrostatic noise and one for bioelectrical signals, at different input impedance settings which are locally processed using analog circuits. Noise analysis and myoelectricity measurements on lower and upper limbs showed that our electrode maintained a low noise level that was comparable to the noise level maintained by commercially available wet electrodes on both resistive and capacitive modes.

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II. Materials and Methods

A. Measurement Principles

Bioelectrical recordings are performed throughout active resistive contact with the skin when the electrodes are capable of electromechanical contact(resistive mode). In the case of poor electromechanical contact conditions, the electrodes measure bioelectrical signals by capacitive coupling with the skin(capacitive mode). The model for our hybrid electrodes contains two built in sensing leads, one for the bioelectrical signals and one for electrostatic noise. The sensor output is given as the difference of potential of both sensing leads as

$$V_{out} = V_{in} - V_{in\_N} \quad (1)$$

where V_{out} is the sensor output, V_{in} is the bioelectrical signal with noise and V_{in_N} is noise originated from motion artifacts or pulses from nearby electrical devices. Figure 1 shows the equivalent circuit when the electrodes are in use. This model also includes noise from capacitive sources as

$$V_{IN} = \frac{R_c}{Z_{nc}} V_{nc} + \frac{R_c}{Z_{nsei}} V_{nsei} + \frac{R_c}{Z_{sei}} V_{BES} \quad (2)$$

where V_{BES} is the bioelectrical signal voltage, V_{nsei} is the total noise source voltage at the skin-electrode surface, V_{nc} is the total noise source voltage on the electrode board, Z_{sei} is the skin-electrode interface impedance, R_c is the electrode input impedance, i.e., the input impedance of the bioelectrical sensing lead, Z_{nsei} is the noise input impedance at the skin-electrode interface, and Z_{nc} is the noise input impedance on the electrode board. This noise can be significant if the electrodes are in capacitive mode. However it can be minimized when the sensor input impedance is optimal. Based on our previous studies [16], we define the input impedance optimal when it is just large enough to allow the sensor electrode to capacitively sense bioelectrical signals. With these settings the sensor input impedance is low enough to reject low frequency capacitive noise signals from the environment. Optimal input impedance is calculated using

$$R_c = \frac{V_{IN}}{V_{BES}} \cdot \frac{d}{\varepsilon_r \varepsilon_0 A 2\pi f} \quad (3)$$

where ε_0 is the dielectric constant in vacuum, ε_r is the relative dielectric constant to the material, A is the electrode lead sensing area nearest to the skin, f is the frequency of the target signal and d is the distance between the skin and the electrode lead.

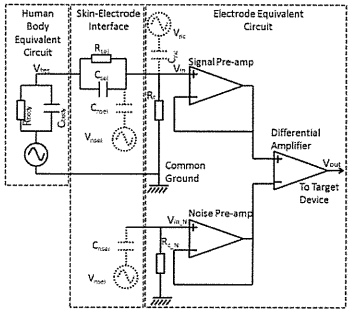

Figure 1. Electrode equivalent circuit

Similar equations are used when calculating the input impedance R_{c_N} of the electrostatic noise electrode lead, but in this case, designing the lead so it can sense only high frequency noise signals over bioelectrical and low frequency noise signals.

B. Developed Hardware and Noise Evaluation

Based on the proposed electrode model and assuming a maximum 3 mm distance between the electrode and the skin, a circular electrode lead with 38mm diameter and signal input impedance of 1 TΩ was developed. Furthermore, in similar fashion the noise electrode lead is designed. Under these conditions a 1 mm thick ring shaped electrode lead with outer radius of 40 mm is designed. Noise input impedance R_{c_N} is also set to 1 MΩ, so that only noise signals with frequency above the myoelectrical frequency spectrum are measured. In resistive contact mode the area of the leads has little effect on the input impedance and low input impedance contact are enough to measure bioelectrical signal. Because of that the noise sensing lead is electrically isolated using a thin layer of plastic coating. Without the coating, in resistive contact mode, very similar bioelectrical signals would be collected by both the bioelectrical and noise sensing leads, canceling each other during the differential preamplifier stage at the electrode. A High Pass Filter circuit is also implemented by using traditional circuits in order to eliminate undesirable offset voltages that can appear due to the difference in potential between both electrode sensing leads. Furthermore, back-to-back diodes are also attached to the leads in order to reduce the effects from input bias current.

In order to further increase sensor robustness, shielding was implemented as shown in Figure 2 by making using of inner layers of the sensor printed circuit board, in which the electronic components as well as most of the circuit pattern is located in the component layer and the sensing leads in the solder layer. The assembled electrode is shown in Figure 3.

The developed electrode data recording and evaluation system is shown in Figure 2, and it includes three stages. In the first stage, a second instrumentation amplifier receives analog

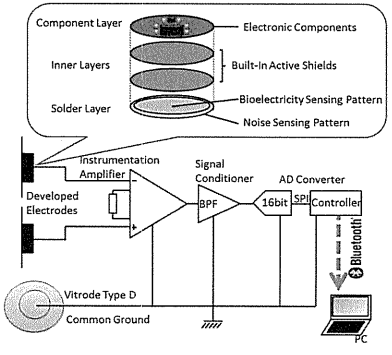

Figure 2. Measurement system diagram

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signals from two electrodes and outputs the amplified difference between them. The second stage is responsible for conditioning the signal for the AD converter. The final stage involved a 16-bit AD converter connected via an SPI channel to a microcontroller. Signal sampling was performed at 1 kHz. Data was transferred from the controller to a laptop computer via a Bluetooth connection. This system is compatible with the hybrid electrodes and the commercially available Vitrode(Nihonkohden, Japan) wet electrodes for simultaneous comparative recordings. The common ground was connected to a clean exposed body area of the user via a stainless steel plate. Each sensor was connected to the system using a 1 meter long cable. Noise frequency spectrum measurement experiments were performed for both resistive and capacitive modes using this system by placing two electrodes face to face on differential input.

C. Upper Limb Myoelectrical Measurement

Lifting objects and moving the arms are important actions when using wearable robotic devices [1-2]. In this study we evaluate the performance of our enhanced hybrid electrodes through a two-part experiment. First part is defined by measuring myoelectrical signals when lifting up and letting down various weights and second part is defined by performing robot arm control using myoelectrical signals.

For the first part of the experiment, myoelectrical signal measurements are performed under various loads. The participant leaves his arm at rest for 5 seconds, slowly starts lifting the load for 5 seconds and then slowly let the load down for another 5 seconds until the arm returns to rest position for the final 5 seconds. Loads of 2.5 kg, 5.0 kg, 7.5 kg and 10 kg were used in this part of the experiment. Simultaneous measurements on both resistive and capacitive mode as well as using standard Vitrode wet electrodes were performed. For both experiments the hybrid electrodes were attached to the biceps of the participant as shown in Figure 4. Methods for attaching the Vitrode wet electrodes and the developed hybrid electrode in both resistive and capacitive modes are shown in Figure 5. The ground electrode was attached to the abdomen of the participant. Electrodes in capacitive mode were separated from the skin through a 1mm cotton shirt. Correlation coefficients between data collected from wet electrodes and hybrid electrodes in resistive and capacitive modes are calculated using Pearson's calculation method.

The second part of the experiment verifies the operation of the hybrid electrodes near electrical appliances by performing simple robot arm control experiment. While leaving the arm at rest, the robotic arm(Jaco by Kinova, Canada) also stayed at a resting position. By lifting the arm in to a 45-degree position, the myoelectrical signals from the biceps switch on the robotic arm, also rotating it 45-degree. Each movement was repeated two times for 10 seconds. The participant's arm was in contact with the robotic arm through the entire experiment. Electrodes were placed in capacitive mode over the arm similarly to the previous weight lifting experiment. Only capacitive mode was measured as it was the weakest to noise and the high correlation coefficient with wet electrodes was confirmed using the results from the first part of the experiment.

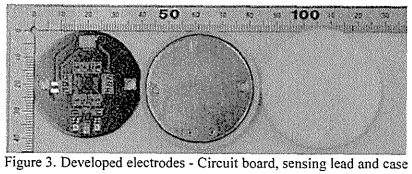

Figure 3. Developed electrodes - Circuit board, sensing lead and case

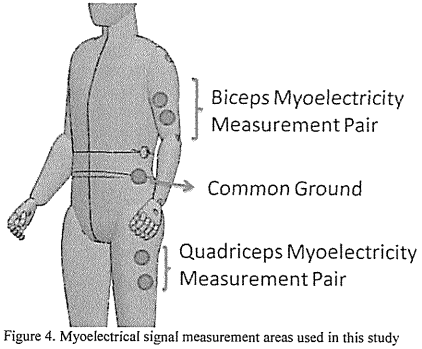

Figure 4. Myoelectrical signal measurement areas used in this study

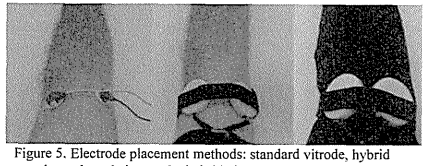

Figure 5. Electrode placement methods: standard vitrode, hybrid electrode resistive mode, hybrid electrode capacitive mode

D. Lower Limb Myoelectrical Measurement

Measurement of myoelectrical signals while walking is a fundamental procedure in lower limb to evaluate walking ability accurately in rehabilitation treatments [3]. In this study we evaluate the performance of our enhanced hybrid electrodes during walking by measuring myoelectrical signals from the quadriceps when the participant walks on a treadmill. The participant walks at a constant speed of 1.2 m/s on a treadmill for a period of 20 seconds. The hybrid electrodes were attached to the quadriceps of the participant as shown in Figure 4. The ground electrode was attached to the abdomen of the participant. Simultaneous measurements on both resistive and capacitive mode were performed. Electrodes in capacitive mode were separated from the skin through a 2.2 mm jeans pants. The correlation coefficient between data sets acquired from both resistive and capacitive modes was calculated.

III. Results

A. Noise Evaluation Results

The noise spectrum in the 1-500 Hz band is shown in Figure 6. The results show that the maximum noise is of 11 $\mu V/Hz^{1/2}$, which happens in capacitive modes at lower frequencies. As myoelectrical signals are in the order of 100-1000 μV and commonly used signals oscillate in the 30-500 Hz band [17], the results show that our enhanced hybrid electrodes are reliable enough for myoelectrical measurements.

B. Upper Lim Myoelectrical Measurement

The recorded experiment data for the bioelectrical signal measurement under variable load part of the experiment is shown in Figure 7. From the results the correlation coefficient between resistive mode and conventional wet electrode mode was of 0.98. The correlation coefficient between capacitive mode and wet electrode was of 0.92. It is important to notice that even though there was constant movement during the period 5-15 s, no motion artifacts were observed in any of the trials with any load. The relatively high myoelectrical signal output observed during the seconds 5 to 7 in all the data sets is the due to the extra power required to surpass the inertia of lifting the load from complete rest.

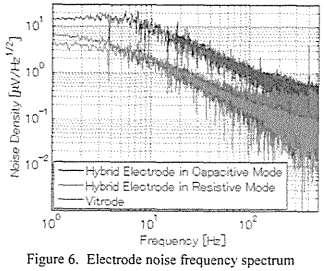

Figure 6. Electrode noise frequency spectrum

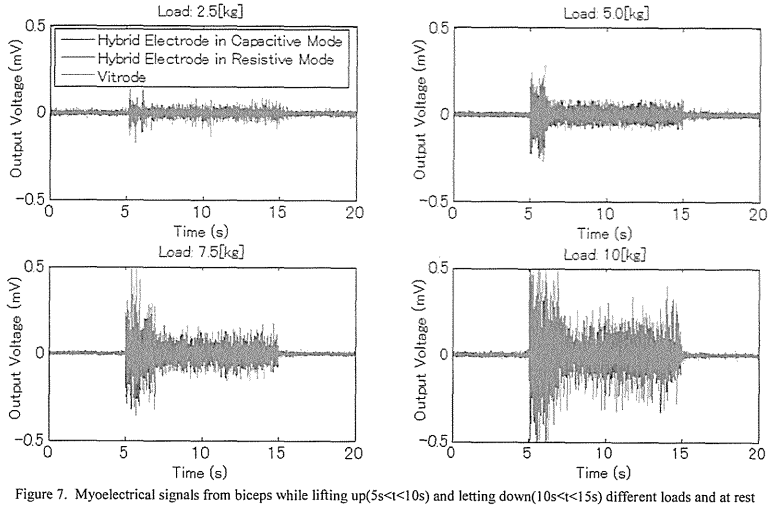

Figure 7. Myoelectrical signals from biceps while lifting up(5s<t<10s) and letting down(10s<t<15s) different loads and at rest

The high correlation coefficient between the hybrid electrode in capacitive mode and wet electrodes suggested that we could use the hybrid electrode for the robot control. Therefore the second part of the experiment was performed using only the hybrid electrode in capacitive mode. The recorded experiment data for the robot arm control experiment is shown in Figure 8. The arm weight was enough to stimulate the biceps and create a signal strong enough to be used as in a simple trigger algorithm. Moreover, the presence of an electrical motor near the electrodes did not interfere with its functionality and no noise was observed.

C. Lower Limb Myoelectrical Measurement

The recorded experiment data for the treadmill walking experiment is shown in Figure 9. The results showed constant myoelectrical activity in the quadriceps suggesting continuous load. In particular, during the walking process, the load is the biggest when there is contact of the leg with the floor. From the results we also can observe that the myoelectrical data collected by the enhanced hybrid electrode in both resistive and capacitive mode is mostly overlapping, with a calculated correlation coefficient of 0.76. No visible motion artifacts from leg movements nor electrostatic noise from the treadmill were observed.

IV. Discussion

One of the key aspects and the breakthrough point of this paper is the implementation of the novel dual signal lead system with a differential preamplifier unit built in the electrode. Comparing to previous studies from other groups [12-15] as well as our own [16], this breakthrough point is better design choice than applying an analog or digital Low Pass Filter during signal conditioning because it removes a

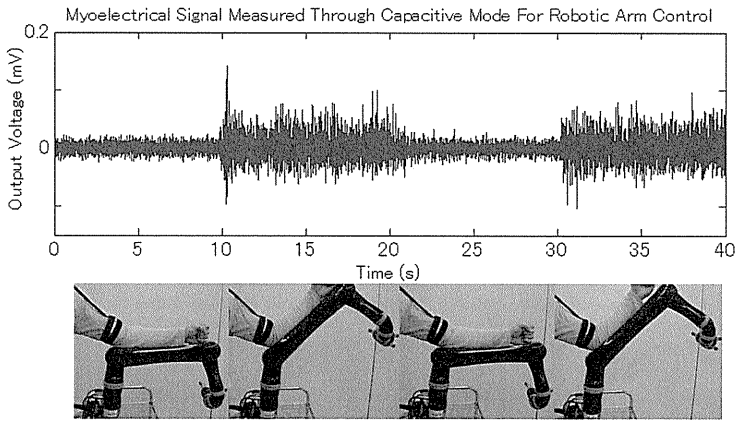

Figure 8. Robot arm movement control experiment using biceps myoelectrical signal measurement

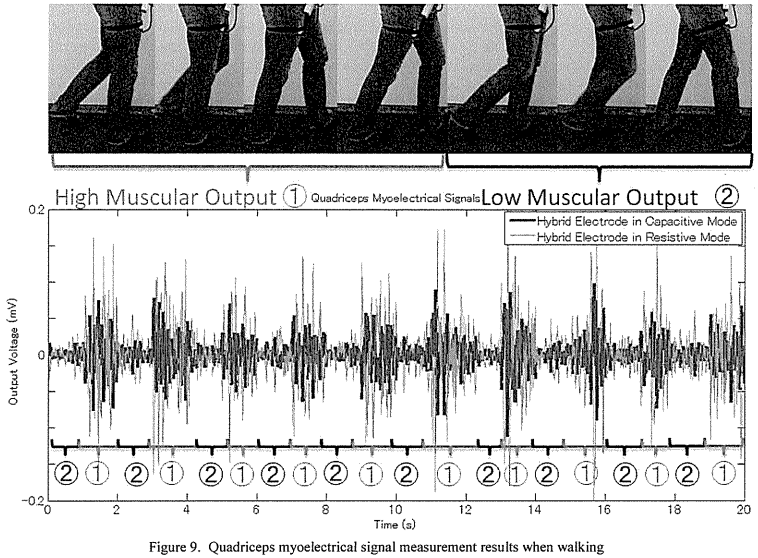

Figure 9. Quadriceps myoelectrical signal measurement results when walking

significant amount of noise before the electrical signal enters our system, avoiding problems caused by the limits on operational amplifiers power supply as well as signal distortion and delays from the filters.

The comparative experiments between our electrodes in both resistive and capacitive mode and standard wet electrodes have shown that our electrodes were capable of measuring myoelectrical signals under conditions simulating real world environments. Measurements performed under the presence of movement and active electromechanical devices nearby matched expected clear recordings that match known phenomena. Our noise frequency analysis shows that our hybrid electrodes have a noise level below 11 $\mu V/Hz^{1/2}$, performing at comparable levels to commercially available electrodes as well as other studies [15]. Furthermore the comparison experiment with commercial electrodes results from Figure 7 and the high correlation coefficient validate the effectiveness of our electrodes.

The single board design which integrates the circuitry, shielding and sensing leads in a single printed circuit board allowed us to make a sensor with 4 mm thickness, which is less than half systems developed in other studies [12-16]. With further miniaturization of electronic components and the use of flexible printed circuit boards, more user friendly sensors can be developed for wearable computing and robotic applications.

In this paper, we used a single conventional electrode made of stainless steel in order to create a robust ground between the user and the electronic system. In order to maximize the usability of the system, we suggest that while designing a wearable robotics or computing system, ground connection should be guaranteed by developing a mechanism in which the user is always in contact with a conductive grounded area of the system.

Myoelectrical signals are used extensively on rehabilitation both as a diagnosis, evaluation tool and as a method for interfacing with assistive devices. Rehabilitation in particular is a medical treatment where user enthusiasm is important, and one of the key factors in maintain enthusiasm is keeping the treatment as accessible as possible, including having an intuitive user interface. The hybrid electrodes developed in this paper using the extended electrode and noise model from Figure 2 are prototype sensors that are capable of measuring bioelectrical signals, regardless of skin contact conditions from both upper and lower limbs while performing movements near electromechanical equipments. This breakthrough is a step towards the prolonged monitoring of bioelectrical signals in a clinical and home environments necessary in rehabilitation treatments. Features such as being able to register myoelectrical signals over clothing, quick sensor placement and being able to using sensors for very long periods of time without signal degradation from sweat and conductive substrate degradation greatly contribute to the increase of usability. Evaluation of the effects that the increased usability have on the total treatment through clinical trials is necessary. Furthermore evaluation of reliability and wearability over long periods of time, such as an entire day or week, is also critical for future medical use as well as for sports and entertainment applications.

V. Conclusion

In this study, we developed a novel hybrid resistive-capacitive electrode using an original sensor based on an model using optimized input impedance for bioelectrical signals while also measuring high frequency noise and removing it from the sensor output. Noise analysis and myoelectricity measurements on lower and upper limbs showed that our electrode maintained a low noise characteristic and bioelectrical sensing performance that was comparable to commercially available wet electrodes.

In future studies, we intend to further increase the accuracy of our electrode model and expand the design to specific applications such as exoskeleton control and virtual reality in the fields of rehabilitation, sports and entertainment. Our sensors help increase the usability and reliability of bioelectrical interfaces and promote the popularization of medical and wearable devices in daily life.

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ORIGINAL ARTICLE

Feasibility of Rehabilitation Training With a Newly Developed Wearable Robot for Patients With Limited Mobility

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Abstract

Objective: To investigate the feasibility of rehabilitation training with a new wearable robot.

Design: Before-after clinical intervention.

Setting: University hospital and private rehabilitation facilities.

Participants: A convenience sample of patients (N=38) with limited mobility. The underlying diseases were stroke (n=12), spinal cord injuries (n=8), musculoskeletal diseases (n=4), and other diseases (n=14).

Interventions: The patients received 90-minute training with a wearable robot twice per week for 8 weeks (16 sessions).

Main Outcome Measures: Functional ambulation was assessed with the 10-m walk test (10MWT) and the Timed Up & Go (TUG) test, and balance ability was assessed with the Berg Balance Scale (BBS). Both assessments were performed at baseline and after rehabilitation.

Results: Thirty-two patients completed 16 sessions of training with the wearable robot. The results of the 10MWT included significant improvements in gait speed, number of steps, and cadence. Although improvements were observed, as measured with the TUG test and BBS, the results were not statistically significant. No serious adverse events were observed during the training.

Conclusions: Eight weeks of rehabilitative training with the wearable robot (16 sessions of 90min) could be performed safely and effectively, even many years after the subjects received their diagnosis.

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Rehabilitation robotics emerged in the 1980s with the aim of using robotic technology to assist people with movement dysfunction.[1] Robotic devices have recently been developed for use in clinical settings. Tefertiller et al[2] reviewed 30 articles (14 randomized controlled trials, 16 nonrandomized controlled trials) that examined the effects of locomotor training with robotic assistance in patients after stroke, spinal cord injury (SCI), multiple sclerosis, traumatic brain injury, and Parkinson's disease. The review supports the conclusion that locomotor training with robotic assistance is beneficial for improving walking function in individuals after stroke and SCI.[2] The development of main gait training machines followed. These machines either involve an exoskeleton robotic device (eg, Lokomat, LOPES exoskeleton robot)[3,4] or a robotic device with foot-driven plates (eg, Gait Trainer GT I, Haptic Walker).[5,6] The exoskeleton robotic device is equipped with programmable drives or passive elements that flex the knees and hips during the swing phase, whereas with the other type of robotic device, the feet are placed on footplates, whose trajectories simulate the stance and swing phases. Other than robotic gait training and conventional therapy, another treatment approach involves treadmill training with partial body weight support.[7] However, this approach requires considerable involvement of a physical therapist, and generally, 3 therapists are required to induce movement of the paretic leg during the swing phase and to shift the patient's weight onto the stance limb.

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A commercial party having a direct financial interest in the results of the research supporting this article has conferred or will confer a financial benefit on 1 or more of the authors. Yoshiyuki Sankai is CEO of Cyberdyne Inc, Ibaraki, Japan. Hiroaki Kawamoto is a stockholder of the company. Cyberdyne is the manufacturer of the robot suit HAL. This study was proposed by the authors. Cyberdyne was not directly involved in the study design; collection, analysis, or interpretation of data; writing the report; or the decision to submit the paper for publication.

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated (Kubota, Nakata, Eguchi, Kamibayashi, Sakane, Ochiai).

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The potentially positive common benefits of robotic gait training are that it involves repeatedly undergoing sufficient and accurate training for a prolonged period. Lokomat is the first robotic-driven gait orthosis with electromechanical drives to assist the walking movements of gait-impaired patients on a treadmill by supporting the body weight.[8,9] Husemann et al[10] compared a Lokomat group that received 30 minutes of robotic training with a control group that received 30 minutes of conventional physiotherapy. After 4 weeks of therapy, although there was no significant difference in walking ability between the groups, the walking ability in both groups as expressed by functional ambulation classification was significantly improved. The researchers reported that the Lokomat group demonstrated an advantage for robotic training over conventional physiotherapy in the improvement of gait abnormality and body tissue composition.[10] However, in a recent randomized controlled study[11] that compared robot-assisted locomotor training with therapist-assisted locomotor training in chronic stroke patients, the results indicated that greater improvements in speed and single limb stance time on the impaired leg were observed in subjects who received therapist-assisted locomotor training. Thus, the usefulness of robot-assisted rehabilitation is controversial.

The robot suit hybrid assistive limb (HAL)[12-15,a] is a new wearable robot that has a hybrid control system composed of 2 subsystems: cybernic voluntary control (CVC) and cybernic autonomous control (CAC) (fig 1). The HAL suit has power units and force-pressure sensors in the shoes. The power units consist of angular sensors and actuators on bilateral hip and knee joints. Muscle action potentials are detected through the electrodes on the anterior and posterior surface of the wearer's thigh. These various biologic signals are processed by a computer. The HAL suit can support the wearer's motion by adjusting the level and timing of the assistive torque provided to each joint according to the surface muscle action potential as well as the pressure sensors. The HAL suit can enhance the wearer's motion through the wearer's muscle action potential; thus, the HAL suit can appear as an actual motion. Therefore, if the wearer's muscle action potential varies, the wearer's motion varies, too. The HAL training, using muscle activity, has the potential to intensify the feedback by inducing an appropriate motion more strongly than standard robot training. Thus, after HAL training, patients with limited mobility will improve their walking abilities (gait speed, number of steps, cadence, or ability to transfer).

Few studies have been conducted to clarify the feasibility of rehabilitation with HAL. Only 1 preliminary study[16] has reported on the short-term effects of HAL on the walking pattern of stroke patients. The purpose of the present study was to investigate the feasibility of 16-session (8-wk) HAL rehabilitation training for patients with limited mobility.

List of abbreviations:

BBS	Berg Balance Scale
CAC	cybernic autonomous control
CVC	cybernic voluntary control
HAL	hybrid assistive limb
MADS	musculoskeletal ambulation disability symptom complex
SCI	spinal cord injury
10MWT	10-m walk test
TUG	Timed Up & Go

Methods

Study design

A quasiexperimental study was used, with measurements before and after the clinical intervention. The target population included patients with limitations in their walking (no matter the diagnosis, the time since the diagnosis, and the patient's age at diagnosis). The protocol of this study was approved by the Institutional Review Board of the University of Tsukuba Hospital and was registered with the UMIN Clinical Trials Registry. The clinical intervention was conducted at the University of Tsukuba Hospital and Cyberdyne, Inc, in Japan between January 2010 and March 2012. The patients included in this study were volunteers recruited through local newspaper advertisements or outpatients at the University of Tsukuba Hospital. They were informed about the aim and design of this study, and they subsequently provided written, informed consent. Informed consent was also obtained from the patient's guardian if the patient was younger than 20 years.

The inclusion criteria were (1) musculoskeletal ambulation disability symptom complex (MADS) or the underlying disorders of MADS, which is a condition newly defined in 2006 by Japanese medical societies[17]; (2) requiring physical assistance or assistive devices in at least 1 of the following daily activities: standing up, sitting down, and walking; (3) ability to understand an explanation of the study and to express consent or refusal; (4) body size that can fit in the robotic suit HAL (height range, 145–180cm; maximal body weight, 80kg); and (5) ability to undergo usual physical and occupational therapies. The exclusion criteria were the following: (1) inadequately controlled cardiovascular disorders; (2) inadequately controlled respiratory disorders; (3) intellectual impairments that limit the ability to understand instructions; (4) moderate to severe articular disorders, including contracture in the lower extremities; (5) moderate to severe involuntary movements, ataxia, or impairments of postural reflex in the trunk or the lower extremities; and (6) severe spasticity in the lower extremities.

Participants

Thirty-eight patients (25 men, 13 women) were enrolled in this study (24 outpatients, 14 volunteers through advertisements). The mean age ± SD of the 38 patients was 53.2±17.8 years (range, 18–81y). Table 1 summarizes their clinical characteristics. Their underlying diseases were stroke (10 men, 2 women), SCI (6 men, 2 women), musculoskeletal diseases (2 men, 2 women), and other diseases (Parkinson's disease, gonadotropin-dependent myopathy, limb-girdle muscular dystrophy, inclusion body myositis, traumatic brain injury, disuse syndrome secondary to malignant lymphoma, cerebral palsy, sequelae of poliomyelitis, and hypoxic-ischemic encephalopathy; 7 men, 7 women). Twenty patients were able to ambulate independently without any help (n=9) or with several assistive devices (T-cane, bilateral crutches, or lateral crutch) (n=11). Eleven patients were able to ambulate with several assistive devices and under supervision. Three patients required human assistance to ambulate at least 10m (cases 33, 34, 38), and the remaining 4 patients were unable to ambulate even

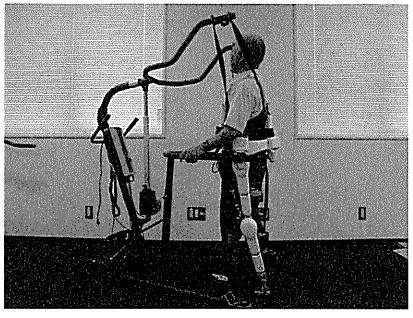

Fig 1 The robot suit HAL.

with assistive devices and human assistance (cases 8, 15, 17, 27). All the patients with stroke and SCI were in chronic stages.

Training program

HAL training was administered twice per week for 8 weeks (16 sessions). The 90-minute training sessions consisted of single-leg motion, a standing and sitting exercise, and walking on the ground with HAL. For safety reasons, a walking device (All-in-One Walking Trainer[b]) with a harness was used. Treadmill training with mild body-weight support (Unweighing System[c]) was also used for some patients. The HAL suit has a hybrid control system comprising the CVC and CAC. The CVC mode of the HAL suit can support the patient's voluntary motion according to the voluntary muscle activity and the assistive torque provided to each joint. The CAC mode provides physical support autonomously, based on output from force-pressure sensors in the shoes. This study mainly used the CVC mode, which allows the operator to adjust the degree of physical support to the patient's comfort and gradually reduce support as training progresses.

Outcome measures

The feasibility of rehabilitation with HAL was assessed by the number of completers and the amount of time or the number of therapists needed to implement training. Patients were asked to report adverse events during the training period.

The primary outcomes were functional ambulation and balance ability. Functional ambulation was assessed with a 10-m walk test (10MWT) and a Timed Up & Go (TUG) test. In the 10MWT, patients were instructed to walk without wearing HAL on a flat surface at their self-selected, comfortable pace. Patients began to walk before they reached the starting line of the 10-m distance so that they could accelerate and attain a stable speed before the test. To calculate gait speed (m/s) as a primary outcome, the 10-m walking time was measured using a handheld stopwatch. In addition, the number of steps between the start and finish line was counted, and patient cadence was calculated from the walking time and number of steps. Patients were allowed to use their assistive device or lower limb orthosis, or both, as necessary. Each patient used the same assistive device or orthosis, or both, during the pre- and postintervention measurements. Therapists closely attended the patients during the 10MWT but did not provide physical assistance. For each measurement, the 10MWT was performed twice. The faster time of 2 trials was selected for analysis. In the TUG test, the following actions were timed: standing up from a standard-height chair, walking 3m, returning to the chair, and sitting down without HAL. Two trials (each turning clockwise and counterclockwise) were carried out for each measurement. Balance ability was assessed with the Berg Balance Scale (BBS), consisting of 14 tasks, as detailed by Berg et al.[18] Each task was scored on a scale ranging from 0 to 4 points (0 indicates inability to complete), and the total score was used as the index of balance ability. All primary outcomes were assessed at baseline and after completion of the 16 training sessions.

Statistical analysis

All parametric data are expressed as means with SDs. Paired *t* tests were used to evaluate differences between the baseline measurements and outcomes after the 16 sessions. Unpaired *t* tests were used to evaluate the differences in characteristics of those who completed 16 sessions and those who did not. An effect-size calculation (Cohen *d*) was used to assess the effect of the training. Pearson correlation coefficients were used to assess the relationship among outcome measures. Data were analyzed using IBM SPSS Statistics 18 software,[d] with the alphas level set at 5%.

Results

A typical 90-minute HAL training session proceeded as follows: assessment of blood pressure, resting heart rate, and walking pattern (10min); preparation of electrodes and putting on the HAL suit (5min); computer setup (5min); HAL training (60min, including resting time during computer operation); taking off the HAL suit and the electrodes (5min); and reassessment of walking pattern (5min). The net walking time was approximately 20 minutes. Typically, 2 therapists implemented the training: one supported the patient and the other operated the computer. All therapists and related staff had participated in a 3-hour training workshop conducted by the manufacturer to learn how to operate the HAL system.

Of the 38 patients (25 men, 13 women), 32 (21 men, 11 women) completed all 16 training sessions. The mean age ± SD of the 32 patients was 53.2±17.3 years (range, 18–81y). There was no statistically significant difference in age between those who completed training and those who did not (54.0±19.8y). It took 10.0±3.1 weeks (range, 8–21wk) to complete 16 sessions. Of the 6 patients who did not complete the 16 sessions, 2 (cases 15, 21) dropped out for medical reasons, and 4 (cases 1, 2, 29, 35) dropped out for personal reasons (difficulty visiting the hospital). One medical reason for dropout was low back pain that developed during the first training session (case 21); the patient withdrew consent at the third session. The other medical reason for dropout was a relapse (after the second session) of neuropathic pain caused by SCI (case 15); the patient withdrew consent at the fifth session. There were no serious training-related adverse events. One stroke patient (case 7) had knee pain (patellar tendinitis) at home after the 15th session but was able to complete the 16th session after 1 month of rest. Another patient with inclusion body myositis (case 31) developed knee

Table 1 Clinical characteristics of patients

Case No.	Age (y)	Sex	Diagnosis	Paralysis Type	Duration Since Disease	Ambulation	Assistive Device	Orthosis	Training	Duration of Training (wk)	Adverse Events
1	69	M	Stroke (cerebral infarcts)	Paraplegia	15y	Independently	T-cane	AFO	Dropout (personal reason)	ND	Nothing
2	61	M	Stroke (cerebral hemorrhage)	Paraplegia	14y8mo	Independently	T-cane	AFO	Dropout (personal reason)	ND	Nothing
3	65	M	Stroke (cerebral hemorrhage)	Hemiplegia	2y2mo	Supervision	Quad-cane	AFO	Complete	8	Nothing
4	37	F	Stroke (cerebral hemorrhage)	Quadriplegia	16y	Independently	NA	AFO	Complete	8	Nothing
5	72	M	Stroke (cerebral infarcts)	Hemiplegia	2y9mo	Supervision	T-cane	AFO	Complete	8	Nothing
6	54	M	Stroke (cerebral hemorrhage)	Hemiplegia	1y1mo	Supervision	T-cane	NA	Complete	8	Nothing
7	63	F	Stroke (cerebral hemorrhage)	Hemiplegia	1y6mo	Independently	T-cane	AFO	Complete	15	Knee pain (patellar tendinitis)
8	52	M	Stroke (cerebral hemorrhage)	Ataxia	2y2mo	NA	NA	NA	Complete	12	Nothing
9	74	M	Stroke (cerebral infarcts)	Hemiplegia	3y4mo	Independently	T-cane	AFO	Complete	9	Nothing
10	53	M	Stroke (subarachnoid hemorrhage, cerebral infarcts)	Hemiplegia	ND	Supervision	Pick-up walker	KAFO	Complete	9	Nothing
11	18	M	Stroke (moyamoya disease)	Hemiplegia	11y	Independently	NA	AFO	Complete	21	Nothing
12	64	M	Stroke (cerebral hemorrhage)	Hemiplegia	1y	Supervision	T-cane	AFO	Complete	8	Nothing
13	58	F	SCI (incomplete)	Quadriplegia	3y3mo	Supervision	Lateral crutch	KAFO	Complete	8	Nothing
14	69	M	SCI (incomplete)	Quadriplegia	1y3mo	Supervision	Pick-up walker	AFO	Complete	8	Nothing
15	43	M	SCI (incomplete)	Paraplegia	3y3mo	NA	NA	KAFO	Dropout (medical reason)	ND	Neuropathic pain after SCI
16	59	M	SCI (spina bifida)	Paraplegia	6y4mo	Supervision	T-cane	NA	Complete	8	Nothing
17	31	M	SCI (complete)	Paraplegia	3y	NA	NA	NA	Complete	10	Nothing
18	64	F	SCI (incomplete)	Quadriplegia	2y	Independently	T-cane	AFO	Complete	9	Nothing
19	54	M	SCI (central cervical cord injury)	Quadriplegia	5y	Supervision	T-cane	NA	Complete	12	Nothing
20	47	M	SCI (spinal dural arteriovenous fistula)	Paraplegia	1y1mo	Independently	Bilateral crutch	AFO	Complete	8	Nothing
21	74	F	Musculoskeletal disease (cervical spondylotic myelopathy)	Quadriplegia	ND	Independently	Bilateral crutch	NA	Dropout (medical reason)	ND	Low back pain
22	81	F	Musculoskeletal disease (OA knee)	NA	ND	Independently	NA	NA	Complete	10	Nothing
23	44	M	Musculoskeletal disease (OA knee)	NA	ND	Independently	NA	NA	Complete	11	Nothing
24	74	M	Musculoskeletal disease (OA knee)	NA	ND	Independently	NA	NA	Complete	10	Nothing
25	62	M	Parkinson's disease	NA	8y	Independently	NA	NA	Complete	11	Nothing

(continued on next page)

Table 1 (*continued*)

Case No.	Age (y)	Sex	Diagnosis	Paralysis Type	Duration Since Disease	Ambulation	Assistive Device	Orthosis	Training	Duration of Training (wk)	Adverse Events
26	72	F	Parkinson's disease	NA	7y8mo	Independently	Nothing	NA	Complete	9	Nothing
27	36	M	Gonadotropin-dependent myopathy	Paraplegia	19y	NA	NA	NA	Complete	8	Nothing
28	52	F	Limb-girdle muscular dystrophy	Quadriplegia	24y	Supervision	T-cane	NA	Complete	9	Nothing
29	57	F	Muscular dystrophy	NA	44y	Independently	NA	NA	Dropout (personal reason)	ND	Nothing
30	67	M	Limb-girdle muscular dystrophy	NA	28y	Independently	T-cane	NA	Complete	8	Nothing
31	73	M	Inclusion body myositis	NA	10y	Independently	T-cane	NA	Complete	10	Knee pain
32	24	M	Traumatic brain injury	Quadriplegia	17y1mo	Supervision	Walker	NA	Complete	8	Nothing
33	19	F	Traumatic brain injury	Quadriplegia	6y2mo	Assistance	Pick-up walker	KAFO	Complete	8	Nothing
34	29	F	Traumatic brain injury	Quadriplegia	10y7mo	Assistance	Pick-up walker	KAFO	Complete	9	Nothing
35	20	M	Disuse syndrome, secondary to malignant lymphoma	NA	3y9mo	Independently	T-cane	NA	Dropout (personal reason)	ND	Nothing
36	31	F	Cerebral palsy	Quadriplegia	30y10mo	Independently	Lateral crutch	NA	Complete	10	Nothing
37	55	M	Sequelae of poliomyelitis	Paraplegia	54y	Independently	Lateral crutch	NA	Complete	19	Nothing
38	48	F	Hypoxic-ischemic encephalopathy	Quadriplegia	2y	Assistance	NA	NA	Complete	12	Nothing

Abbreviations: AFO, ankle-foot orthosis; F, female; KAFO, knee-ankle-foot orthosis; M, male; NA, not applicable; ND, no data; OA, osteoarthritis.

Table 2 Functional ambulation and balance ability at baseline and after 16-session HAL training

Outcome Measurements	Baseline	After Training	Difference	*P*	n
10MWT					
Speed (m/s)	0.52±0.40	0.61±0.43	0.09 (0.05 to 0.14)	<.001	27
No. of steps	34.0±20.4	31.0±18.8	−3.0 (−4.9 to −1.0)	<.001	27
Cadence (steps/min)	74.3±34.1	81.1±32.9	6.8 (4.0 to 9.6)	<.001	27
TUG (s)	43.7±45.0	37.3±34.1	−6.4 (−13.0 to 0.2)	.057	26
BBS	33.6±16.9	35.5±16.3	1.9 (−0.1 to 3.9)	.059	32

NOTE. Values are mean ± SD, mean (95% confidence interval), or as otherwise indicated.

pain at home after an early session but was able to complete 16 sessions.

Outcome measures

Functional ambulation was not assessed for 5 patients at baseline because 3 were unable to ambulate with any assistance (cases 8, 17, 27), and the other 2 patients needed considerable human assistance to ambulate (cases 34, 38). The other 27 patients had significant improvements ($P<.05$) in gait speed, number of steps, and cadence after the 16-session HAL training (10MWT, table 2). Improvements in gait speed, number of steps, and cadence are defined as an increase, a decrease, and an increase in the respective parameters. The mean ± SD improvements and effect sizes (Cohen *d*) in gait speed, number of steps, and cadence were .09±.11m/s ($d=.82$), 3.0±4.9 steps ($d=.61$), and 6.8±7.1 steps/min ($d=.96$), respectively. Improvements in gait speed, steps, and cadence were observed in 25, 18, and 25 patients, respectively (figs 2–4). Worsened gait speed and cadence were observed in 2 patients (cases 28, 30). In regards to the number of steps, we observed no change in 8 patients (cases 3, 5, 16, 25, 28, 30, 33, 37) and increased steps in 1 (case 20). Correlation coefficients for gait speed with number of steps and with cadence were $r=.30$ (not significant) and $r=.73$ ($P<.01$), respectively. The effect sizes for gait speed in patients with stroke (n=9), SCI (n=6), musculoskeletal disease (n=3), and patients with other diseases (n=9) were 1.41, .78, 2.43, and .63, respectively. The results of the TUG test (n=26; case 10 was unable to perform the test) and the BBS (n=32) indicated improvement after the 16 training sessions, but these improvements were not statistically significant. The mean ± SD decrease (Cohen *d*) in the TUG test was 6.4±16.4 seconds ($d=.39$). Twenty-one of 26 patients were faster after training, and 5 patients were slower (cases 5, 13, 30, 31, 36) (fig 5). The mean ± SD increase (Cohen *d*) in BBS was 1.9±5.5 ($d=.35$). Nineteen of 32 patients had higher scores compared with baseline; no change was observed in 6 (cases 12, 17, 23, 27, 36, 37), and 7 had lower scores (cases 11, 16, 26, 30, 31, 32, 34) (fig 6).

Discussion

We investigated the feasibility of rehabilitation using a robot suit HAL. We demonstrated that HAL rehabilitation could be implemented safely and effectively. Although a few patients developed lumbar or knee pain during the training, no serious training-related adverse events occurred. Significant improvements in gait speed, number of steps, and cadence were observed, as assessed by the 10MWT. Improved TUG test and BBS results were also observed, but because of the small sample size of this pilot study, these improvements were not statistically significant. Overall, our results suggest that HAL rehabilitation has the potential to improve ambulation in patients with limited mobility.

Two patients (cases 15, 21) dropped out for medical reasons. One developed lumbar pain (case 21), and 1 had a relapse of neuropathic pain caused by SCI (case 15). Although it is unclear

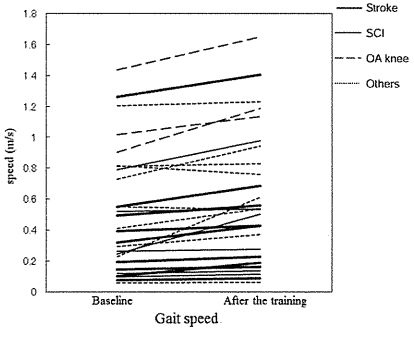

Fig 2 Change in 10MWT gait speed for 27 patients after HAL training. Abbreviation: OA, osteoarthritis.

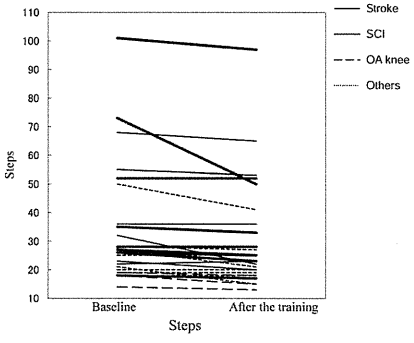

Fig 3 Change in number of steps during 10MWT for 27 patients after HAL training. Abbreviation: OA, osteoarthritis.

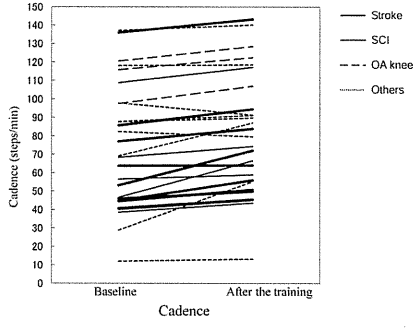

Fig 4 Change in 10MWT cadence for 27 patients after HAL training. Abbreviation: OA, osteoarthritis.

whether there was a causal relationship between HAL training and the pain that developed, the lumbar pain in case 21 had been persistent before the HAL training and even after the training ended, and the neuropathic pain in case 15 followed a previous pattern of symptom flares associated with seasonal change. Therefore, it is likely that HAL training did not directly cause the pain that developed in these 2 cases. Two other patients complained of knee pain during the training period, but this pain was not severe, and the patients were able to complete the training. Although, once again, direct causality is unclear, safe implementation of HAL rehabilitation requires adequate caution on the part of therapists and self-awareness on the part of patients who have lumbar and knee pain. Regarding feasibility, approximately 10 minutes was required for 2 to 3 therapists to put electrodes and the HAL suit on or take them off the patient. This procedure is a slight inconvenience to address but not a major obstacle to HAL rehabilitation.

Significant improvements in functional ambulation were observed, and the effect sizes (Cohen *d*) for gait speed, number of steps, and cadence were .82, .61, and .96, respectively. The correlation coefficient for gait speed with cadence was higher than

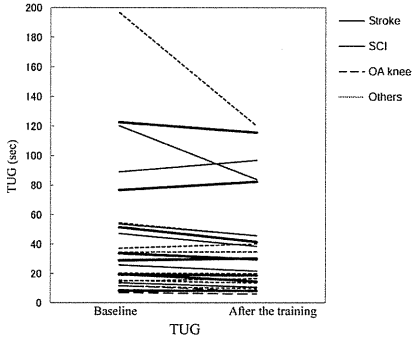

Fig 5 Change in TUG test results for 26 patients after HAL training. Abbreviation: OA, osteoarthritis.

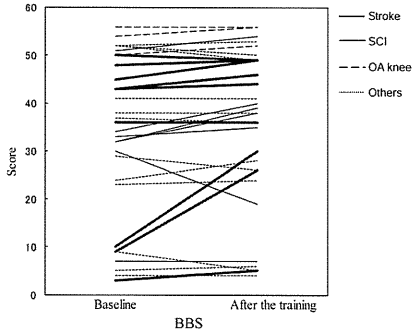

Fig 6 Change in BBS score for 32 patients after HAL training. Abbreviation: OA, osteoarthritis.

that of gait speed with steps (r=.73 vs r=.30). Therefore, the improvement in gait speed with HAL training was mainly brought about by improvement in cadence. That is, HAL training improved stride frequency more than stride length. This finding is in agreement with that of a previous robotic training study.[19] The effect sizes for the TUG test and BBS were smaller than the effect sizes for the 10MWT. This result seems to occur because the TUG test and BBS involve complicated motions such as moving from sitting to standing, walking and returning, reaching forward, and alternating feet on each step. The effect sizes for gait speed in 9 patients with stroke and in 6 patients with SCI were large (1.41 and .78, respectively). Therefore, training effectiveness in patients with stroke and those with SCI can be expected. The effect size in 3 patients with musculoskeletal diseases was also large (2.43), but the number of patients was small. Therefore, further studies are needed. In this study, we recruited patients with a wide range of stroke and SCI severities. Future studies should examine the influence of the severity of stroke and SCI on the effectiveness of HAL rehabilitation.

Many recent studies have reported the efficacy of robot-assisted rehabilitation. It is very difficult to directly compare these studies and our study, because of differences in diseases, severity and duration of the disorder, robotic features, methods of intervention, and outcome measures.[20] Wirz et al[21] reported that after locomotor training with Lokomat, the 10MWT gait speed of 20 patients with chronic incomplete SCI increased by .11±.10m/s (d=1.10). The number of patients with SCI in our study was limited to 6, but our results also indicate the efficacy of HAL rehabilitation for these patients (d=.78). Hornby et al[11] reported that after robotic-assisted locomotor training, the gait speed in chronic stroke patients increased by .07±.07m/s (d=1.0). Our results also indicate the efficacy of HAL rehabilitation for 9 patients with chronic stroke (d=1.41). We conjectured that the mechanism of this recovery of functional ambulation was due to changes in plasticity in the spinal cord and supraspinal centers. Appropriate sensory inputs, such as maximum weight loading, facilitating proper trunk posture, and hip extension, are essential for maximizing functional recovery.[22] Our experience with HAL indicates that the HAL-induced motion might evoke the sensory input, which has a favorable feedback effect on the central nervous system for a recovery of locomotor function. In addition, even if a patient's condition were too severe for medical therapists to

provide adequate rehabilitation training, HAL might still make adequate training possible. HAL is a robotic device with potential rehabilitation applications that are dependent on the physical support it can provide.

Study limitations

This study was not a randomized controlled trial and could not compare the efficacy of HAL training with conventional rehabilitation. Second, long-term efficacy was not assessed after HAL training. Third, this study could not exclude observer bias and subject bias because the same staff implemented assessment and training, and approximately half of the patients were recruited through local newspaper advertisements. Finally, the statistical power was low because of the small number of patients with each disease.

Conclusions

This quasiexperimental study revealed the feasibility of HAL training for rehabilitating patients with limited mobility. This study has shown that it is possible to manage 8 weeks of rehabilitation with HAL training (16 sessions of 90min) safely and effectively, even with persons who received their diagnosis many years ago. After HAL training, significant improvements in gait speed, number of steps, and cadence were observed. Although improvements were observed in the TUG test and BBS, they were not statistically significant. There were no serious adverse events. Further studies are needed to compare the effectiveness of HAL training and conventional rehabilitation.

Suppliers

a. Cyberdyne Inc, D25-1, Gakuen Minami, Tsukuba, Ibaraki, Japan 305-0818.
b. ROPOX A/S, 221 Ringstedgade, Naestved, Denmark 4700.
c. Biodex Medical Systems Inc, 20 Ramsay Rd, Shirley, NY 11967.
d. SPSS, Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Keywords

Feasibility studies; Mobility limitation; Orthopedic equipment; Rehabilitation; Robotics

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RAPID COMMUNICATION

Neurol Med Chir (Tokyo) 53, 287 ~ 290, 2013

Feasibility and Safety of Acute Phase Rehabilitation After Stroke Using the Hybrid Assistive Limb Robot Suit

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Abstract

Acute phase rehabilitation is an important treatment for improving the functional outcome of patients after stroke. The present cohort study analyzed the feasibility and safety of acute phase rehabilitation using the hybrid assistive limb robot suit in 22 patients, 7 males and 15 females (mean age 66.6 ± 17.7 years). Neurological deterioration, mortality, or other accidents were recorded as adverse events. Baseline characteristics of each patient were recorded at the first hybrid assistive limb rehabilitation. Hybrid assistive limb rehabilitation was conducted for 12.1 ± 7.0 days with the patients in stable condition. Acute phase hybrid assistive limb rehabilitation was performed a total of 84 times with no adverse events recorded except for orthostatic hypotension. Good functional outcomes were obtained in 14 patients. Orthostatic hypotension was observed during the first hybrid assistive limb rehabilitation in four patients, and was significantly associated with intracerebral hemorrhage ($p = 0.007$) and lower Brunnstrom stage ($p = 0.033$). Acute phase rehabilitation using the hybrid assistive limb suit is feasible and safe. Patients with intracerebral hemorrhage and lower Brunnstrom stage should be carefully monitored for orthostatic hypotension.

Key words: acute phase rehabilitation, hybrid assistive limb robot suit, stroke, orthostatic hypotension

Introduction

Acute phase rehabilitation is an important part of the treatment for improving the functional outcome of patients after stroke in the acute hospital setting.[3,5,6,8,9,13–15,17] The hybrid assistive limb (HAL) suit is one of a number of advanced technologies that have been developed for the assistance of stroke patients.[12,16] This robotic device was originally designed to support elderly patients with muscle weakness, and to assist with independent mobility in people with impaired motor function. However, whether the HAL suit can be used for the rehabilitation of patients with acute stroke without adverse complications remains unclear. The present study investigated the feasibility and safety of the HAL suit in the rehabilitation of patients in the acute phase after stroke.

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Materials and Methods

This prospective cohort study was designed to evaluate acute phase rehabilitation after stroke using the HAL robot suit in the Department of Neurosurgery, Fukuoka University Hospital from November 2011 to March 2012. A total of 22 patients, 7 males and 15 females (mean age 66.6 ± 17.7 years) were enrolled. The oldest participant was aged 90 years. The Fukuoka University Institutional Review Board approved the study and informed consent was obtained from all participants or their representatives. The protocol included subjects satisfying the following criteria: hemiplegia or ataxia after stroke, height >120 cm, weight <100 kg, Glasgow Coma Scale (GCS) score >9, systolic blood pressure between 100 and 160 mmHg, oxygen saturation without supplementation >90%, heart rate between 40 and 120 beats per minute, and body temperature <37.5°C. The limitations of height and weight were determined by the size restrictions of the HAL suit, as recommended by the manufacturer (CYBERDYNE Inc., Tsukuba, Ibaraki). GCS score ≤9 was used to exclude coma status. Nine patients with subarachnoid hemorrhage, seven with intracerebral hemorrhage, and six with cerebral infarction were enrolled. Vital signs were carefully monitored during the rehabilitation. Anthropometry data, vital signs, time scheduled for HAL rehabilitation, time after eating, antihypertensive and diuretic medication, presence of diabetes mellitus, GCS, National Institute of Health Stroke Scale (NIHSS), Brunnstrom stage (Br), modified Rankin scale (mRS), mini-mental state examination (MMSE), presence of sensory disturbance, presence of neurocognitive impairment, disease entity (intracerebral hemorrhage, cerebral infarction, and subarachnoid hemorrhage), and adverse events including mortality, neurological deterioration, orthostatic hypotension (OH), fall, bone fracture, or skin erosion were recorded. OH was defined as a decrease in systolic blood pressure of over 20 mmHg immediately after sitting or standing.

Normally distributed data are expressed as mean ± standard deviation. Age, systolic and diastolic blood pressure before HAL rehabilitation, time scheduled for HAL rehabilitation, time after eating, GCS, NIHSS, Br, mRS, and MMSE were treated as continuous variables. Sex, antihypertensive and diuretic medication, presence of diabetes mellitus, presence of sensory disturbance, presence of neurocognitive impairment, and clinical entity were treated as categorical variables. Fisher's exact test, t-test, and U-test were used to compare each variable and OH in the participants. Statistical differences of $p < 0.05$ were considered significant. Data analyses were performed using the SPSS 14.0.J program (SPSS Inc., Chicago, Illinois, USA).

Results

Acute phase rehabilitation using the HAL suit was performed a total of 84 times (mean 3.8 ± 3.1 times). HAL rehabilitation was conducted over 12.1 ± 7.0 days when the vital signs of the patients were stable (Fig. 1).

Following HAL rehabilitation, two patients had improved walking and torso posture, 12 patients could stand with HAL assistance, and two patients showed no change. Six patients withdrew from the study due to depression status, inappropriate size of shoes, and lumbar spondylosis, which prevented correct fitting of the backpack and mounting of the gyroscope and accelerometer required for torso posture estimation (Table 1).

No episode of mortality, neurological deterioration, falling, bone fracture, or skin erosion occurred throughout the acute phase rehabilitation using the HAL suit. However, four patients demonstrated OH as an adverse event, which prevented one patient receiving second HAL rehabilitation. Intracerebral hemorrhage and lower Br were significantly associated with OH, as demonstrated by Fisher's exact test and U-test ($p = 0.007$ and $p = 0.033$, respectively; Table 2). No other variables were associated with OH (Table 2). Lower Br was not associated with any of the clinical characteristics (Kruskal Wallis test, $p = 0.266$).

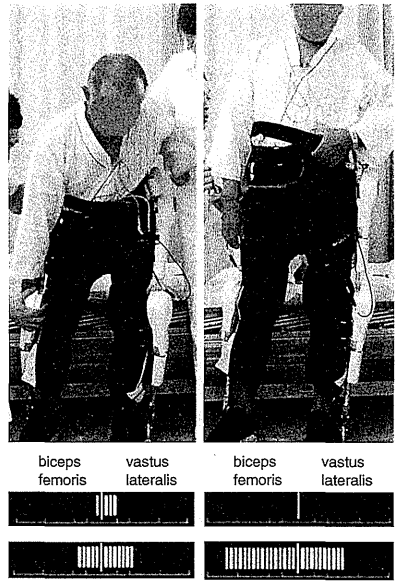

Fig. 1 Photographs during hybrid assistive limb (HAL) rehabilitation showing the patient in Brunnstrom stage II getting up (*left*) and standing upright (*right*) with HAL assistance. Electromyogram (EMG) was detected on the paralytic side while upright. L: left side, R: right side.

Table 1 Outcomes of hybrid assistive limb (HAL) training in stroke patients

Outcome	No. of cases
Improvement of walking and torso posture	2
Standing with HAL assist	12
No change in activity	2
Refusal of second HAL rehabilitation	6

Table 2 Factors correlated with orthostatic hypotension

Factors	Orthostatic hypotension		p Value
	No	Yes	
No. of patients	18	4	
Age (yrs)	66.0 (19.0)	69 (12.2)	0.772
Sex, men/women	6/12	1/3	1.000
Body mass index	21.2 (4.8)	21.0 (4.0)	0.953
Pre-HAL systolic BP (mmHg)	130.9 (20.8)	129.5 (18.5)	0.900
Pre-HAL diastolic BP (mmHg)	73.4 (13.2)	86.3 (12.8)	0.092
Time scheduled for HAL (hrs)	2:00 PM	1:00 PM	0.218
Time after eating (hrs)	3.5 (1.3)	3.0 (0.4)	0.220
Antihypertensive medication	13	9	0.264*
Diuretic medication	21	1	1.000*
Diabetes mellitus	19	3	0.470*
GCS score	14.1 (1.6)	12.5 (1.9)	0.102
NIHSS score	6.9 (7.9)	14.8 (13.9)	0.094
Brunnstrom stage	4.1 (1.6)	2.0 (2.0)	0.033
MMSE point	17.8 (11.2)	11.5 (13.9)	0.338
Modified Rankin scale score	4.0 (2–5)	4.8 (0.5)	0.062†
Presence of sensory disturbance	13	3	1.000*
Presence of neurocognitive impairment	11	3	1.000*
First HAL rehabilitation day	12.7 (7.6)	9.5 (2.4)	0.426
Times of HAL rehabilitation performed	3.5 (2.4)	5.3 (5.7)	0.585
Disease entity			0.007*
subarachnoid hemorrhage	9	0	
intracerebral hemorrhage	3	4	
cerebral infarction	6	0	

Values in normal distribution are shown as the mean (standard deviation), and values in non-normal distribution are shown as the median (minimum–maximum). All variables were recorded on the first day of HAL rehabilitation. p Values are calculated by t-test, *Fischer's exact test, or †U-test. BP: blood pressure, GCS: Glasgow Coma Scale, HAL: hybrid assistive limb, MMSE: mini-mental state examination, NIHSS: National Institute of Health Stroke Scale.

Discussion

The present study demonstrated that HAL rehabilitation is feasible and safe after stroke in the acute phase. To prevent falls, neurological deterioration, or any other morbidity, the presence of OH should be monitored in patients with intracerebral hemorrhage and lower Br. An elastic stocking on the paralytic side or delaying rehabilitation for a few days enabled us to continue HAL rehabilitation in three of four patients with OH. OH has been attributed to the time after eating, antihypertensive and diuretic medications, and the presence of diabetes mellitus, implying the involvement of autonomic dysfunction.[18] However, we found no significant differences in these variables between the patients with and without OH, as only intracerebral hemorrhage and lower Br were significantly associated with OH. Lower Br was not associated with any clinical characteristic, suggesting that intracerebral hemorrhage and lower Br were not confounding factors. The variable of intracerebral hemorrhage may be an independent risk factor for OH. The severe degree of autonomic dysfunction in patients with intracerebral hemorrhage is a likely mechanism of OH in the present acute setting. Further studies with more cases are required to avoid type II error.

The HAL suit consists of a 'cybernics voluntary control system,' which provides complete control using bioelectric signals, and a 'cybernics robotic autonomous control system,' which generates the characteristic motor patterns of human motion.[12,16] The HAL system functions by utilizing several sensing modalities: skin-surface electromyographic electrodes placed on the rectus femoris, vastus lateralis, gluteus maximus, and biceps femoris muscles, potentiometers, and a gyroscope and accelerometer mounted in a backpack for torso posture estimation. The objective of the HAL suit is to increase and assist the voluntary motor functions of stroke patients. We found that some patients exhibited electric signals on the paralytic side, which might have been facilitated by the HAL suit (Fig. 1). Standing with assistance of the HAL suit in the acute phase may not only facilitate the recovery of the paralytic side, but also prevent the non-paralytic side from disuse, allowing patients to have a better quality of life. Indeed, a prospective study reported that earlier and more intensive mobilization after stroke may facilitate more rapid return to unassisted walking and improve functional recovery.[6] We expect that HAL acute phase rehabilitation will also result in earlier and better recovery. Standing and walking are also reported to induce plasticity in the spinal cord network and central pattern generator.[7]

Age,[2] depression,[4] and cognitive impairment[11] are potential negative factors hindering good functional outcomes. In this feasibility study, depression was the main reason for the refusal of HAL rehabilitation. Furthermore, particular attention should be paid to the presence of OH which can induce falls[10] and result in serious consequences.[1] The efficacy and indications of acute phase rehabilitation using HAL are being examined in a follow-up cohort study.

Acknowledgments

The patient and physical therapist provided written informed consent for the use of the photograph in Fig. 1.

Conflicts of Interest Disclosure

None declared. All authors who are members of The Japan Neurosurgical Society (JNS) have registered online Self-reported COI Disclosure Statement Forms through the website for JNS members.

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Measurement method of interaction force between human and wearable assistive robot based on strain of contact part

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Abstract: In order not only to realize the functions of wearable robots, but also to improve the the design of mechanism and controller, and to establish a safety standard of these types of robots, a method to measure the physical interaction at the contact sites of robot and wearer is required. To evaluate the physical interaction, we propose a measurement method based on strain gauge. A basic experiment was conducted to evaluate the proposed method. The proposed method is also applied to Robot Suit HAL for Well-being to evaluate its interaction with a wearer during several kinds of single joint motion task. Experimental results show the plausibility of this approach for the measurement of the interaction force.

Keywords: exoskeleton, human-machine interaction, motion assist, force measurement

1. INTRODUCTION

Wearable robots, which support, enhance and extend human physical capabilities, are expected to be used for various kinds of purposes, by incorporating adaptability of computer programming and physical strength of mechanical structures[1]. In the field of medical care and welfare, wearable robots are expected to support physically challenged persons so that they can, for example, eat[2] and locomote[3] independently. In rehabilitation of the impaired motions, they are expected to assist motions of the affected limbs, as well as helping physical therapists from repeating many times the burdensome exercises for functional recovery[4]. Nowadays, interactive bio-feedback loop of motion intention and excution and resultant sensation realized by a wearable robot is thought to be able to play an important role in the neural recovery of the impaired motions[5]. Care givers may also have benefit wearing these robots in carrying and moving the patients[6].

Wearable robots assist motions by applying forces directly on the wearers body[1]. When they push or pull each other, interaction force between them are caused at the contact sites. Measuring interaction force provides a criteria to evaluate the effectiveness of assist given by the robot to the wearer, and to evaluate usability, comfort, and safety from the wearer's viewpoint. This gives critical information to improve the design of mechanism and controller[7]. It may also lead to establishment of a safety standard for these types of robots, which is needed since wearable robots are abundantly developed and even already used in some clinical situations.

Cuff accompanied with stretching belt is one of the major methods of mounting robot to human body, since it is adaptive to the shape of human leg and lessens peak pressure by widening contact areas. Cuff is used for example in HAL[8], LOPES[9], Locomat[4], etc.

In human biomechanics, each body segment is considered as a rigid body, and motion of it is determined by the total force acting on it according to the Newton's law. Likewise in evaluation of the effectiveness of assist and support provided by the robot, total force on each body segment gives the most direct value related to the resulting motion. Therefore, we are interested in the amount and direction of total force at each cuff, instead of pressure at each point in the contact area. De Rossi et al. [10] has proposed tactile sensors (Skilsens) to measure the interaction force at the cuff of LOPES, however it can measure only component of the foces perpendicular to the sensor surface. There are some proposed methods using load cells[11][8], they measure load on robot structure rather than interaction force at the contact site.

In this paper, we propose a method to measure interaction force between robot and human body using strain gauses installed on the metal frame of cuff. To restrict the number, location, and direction of the forces applied on the metal frame, we propose to introduce load bearings of the same number of the strain gause pairs into the gap between the metal frame and the contacting surface. In section II, our target robot HAL is briefly depicted. In section III, installation of strain gauges and bearings, model of strain-foce relationship, and its calibration is described. In section IV, a basic experiment to evaluate the plausibility of the obtained forces is shown. In section V, the paper is concluded.

2. HAL (HYBRID ASSISTIVE LIMBS)

Robot suit HAL for well-being (Fig.1) is developed for the purpose of assisting motions of neurologically impaired persons[5][12]. It is composed of power units to actuate the hip and knee joints on both sides, exoskeleton frame to transfer actuation and to support the wearer's posture, and several sensors including joint angle sensors, floor reaction force sensors, and current sensor for each motor.

HAL has two modes of assistive control; CAC (Cybernic Autonomous Control) and CVC (Cybernic Voluntary Control). According to situation of the patient, one or combination of them is applied. In CVC mode, HAL provides assist according to the bio-electric signal detected on the surface of the skin, which represents the wearer's intention to activate muscle. This method is useful for augmenting or supporting healthy and lightly impaired

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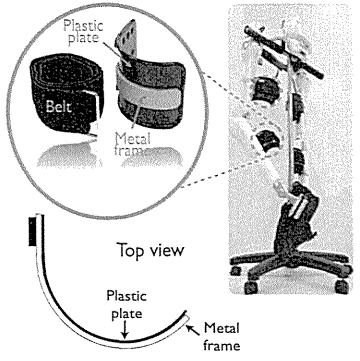

Fig. 1 HAL for well-being and its cuff: the cuff is structured with a metal frame and a plastic plate, and attached to the robot frame. A belt is used to wrap around them and human leg.

person's motion. CAC mode is for spinal cord injury patients and stroke patients whose motor center of nervous system is damaged and bio-electric signal cannot be detected. In this mode, HAL utilizes floor reaction force and accelerometers to estimate the intention of motion, and presents pre-planned trajectory.

Cuff of HAL is used to contact thigh and shank of the wearer to the robot frame for the left and right legs. Its structure, as shown in Fig.1, has a plastic frame that interfaces with human leg through a thin sponge on it and a metal frame which keeps the curved shape while bearing the interaction force. They are attached to the robot frame which transmits motor actuation. The metal frame is binded between the plastic frame and the robot frame. A stretching belt is used to wrap around human leg and the cuff. Strain gauges are attached to measure the bending of the metal frame, as will be described in the next section.

3. METHOD

3.1 Model of Cuff Strain - Force Relationship

On a thin cantilevered curved beam, when the thickness is enough smaller than than the radius of the whole shape, the relation among the bending component of strain ϵ, which can be obtained by the subtraction between the measured strain on one side(ϵ_a) and the other side(ϵ_b)

$$\epsilon = \epsilon_a - \epsilon_b, \tag{1}$$

the applied external force $\vec{f}$, and the vector $\vec{l}$ starting from the position of strain gauges to the point where the force is applied, is given by the following equation

$$C\epsilon = \vec{l} \times \vec{f}. \tag{2}$$

C is a constant representing the local properties of shape and material characteristics. Strain ϵ is given by the subtraction between the two strains measured on two opposite sides at a location on the beam.

Supposing that we have n pairs of strain gauses and m forces applied on the beam,

$$C_i\epsilon_i = M_i (i = 1 \cdots n) \tag{3}$$

$$M_i = \sum_{j \in q(i)} \vec{l_{ij}} \times \vec{f_j}, \tag{4}$$

where M_i represents total bending moment working on the ith strain gauge pair and $q(i)$ represents the set of forces that can apply bending moment at i th strain gauses. Outer product $\vec{l_{ij}} \times \vec{f_j}$ is equal to the scalar product of d_{ij} and f_j

$$M_i = \sum_{j \in q(i)} d_{ij} f_j, \tag{5}$$

where d_{ij} is a perpendicular distance between the location of strain gauges and the force vector crossing the applied point, and f_j is the amplitude of the force.

By arranging the indexes in eq.(5) and considering eq.(3), we can get the following matrix representation.

$$C\epsilon = Df, \tag{6}$$

where C is a diagonal matrix with C_i in the diagonal components, ϵ is a vector composed of ϵ_i, D is a matrix composed of d_{ij} considering $q(i)$, and f is a vector composed of f_j. In practice, values of strain is affected by the weight of the beam and initial state of the gauses in attachment, which should be counted as an offset b,

$$C\epsilon - b = Df \tag{7}$$

By designing the location of strain gauses so that D is invertible, the interaction forces f can be obtained as,

$$f = D^{-1}(C\epsilon - b) \tag{8}$$

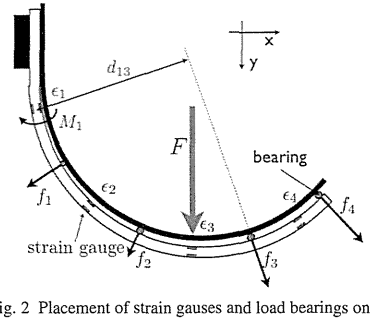

Fig. 2 Placement of strain gauses and load bearings on a cuff of robot suit HAL.

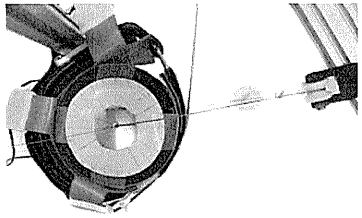

Fig. 3 Setup in the calibration experiment.

In calibration process, values of strain are obtained corresponding to the known applied forces. Using these values, coefficients of eq.(8) can be computed by regression. Knowing the coefficients, the equation can be used to estimate the applied forces according to the measured strains.

However, on cuff of wearable robots, because of the flexible interface with the human leg like plastic plates and sponges, the forces are scattered all over the interfacing surface, and it is difficult to assume the number, direction, and applied points of the forces. To deal with this problem, we would install load bearings between the metal frame and the plastic plate, in the next subsection.

3.2 Installing Strain Gauges onto Cuff

For the derivation in the previous subsection to hold, the number, direction, and applied points of the forces on the metal frame, on which the strain gauses are attached, have to be known. For this reason we introduced four load bearings between the metal frame and the plastic plate of a cuff of HAL (Fig.2). In this way, the number of the forces acting on the metal frame are restricted to be the same number as the bearings, the direction is restricted to be perpendicular to the metal frame, and the applied points are restricted to be same as the attachment points of the bearings. By this way, we can apply eq.(8).

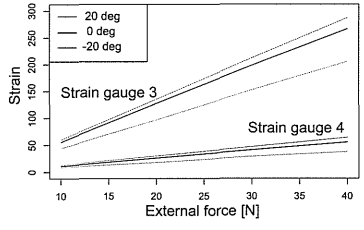

Fig. 4 Linear relationship between the applied external force and the strain. The external forces are applied with various amplitude and direction.

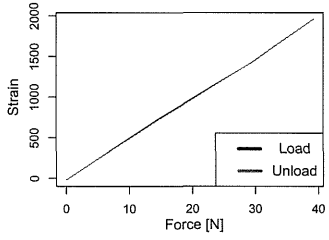

Fig. 5 Hysteresis test to compare the change of strain with the increasing and decreasing external loads.

As we have discussed in the introduction, we are interested in measurement of total force acting between the human leg and the robot through cuff. Since we have introduced four bearings, the total force $\boldsymbol{F}$ is computed as

$$\boldsymbol{F} = \vec{f_1} + \vec{f_2} + \vec{f_3} + \vec{f_4} \tag{9}$$

By introducing the coordinate frame (x, y) shown in Fig.2, $\vec{f_i}$ can be written in x and y components.

$$\vec{f_i} = \left[t_{ix},\ t_{iy}\right]^{\mathrm{T}} f_i \tag{10}$$

Considering eqs.(9), (10), and (8), we have

$$\begin{aligned} \boldsymbol{F} &= \boldsymbol{T}\boldsymbol{f} && (11)\\ &= \boldsymbol{T}\boldsymbol{D}^{-1}\boldsymbol{C}\boldsymbol{\epsilon} - \boldsymbol{T}\boldsymbol{D}^{-1}\boldsymbol{b} && (12)\\ &= \boldsymbol{A}\boldsymbol{\epsilon} - \boldsymbol{b}', && (13) \end{aligned}$$

where $\boldsymbol{T}$ is a matrix with t_{ix} and t_{iy} in the components, and $\boldsymbol{A}$ and $\boldsymbol{b}'$ are simplified representation of the coefficients. It shows that the total force $\boldsymbol{F}$ and the bending strains ϵ have a simple relationship represented by a linear coefficient matrix with an offset vector. These coefficients will be calibrated in a basic experiment in the next section.

Before calibration of the parameters, several basic characteristics of the strain were tested. Fig.4 shows linearity between the applied external force and the bending

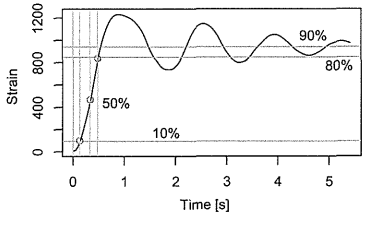

Fig. 6 Step response of the strain.

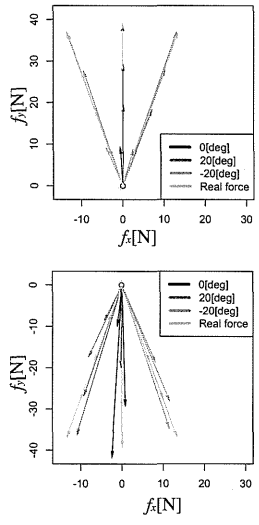

Fig. 7 Result of calibration: estimated forces can be compared to the real forces. Top: pushing direction. Bottom: pulling direction.

component of the measured strain value (eq.(1)). The angles of the external force conform to the definition in the next section.

Fig.5 shows the result of hysteresis test, in which the external force was gradually increased and then decreased with the interval of 0.5[kg]. It shows that there is no significant hysteresis in the strain value, which allows simple mapping of the strain values to estimate force.

Fig.6 shows step response of the strain value to the external force. 3[kg] load was initially applied and at one moment it was reduced to 1[kg]. In the graph, the value of strain is normalized to 0 initial value, and the amount of change to positive. It shows that the response is fast enough for our purpose of measuring human walking or leg swinging.

3.3 Calibration of the Model

To calibrate the parameters $\boldsymbol{A}$ and $\boldsymbol{b}'$ in eq.(13) the cuff was attached to a soft cylinder which mimics human leg, and external forces were applied by pulling the cylinder into several directions at several amplitudes (Fig.3).

Parameters of the applied forces were 1.amplitude (from 0[N] to 40[N] with 10[N] interval), 2. direction (pulling and pushing the metal frame), 3. angle (0[deg], 20[deg], -20[deg]). These parameters were applied to each channel, therefore generating 5×2×3×4=120 sets of data. Among the 120 sets randomly chosen 80 sets

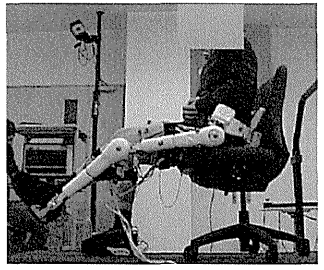

Fig. 8 Single joint experiment with HAL. HAL and the wearer swing the knee joint and the interaction force at the shank cuff is measured.

were used for regression, and the resting 40 sets were used to test the calibration.

The result is shown in Fig.7. The estimated forces are enough close to the given force shown in gray arrow, in both of the pushing (Left) and pulling (Right) direction. Statistically, in the pushing direction, 95% of the error was less than 1.7[N] and 2.5[deg], and in the pulling direction, it was less than 4[N] and 4.3[deg]. We suspect that the cause of the difference in the directions may be the structural difference. For example, the curvature of cuff is different between the directions, a plastic plate is attached only on the inner side of the metal part, and a belt wraps around the metal part. It has to be investigated into more detail in future.

4. EXPERIMENT

We tested the plausibility of the estimated interaction force in a situation where a human wears HAL. For this purpose, single joint motion, where the wearer (one healthy subject) sits on a chair wearing HAL and moves his left lower leg around the knee joint, was tested (Fig.8). Control mode of HAL was either fully autonomous, no actuation, viscosity compensation or CVC (c.f. section 2). In the fully autonomous mode, it was controlled to track a pre-planned sine wave trajectory of 0.5[Hz] with 45[deg] amplitude at the knee joint with a comparatively high feedback gain. In this control mode, the wearer was asked to swing his leg in accordance with the HAL motion, earlier than HAL as if to increase the pace of swinging, or later than HAL as if to decrease the pace. In the other control modes the wearer was asked to swing his leg according to a metronome ringing at 0.5[Hz]. We referred to [13] to design the experiment.

Fig.9 shows knee joint angle, its velocity and the estimated interaction force at the shank cuff. Larger joint angle indicates flexing and positive force indicates pushing (ex. HAL pushes human leg into extension). In the case where the wearer tries to swing earlier than HAL (Top Left), the interaction force is almost in phase with the velocity reflecting that the wearer is trying to accelerate HAL. Contrarily, in the opposite case (Top Right),