呼吸困難感が起きる前にNPPVの必要性を多専門職ケアチームと患者・家族が共通理解できるかどうかが重要である．そのためには呼吸機能評価を行いつつ十分な説明をする．NPPV導入のポイントは目的を再確認することである．NPPVは呼吸筋疲労の回復，呼吸筋力維持[12]，低酸素血症と高炭酸ガス血症の治療，今後おきる呼吸苦の予防，QOLの改善，生命予後の改善，病気の全体のコースを改善するために行うのであり[3),9),13]，単なる延命治療ではない．

NPPVを呼吸困難感が始まってから導入すると，技術と多大な労力が必要になるので，呼吸困難感を感じる前に導入する[10]．導入には慣れた担当者なら外来や在宅でも可能である．多専門職種チームとの出会いを兼ね，入院して行うとさらにスムーズにできる．装着し，慣れてもらう．初日は1時間～2時間くらいから始め，装着時間を伸ばし3～4時間可能なら，その後，夜間中心に移行する．一日6時間以上できるかどうかが，一つの目安となる．理解できる方は1週くらいで慣れる．本人・家族，担当者なども装着を経験し，学び，慣れていく．NPPVの効果を実感できた患者は習得したといえる．NPPVが導入できれば，低酸素血症にさらすことなく，バイタリティを維持し，二次的な筋力低下の予防ができ，自立度も向上する．

呼吸器はあくまでも発展段階にある機械でしかないが，導入がうまくいかないのはほとんど導入者のスキル不足に起因する．導入時期が遅すぎることやALSの告知の失敗なども影響する．どうしてもうまくいかないときは，患者側の要因も考える．不安感が先になり，病気とともに生きる人生を肯定できていないと，NPPVはなかなか使えない．NPPVは気管切開手術を伴うTPPVより心理的に無理がないが，心理サポートを含む包括的ケアサポートを必要とする[14]．

D. ALSにおける機器とマスクの選択

1. 機器の選択の重要性

BiPAPシンクロニー2やTrilogy 100（パッシブ回路）（Philips/Respironics製）に代表されるNPPV専用装置が，ALSのNPPVに適している．一方，喉頭・咽頭機能が保たれるデュシェンヌ型筋ジストロフィーの場合はBilevel PAPモードではなく，従量式でTrilogy 100（アクティブ回路）やLTVなどを使い在宅療養すると良い．在宅ALS患者にNPPVを行う場合は，気道内圧，呼吸数，リーク量，分時換気量，アラームなどを内臓メモリーに経時的に記録できる装置を使う．BiPAPシンクロニー2にはEncorePro®，Trilogy 100にはDirectView®があり上記データが時系列で分析できる．

2. マスク選択と装着時の注意

マスクは人と機械をつなぐインターフェースであり，進歩が著しい．口が閉じられる場合はできる限り鼻マスク（nasal mask）を使い，眼鏡もつけられるタイプが良い．口鼻マスク（oronasal mask）は，睡眠中などに口が開いて換気量が低下する場合に有用である．できればタイプにかかわらず，複数のマスクに慣れてもらい，スキントラブルを起こさないように，ローテーションする．圧迫部位のスキントラブルに対してはトータルフェイスマスクも役立つ．導入時点でマスクタイプと大きさをしっかり患者に合わせる．医師だけでなく，臨床工学技士，看護師，呼吸器の販売技術担当者などに導入スキルが必要である．NPPV用のマスクには，原理の異なる2種類があることを安全管理上知る必要がある．呼吸回路に呼気弁がある場合のマスクは「呼気ポート無し」を使い，呼吸回路に呼気弁がない場合のマスクは「呼気ポートあり」を使う．この組み合わせを間違うと，換気量が低下するか，呼気がどこにも排出できなくなる医療事故となる．

3. マスクフィッティングのこつ

初めての方は慣れた方と二名で装着する．担当者すべてが習熟する必要がある．マスクは軽く手で固定し，患者がOKであることを確認した後に，締め付け過ぎない様にストラップで固定する．過度な圧迫が発赤・創傷の原因になる．ストラップの引っ張りは左右対称が原則で，不均等だと引っ張りが強い方にマスクはずれていく．これも発赤・創傷の原因になる．マスクを装着したら，必ず，リーク量を確認・計測する．ALS患者で上肢機能があまり障害されていない場合は，家族だけでなく，患者自身にも装着方法を習得してもらう．

4. 呼吸器の初期設定値

NPPV導入時のBiPAPシンクロニー2を使った設定例を示す．自発呼吸と機械による換気を併用するS/T（Spontaneous/Timed）モードを使う．初日は，呼気気道陽圧（expiratory positive airway pressure: EPAP）と吸気気道陽圧（inspiratory positive airway pressure: IPAP）をそれぞれ4 cmH_2O，8 cmH_2Oに設定する（バクテリアフィルターを回路中に挿入しない場合の例）．この圧差で換気が行われる．マスクからの呼気排出のため，呼気時も一定の空気を送り込む必要があり，EPAP 4 cmH_2Oは必要である．導入時の呼吸回数は12回/分にする．吸気の立ち上がり時間であるRise timeは適宜微調整する．マスクからの漏れが40L/

分未満になるくらいにマスクフィッティングを行う．動作時に胸郭がうまく動いているか観察する．慣れてきたら，前述の様に装着時間を伸ばしていく[14]．短期間に，IPAP を 1 cmH_2O くらいずつ増やし，12 cmH_2O くらいまでは早期に増やすとよい．
（注：バクテリアフィルターを回路中に使用する際は、本稿の IPAP 値に 2 ～ 3cmH_2O 足して設定すること）

E. ALS における NPPV 維持と問題解決

1. 換気量維持の方法

IPAP 12 cmH_2O でしばらく患者の換気状態が安定していても，呼吸筋力の余力がなくなり，胸郭も硬くなると，換気量が不十分になり，呼吸不全が悪化する．夜間睡眠中に SpO_2 の低下がある場合や呼吸苦を感じる場合は IPAP を 1 cmH_2O ずつ増やして行く．16 cmH_2O 以上になると，圧が強すぎると感じる患者が増える．圧が高まるとマスクからのリーク量も増え，締め付けを強めるため皮膚トラブルが多くなる．そこで，日中には問題がない場合は，EncorePro®，DirectView® などの換気データの分析ソフトウエアを使い，SpO_2 と換気量の関係を評価するため，就寝中の装着時間，呼吸回数，一回換気量，分時換気量，リーク量などを確認する．夜間など特定状況でのみ換気量低下による SpO_2 の低下がおきる場合は，S/T モードから AVAPS（Average Volume Assured Pressure Support）モードに変更する[14]．このモードは，設定した換気量に至らないと自動的に IPAP を増やすモードである．たとえば，IPAP 16 cmH_2O で夜間のみ SpO_2 の低下がおきる場合，夜間の SpO_2 低下データと同時刻の一回換気量のデータを評価する．たとえば，SpO_2 が維持できる一回換気量の下限が 350ml であるならば，AVAPS の最低保障の換気量を 350ml と設定する．通常の IPAP は変えず，換気量が低下した時の最高の IPAP を 20 cmH_2O と設定すると，機械は一回換気量を 350ml に維持できるように IPAP 16 cmH_2O から 20 cmH_2O の間を動的に調整していく．必要な時のみ IPAP が徐々に増加するので，患者は楽で合理的である．

2. 機械的咳介助（MAC）の必要性

FVC の低下に対しては IPAP を増加することで対応可能だが，気道に痰などの分泌物があると，Bilevel PAP では有効な換気量に至らない．気道内分泌物をどうやって除去するかが重要である．CPF は気道内の痰などの分泌物のクリアランス（清浄化）能力を示す測定値である．最初は，CPF が低下しないように，呼吸理学療法を導入する．症例によるが CPF が 270L/ 分未満となったら，機械的咳介助（mechanically assisted cough: MAC）も導入することを検討する[15]．CoughAssist®（図 4）をマスクを介して，気道に陽圧（+40cmH_2O）を 2 秒ほど加えた後，瞬間的に陰圧（-40cmH_2O）を 2 秒程度加えることで咳のかわりになる強い呼気流量を発生させる．これを 4 回くらい繰り返し，同時に胸郭圧迫を加えると効果が高まる．その後，口腔から咽頭・喉頭の吸引をおこなう．痰や気道分泌物の除去効果をみながら繰り返す．最初は 1 日 1 セッション程度で慣れてもらい，気道内分泌物の多い場合は 1 日数回行う．上気道炎，肺炎の場合は抗生剤投与に MAC を繰り返すことで早期に治癒できることが多い．2010 年から在宅での保険が適応されている．

図 4：機械的咳介助を行う CoughAssist®

3. TPPV への移行

MAC の回数を増やしても十分に気道分泌物を除去できない場合は．気管切開による陽圧換気療法（TPPV）が必要となる[16]．TPPV では NPPV より容易に気道分泌物が除去できる．TPPV が必要となるもう一つの理由は，NPPV では IPAP を増加していくと体位変換でリークがおきやすくなり，車椅子乗車や坐位，立位という ADL 活動やリハビリテーションで低酸素血症を起こしやすくなるからである．24 時間 NPPV の場合は，日常生活動作でのマスクのずれで急変する危険性が増える．この時期になったら，安定した換気療法のために TPPV が必要となる．一方，デュシェンヌ型筋ジストロフィー患者の場合は，ALS と異なり喉頭・咽頭機能が保たれているため，NPPV ができなくても舌咽頭呼吸などを使い，短時間なら低酸素血症にならず日常生活動作が可能である．ALS 患者が NPPV から TPPV に移行するとほとんどの患者は，換気が安定し，ADL 制限もなくなり，良かったと感じる．ALS の進行期においては，NPPV は患者負担

とADL制限が多くなるので，患者・家族に対しては，NPPVが成功していれば，TPPVはより容易だと説明している．

Ⅳ．NPPV成功のための多専門職種ケア

A．栄養療法とPEG

1．栄養がALSの予後を決める－NSTの導入

最近の論文では，ALS患者の余命はBMI（body mass index）に依存することが報告された[3,17]．また，NPPV継続の忍容性は栄養状態に依存している．このため栄養療法を適切におこなうために，多専門職種チームの中に栄養サポートチーム（nutrition support team: NST）を立ち上げる必要がある．食形態を患者の嚥下機能に合わせ，むせず経口摂取が楽しく継続できる様にすべきである．最近の研究では，ALSでは筋萎縮が進行中は代謝亢進状態にあることが分かってきた[18]．このため，痩せによる栄養障害がこないように，栄養摂取量を増やす努力が病初期には必要である．体重，BMIなどを参考に栄養摂取量を調整するが，筋萎縮にともなう体重の減少がどのくらい影響しているのか分析することは難しい．二重標識水を使った測定がすすめられているが，個別の患者ごとに測定するまでには至っていない．一方で，筋萎縮が高度になったら，栄養必要量は低下するが，摂取エネルギー量を低下させた場合は，微量元素やビタミンなどの栄養素の低下を来さないようにする．

2．PEGをNPPV導入前に造設する

ALSの呼吸不全と嚥下障害の出現する順序は患者によって異なるため，ALSのNPPV導入のタイミングとPEGのタイミングの判断は大変むずかしい[2,3]．NPPVを導入して順調にみえていても，嚥下障害が進行し，栄養の摂取が経口から十分にできなくなる．栄養障害のため，痩せが進行し衰弱してしまう．経鼻経管栄養を開始しようとすると，挿入したチューブのために，マスクと皮膚の間からエアリークが発生し，エアリークを最小限にしようとしてマスクを締め付けることにより，チューブと皮膚の接着部位に褥瘡を形成し，NPPVの継続が阻害される．この時にPEGを作ることを患者が希望しても，％FVCが50％以下では経口の内視鏡操作による呼吸不全悪化の危険性が高く，PEGの造設をあきらめなくてはならない事態に遭遇する[3]．この問題を回避するためには，ALS患者の場合はPEGをNPPV導入前に造設することが推奨される[2]．

3．NPPV後のPEG造設は可能か

ALS患者は，PEGがないと栄養障害のためNPPVの継続が難しくなる．球麻痺で発症した方以外は，NPPVの導入時期は，経口摂取に不便を感じないことが多く，PEGの同意が得られにくいジレンマに遭遇する．NPPV前に，PEGがどうしてもできなかった場合は，呼吸不全がある場合は，鼻マスクによるNPPVを行いながら，経鼻内視鏡を経口挿入しPEGを作る検討をする．この方法は確立したが[19]，まだ普及していない．患者が鼻マスクを使用できることが条件であり，術中はセデーションをせず，局所麻酔でPEGを造設する．術中にIPAPを動的に増加させるコツが必要である．海外ではRIG（radiologically inserted gastrostomy）が推奨されているが[2]，本邦での経験例はない．これは，経鼻内視鏡を使った上記の方法より，はるかに危険と思われる．

B．リハビリテーションの考え方と方法

リハビリテーションを機能回復訓練と定義すると，ALSにおけるリハビリテーションの意味が分からなくなる．リハビリテーションとは本来，「復権（re-habilitate）」概念であり，どのような難病であっても，自分の身体を再度とらえなおし，障害とともに生きることを肯定できるように援助していく事を意味する．

理学療法的には，ALSの罹患筋には本来十分な休息が必要で，休息により機能が蘇ると考える．一方で，あまり病的でない筋群には廃用症候群の予防が必要で，ストレッチやADL活動が重要である．ALS患者の筋には休息が必要な筋群と，運動が必要な筋群が混ざり合っていることが理学療法上の課題である．十分な補助と運動を組み合わせる必要がある．障害が進むと，筋力が低下するにもかかわらず，新たな運動パターンや器具などの学習が必要となるジレンマも課題となる．このため，ADL調整として，日常生活全体における身体動作の評価を行い，長時間過ごす椅子・クッション・背もたれ・テーブルやベッド・マットレス・枕などを最適化する．作業療法的にbalanced forearm orthosis（BFO）やポータブルスプリングバランサー（PSB）を使い，重力に抗した筋力がなくても，遠位部の動作が可能ならば，上肢の自立度の改善を試みる．日常生活の日課表を作り，最適な運動負荷を日常生活の中に組み入れると同時に，離床と臥床の援助をおこなう．評価とプランニングは理学療法士，作業療法士などのリハビリスタッフと看護師が行い，日々の支援は看護師とヘルパーが行う．

C．言語・非言語的コミュニケーションの充実

書字能力や発話能力が低下してくると，言語によ

るコミュニケーションの能率が低下する．それ以前に信頼関係を構築できれば最高である．ALSケアでは手，足，額，ほほなどに各種センサーを装着し，ナースコールの代用としたり，意思伝達装置を導入することが推奨されている．透明文字盤も含め，いろいろな方法を工夫すべきである．脳血流変化，脳波によるP300，視線入力なども検討されている．生活に直接関係する内容だけでなく，信頼関係の構築や楽しみのために，コミュニケーション時間を増やしていく必要がある．

ALSにどの程度，前頭側頭葉変性症が合併するかの頻度はまだ不明であるが，合併する場合には病初期にわかる事が多い．NPPVの導入前後に性格変化が分かったり，言語の意味が捉えにくくなったり，表出する言語内容が単純なものに限られてくることが，前頭側頭葉変性症の症状と考えられる．病識が乏しく，感情失禁なのか強制笑いか判断できないような症状を含む上位運動ニューロン症状を合併する場合もある．何れの場合も文字盤，スイッチによる言語的コミュニケーションは著しく難しくなる．この様な場合には，支援者は言語によるコミュニケーションに固執することはやめて，表情変化，感情，体調などを総合的にとらえるようなコミュニケーション方法に切り替えると，患者も家族も落ち着きを取り戻せる．前頭側頭葉変性症を合併するALSが，林らの言うTLS（totally locked-in state）に対応するのかどうかの結論はでていないが[20]，非言語的なコミュニケーションをいれてケアを行うと，患者・家族の状態は明らかに改善する．

D. 心理サポート：ナラティブ・アプローチとCBT

治らない病気に対応する方法として，前述のナラティブ・アプローチがある[21]．人のナラティブ（narrative）とは語られた言葉（ナラティブ・ディスクール）で作られるが，そこには何らかのストーリー（物語），すなわち事象（event）に対する自分自身の認識が含まれている．医療におけるナラティブ・アプローチとは，客観化された病気の治癒を目標とするのではなく，患者・家族のナラティブの改善を目標にケアを構築する方法の事である．プライマリケアから生まれたNBM（ナラティブに基づく医療）を筆頭に，社会構成主義，家族療法，構成主義心理療法などの流れがあるが，いずれも「人間とは，現実を単に心に映し出すだけでなく，それを構成しながら意味を作り出している動的な存在」という認識を基本としている．人は適切な支援さえあれば，治らないどんな病気でも，新たな人生の意味を再構成しながら生きていけると考える．ALSの包括的ケアで行なわれる心理アプローチはこのナラティブ・アプローチであり[7, 22]，ALSの呼吸ケアにも必要なアプローチである．人工呼吸器を使い生きることを延命と考えるのも，一つのナラティブでしかないため，その捉え方を変えて，ナラティブを書き換えることができれば，延命ではなくQOLは向上すると考える．

慣れた心理療法士などは「認知行動療法（cognitive behavioural therapy: CBT）を取り入れている．行動レベルの異常は，患者の認識枠の異常に基づくという考えを基本的背景にもつCBTは，認識枠を再構成するための直接的な心理介入である．病とともに歩むとき，患者は自分の認識枠と周囲との関係性の両者を再構築しなければ生きづらくなる．患者自身でそれができるように非指示的にアプローチするのがナラティブ・アプローチであり[23]，それを意図的・指示的に心理介入する方法がCBTである[23, 24]．本来は別個の考え方であるが，両者ともALSケアに有用である．

V．緩和ケアと難病ケア

A. 緩和ケア概念の誤解をとく

英連邦ではALSは緩和ケア対象疾患であるが，それはALS患者が安心して痛み無く死を迎えられるためのケアをしようという意味ではない．この緩和ケア概念は完全に誤解である[25]．緩和になるかどうかは状態や関係性によって決まるのであり，人工呼吸療法もPEGも患者・家族にとって緩和になるならば，適切に行なえると考えることが緩和ケアである．医療技術自体に「緩和 」か「延命治療」かが定められているのではない．治癒困難な患者にとって症状コントロールのために必要な治療内容を「緩和（palliation）」と呼ぶのである．この意味では難病ケアと緩和ケアは同じである[7]．患者・家族が人生を放棄しようと悩んでいるとき，適切な緩和療法をおこない，支援し励ましていく．そのとき，患者・家族の心のギアは自然に切り替わっており，生命を支えられることへの不安感もないし，“無駄な延命治療にすがっている”わけでもない．緩和になっていれば，呼吸器の使用は，本来死んでいる人に対する「延命」と言う意味にならず，主体的な人生の歩みになっている．そうなると「法的に人工呼吸器は外せない」と患者・家族は考えなくなる．「人工呼吸器を外さないのは法や倫理の問題ではなく，私たちは苦労しても一緒に生きて行きたいし，お別れもしたくないから外さない」というナラティブに自然になっていく．

B. スピリチュアルケアの普遍性

スピリチュアルケアは，宗教的だと思われているが，誤解である．人は信仰の有無にかかわらず，それを必要とするからである．スピリチュアルケアとは，本来，どのような病気でも自らの「生を放棄せず（Do not abandon life）」，「生を肯定し（Affirm life）」再び生きられるようにサポートするケアの事である．この考え方は，英国のセントクリストファー・ホスピスの原点である[25]．喪失・絶望から心の復活・再生に向かうケアのことであり，身体の所有論を超えて，人の心が変化しながら，何らかの永遠性に至る道である．セントクリストファー・ホスピスでは最初，ピルグリムルームにキリストの三部作の油絵と十字架をおいていた．十字架刑を受けるイエス・キリストとALSやがんで苦しむ患者を重ね合わせ，復活と救いを考えた．その理念は今も変わっていないが，最近になり十字架とこの油絵はしまわれた[25]．彼らは，宗教的シンボルや典礼を使わなくても，スピリチュアルケアはできると自信をもったからである．人間が感じ悩むすべてを科学的に深められると考えるならば，スピリチュアルケアもまた科学することができる．これは科学の構成主義による見直しであるが，ナラティブ・アプローチも構成主義による心理療法の見直しでもある．

C. ALSケアにおける麻薬乱用への対処

全人的苦痛と訳される「total pain」は，緩和ケアで行なわれる全人的（holistic）ケアの文脈で，現代における緩和ケアの創始者，セントクリストファー・ホスピスの設立者であるシシリー・ソンダースが使った言葉である[25]．緩和ケアとは，麻薬だけで痛みなどの症状をコントロールしようとするのではなく，多様で細かな症状コントロール，麻薬以外の各種薬剤の使用，社会・心理的問題の解決，患者・家族のもつスピリチュアルニーズに対するケアによって，痛みなどの症状がとれ幸せになれるというケア概念である．各種のケア介入と麻薬の使用量は，実は逆比例している．イギリスには，医療用麻薬を多く使うほど良い緩和ケアだという考え方はない．我が国では，オピオイド（麻薬様物質）をALSの症状緩和に使う事についての混乱と緩和ケア概念の誤解がおきている[25]．

アメリカのEBMに基づくALSガイドラインにはALSのオピオイド使用は推奨されていないが[3,4]，耐え難い呼吸困難感や体の痛みにより，ALS患者と家族がパニックになっている場合，オピオイド使用の検討が行われる[2]．しかし，実際の体の痛みは，ほとんど，理学療法や心理・社会的なサポート不足によるものが多い．また，呼吸困難感でパニック症状になる方のほとんどは，十分な多専門職種ケアが提供されておらず，患者・家族に不安感が高く，病気とともに生きていく事への恐怖心が基になっている．告知時点から適切なケアが行われなかったためであり，遅きに失したとしても十分に多専門職種ケアを提供することからケアを検討しなおすべきである．しかし，この時ケアチームは燃え尽きているか被害者的になっており，問題の根は深い．この悪循環を断ち切るために，症状コントロールに少量のオピオイドが役立つ場合は投与する．十分に多専門職種ケアを提供するという前提を無視すると，単にオピオイドの量を増量するだけになり，期待した効果が得られないと，裏切られた思いの患者・家族はパニックになって，さらに悪循環に陥るため大変危険である．

ケアの質を高めると同時に，薬物もオピオイドにこだわらず，抗うつ薬などの薬物療法も検討する．どうしても，オピオイドを使う場合には，エビデンスとして，呼吸困難感の緩和効果はモルヒネにのみあることを知っておくべきである．英国の十分なホスピスケアの環境の下では[26,27]，モルヒネを低用量で長期に使うことで，ALS患者の生命予後をむしろ伸ばすと考えられている[28]．一方で，短時間でモルヒネを増量していくと，薬理作用から自発呼吸抑制がおき死に至るし，別の副作用として，呼吸筋群の硬直や声門の閉鎖がおき，NPPVによるマスク換気ができなくなり，死に至る．このため，モルヒネを急激に高用量にしてはならない．合成モルヒネのフェンタニルはこの筋硬直作用がモルヒネよりも多いため，ALS患者に対し使用すべきではないという警告が出ている[29]．

私たちの経験では，デュシェンヌ型筋ジストロフィーでは，心不全症状から強い呼吸困難感を呈する場合に，オピオイドは大変有用である．一方で，診断時から適切にケアされ，不安感の少ないALS患者は，呼吸器の使用・不使用に関わらず，少量の酸素投与を行うことがあっても，オピオイド投与が必要になる様な呼吸困難感が出現することはない．

Ⅵ．医療・福祉制度を活用した多専門職種ケア

A. 在宅ケアカンファレンスでケア方針を共有

在宅ALSケアを行うためには，診療所，病院，訪問看護ステーション，ヘルパー事業所などが連携し，呼吸ケアのみならず，リハビリ介入，摂食・嚥下・栄養管理などの方法を検討する（図1）．医療保険だけでなく，障害者自立支援法と難病対策制度を利用する．40歳以上であれば介護保険制度も利

用する．診療所医師，病院医師，看護師，ケアマネジャー，MSW，保健師の中でリーダ役をだれかに担ってもらう．ヘルパー事業所も加えて定期的にケアカンファレンスを行い，情報を共有する．チームの共通方針は難病とともに生きる「人生（生）の肯定」であり，患者・家族がつらいことを理由に「人生（生）を放棄」しないように援助することである．患者・家族の気持ちを尊重することとは，患者・家族による「生の放棄」の意思を実行することではなく，患者・家族が「笑顔と楽しみ」を得られるように援助し，苦難においても心の余裕を取り戻し，振り返り，変化していける援助としていくことである．人は，法や倫理のために生きるのではなく，楽しいから，大切な人と別れたくないから生きるのである．「人生には意味と目的があり，それが無ければ生きる意味がない」というナラティブは混乱をまねきやすい．目標喪失が生きる意味の喪失になるからである．「人は意味や目的を授かって生まれたのではなく，生きていく中で，楽しみや目的が生まれるのが人生なのだ」というようなナラティブでケアを行う．

B. レスパイト入院の意味

定期的なレスパイト入院は，ALS在宅ケアには大変有用である．レスパイト入院は英国ホスピスで生まれた在宅支援の仕組みであり，医療専門職種は栄養，呼吸，身体障害の再評価や症状コントロールをする．ケア全般を振り返るためにカンファレンスを行う．患者・家族も医療専門職も今までの状況を振り返り，新たな気持ちで在宅ケアを再出発する．レスパイト（respite）入院を医療保険で行う際に，単なる息抜き入院にしないことが重要である．

C. 在宅を支援する療養介護事業

在宅生活が順調に見えても，家族の病気などで，限界に達したらどうなるのだろうかという不安は消えない．これが心理的負担になると，実際より病状が悪く感じられ，生きていく力が削がれてしまう．これを回避するためには，療養介護事業（障害者自立支援法）で終身入院が可能なことを説明する．この事業では障害区分6で気管切開人工呼吸療法をおこなっている患者に，入院医療と生活支援の両者が保証される．旧国立療養所の筋ジストロフィー病棟などがこれに対応しているが，新規にこの事業を導入する病院が増えている．ALSの入院生活が長期的に支えられるこの制度は安心感を生み出すため，患者・家族に伝えるべきである．障害者など一般病棟は在院日数制限の縛りがなく，長期入院できるように制度設計されているが，療養介護事業を平行して行っていない場合は生活支援員の配置がなく，生活支援が不十分なため，在宅生活と入院をキャッチボールの様に繰り返すとよい．

Ⅶ. まとめ

エビデンスに基づくALSの標準診療を反映したALS臨床評価指標アップデート（2009年）[3,4]では，リルテック内服，NPPV，PEG，多専門職種ケアの何れもが有用として推奨されている．一方，それらが実際の在宅ケアに十分に導入されていないことが問題である．その理由として，医療提供者側のスキル不足が考えられる．さらに，医療技術を提供する際のソフトパワーであるナラティブ・アプローチが十分活用されておらず，その前提となる，「難病と共に生きていく人生の肯定」を意識したケアができていない場合が多い．その様な状況下で患者・家族の喪失感，絶望感に直面するとすぐ担当者は混乱してしまう．患者の意思の尊重とは本来何なのかが分からなくなってしまうのである．この解決法を，本稿で詳細に論じ解説したので，参考にしていただければ幸いである．

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Gait Support for Complete Spinal Cord Injury Patient by Synchronized Leg-Swing with HAL

Atsushi Tsukahara, Yasuhisa Hasegawa and Yoshiyuki Sankai

Abstract— **Biped walking improves the circulation of blood as well as bone density of the lower limbs, thereby enhancing the quality of life (QOL). It is significant not only to healthy people but also to physically challenged persons such as complete spinal cord injury (SCI) patients. The purpose of this paper is to propose an estimation algorithm that infers the intention related to the forward leg-swing in order to support the gait for complete SCI patients wearing an exoskeleton system called a Hybrid Assistive Limb (HAL), and to verify the effectiveness of the proposed algorithm through a clinical trial. The proposed algorithm infers the patient's intention in synchronization with the deviation of the center of the ground reaction force (CoGRF) that is observed immediately before a person starts walking. The patient conveys this intention by inducing the deviation of the CoGRF, using crutches or handrails with both of his/her arms. In the clinical trial, we confirmed that the algorithm inferred the patient's intention to swing the leg forward, and achieved a smooth gait in synchronization with it. As a result, the gait speed and cadence of the SCI patient with HAL during the 10-meter walking test increased to 6.67 [m/min] and 20 [steps/min], respectively after several trials.**

I. Introduction

Due to the accumulation of blood in the venous system of the lower limbs, paraplegic patients who are forced to live in a wheelchair or live bedridden lifestyles are likely to develop deep-vein thrombosis (DVT) [1]. It was reported that DVT occurs in 60-80% of spinal cord injury patients [2]. The incidence and mortality from pulmonary embolism (PE) increases, if the thrombus formed by DVT (i.e., embolus) is pumped to a pulmonary artery [3]. To prevent such an incidence of thromboses, patients need to move their legs actively because muscle contraction of the lower limbs has a functional role to return blood to the heart, and to improve the blood circulation. Walking is particularly effective not only for prevention of these thromboses but also for increasing the bone mineral density (BMD) of the patient's lower limbs [4]. However, complete paraplegic patients cannot stand up and walk by themselves due to the SCI. From the point of health maintenance, it is important for the patients to walk using their own legs to improve the circulation of blood in their lower limbs and thus, as a final result, to enhance their quality of life (QOL). Orthoses for walking e.g., a reciprocating gait orthosis (RGO) for severe physically challenged persons is widely utilized as a means to support the stance phase and the swing phase of the contralateral lower limb [5]–[7]. It is also effective to increase the BMD of the patient's lower limbs. However, the orthosis that is rigidly secured to the patient's lower limbs restricts the range of the motion of each joint and requires considerable force from his/her upper body in order to swing the leg forward. Therefore, it is difficult for him/her to perform a natural gait.

A. Tsukahara, Y. Hasegawa and Y. Sankai are with Funding Program for World Leading Innovative R&D on Science and Technology, Center for Cybernics Research, University of Tsukuba, 1-1-1, Tennodai, Tsukuba, Ibaraki, 305-8577, JAPAN. `tsukahara@ccr.tsukuba.ac.jp`

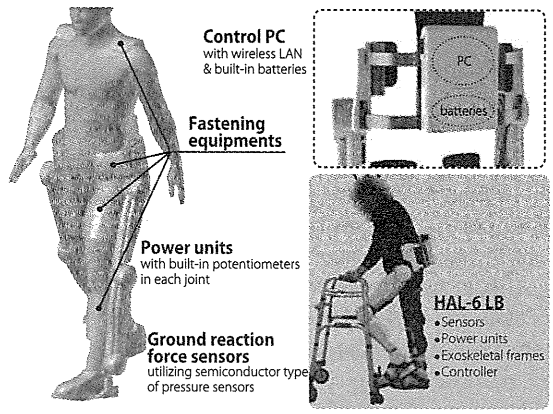


Fig. 1. System configurations of the HAL-6 LB which was developed to support the whole weight of complete spinal cord injury (SCI) patients. Exoskeletal frames are firmly attached to the wearer's legs with molded fastening equipment. Power units and potentiometers are directly attached on each joint of HAL. A computer and batteries are attached on a box on the back side. A tri-axial accelerometer, a gyroscope, a motor driver and other electrical circuits are allocated on each link. HAL calculates the center of the ground reaction force (CoGRF) using the GRF sensors.

The Hybrid Assistive Limb (HAL) was developed to physically support not only healthy people but also paraplegic patients. In order to support various types of people, we have designed the control algorithms specialized to different types of wearers. One algorithm delivers sufficient performance by using the wearer's voluntary muscle activity [8]. The muscle activity is detected from the bioelectrical signals (BES), including the muscle potential. Since the signals can be measured just before the corresponding muscle contraction, they are useful and reliable to synchronize the motion support with the wearer's movement. However, it is difficult to measure the proper BES from the lower limbs of paraplegic patients such as complete SCI patients. The second algorithm, therefore, copes with the functional motion support of the patient without using the BES signals [9], [10]. In this control method, once a certain movement associated with the desired movement is detected, HAL autonomously assists the functional movement of the wearer. For instance, the sit-to-stand and stand-to-sit supporting motions are initiated when preliminary movements are observed in the initial phase [9].

This approach is an ideal solution to support the lower limbs of paraplegic patients because it utilizes the wearer's residual functions and operates based on their intention for physical movement. So far, HAL successfully supported the gait of an incomplete SCI patient and as well as hemiplegia patient [10], [11].

In related work, the Wearable Power Assist Locomotor (WPAL) detects the wearer's intention related to the forward leg-swing by using acceleration sensors attached to the walking aid and then controls the stride length [12], [13]. This particular walking aid to infer the wearer's intention is always necessary. However, patients usually employ simpler walking aids such as a cane or crutches according to the restoration process of their sensory and motor function. It is important to note that an inference device for patients' gait should be equipped on a wearable robot rather than a walking aid. Even though the similarly operating ReWalk and eLEGs support the gait of severe paraplegic patients, who cannot walk without assistance while the patient utilizes a crutch to maintain the balance, the efficacy of these systems to the patients has not yet been reported.

The purpose of this paper is to propose an estimation algorithm that infers the intention related to the forward leg-swing in order to support the gait of complete SCI patient wearing HAL shown in Fig. 1, and to verify the effectiveness of the proposed algorithm through a clinical trial with a 10-meter walk on a treadmill. The algorithm infers the intention in synchronization with the deviation of the center of the ground reaction force (CoGRF) that is observed immediately before a person starts walking.

II. Methods

A. Estimation algorithm for gait-intention

BES measurement such as electrical potential of the muscles is one of the methods to detect the wearer's intention related to target movement. Unfortunately, the proper signals cannot be obtained from the lower limbs of complete SCI patients. This paper, therefore, proposes an algorithm called "Gait-intention estimator" for patients who can intuitively move their CoGRF by using a cane or a walker with both of their arms. Generally, a healthy person starts to walk based on a shift of the CoGRF in the sagittal and lateral planes, which is a preliminary movement. Such a phenomenon is also seen in the SCI patients. The estimator infers the patient's intention related to the initiation of the forward leg-swing in synchronization with the deviation of the CoGRF instead of detecting the BES. This algorithm is the most simple and effective method to detect the intention of SCI patients because a patient wearing HAL can walk by slightly moving the CoGRF with walking aids instead of requiring additional training combined with another particular device such as a remote-controller. The algorithm also combines short-term phases divided into three sequences, as shown in Fig. 2, in order to generate a whole gait cycle. Definitions of the short-term phases are determined by the contact conditions of both legs.

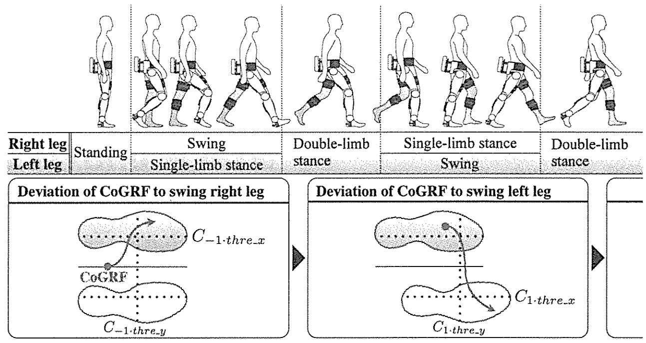


Fig. 2. Definition of walking phases. Walking is divided into three phases based on the contact conditions of both legs; swing phase, single-limb stance phase and double-limb stance phase.

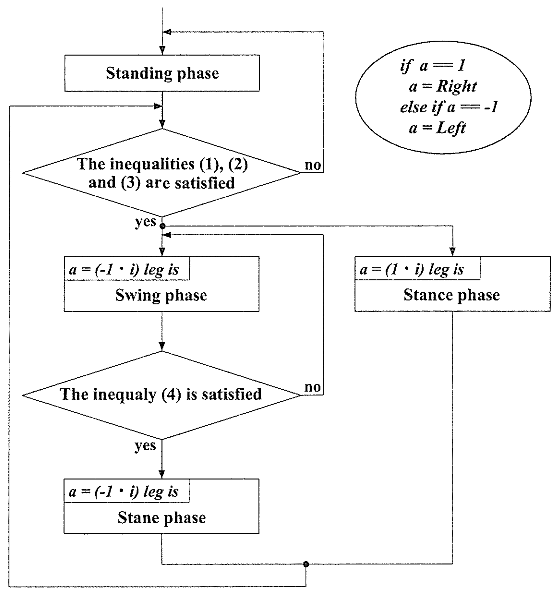


Fig. 3. Flow chart of the gait-intention estimator for a full gait cycle. The system including the estimator infers the intention related to the forward leg-swing when inequalities (1), (2) and (3) are satisfied for the decision of i=1(right leg) or i=-1 (left leg) during the standing phase. The wearer can intuitively start a walk by moving the CoGRF to either the left leg or the right leg using his/her upper body. The system detects the landing of the swinging leg when inequality (4) is satisfied during the swing phase, thereby, shifting from the swing phase to the double-limb stance phase.

Figure 3 shows the flow chart of the gait-intention estimator. This algorithm infers the intention related to the forward leg-swing during the stance phase, which consists of the single-limb stance phase and the double-limb stance phase, when the following inequalities are satisfied:

$$\theta_{i\cdot k} < \theta_{i\cdot(thre\_k)}, \tag{1}$$

$$f_{i\cdot h} > f_{i\cdot(thre\_h)}, \tag{2}$$

$$|C_x| > |C_{i\cdot(thre\_x)}| \text{ and } C_y > C_{i\cdot(thre\_y)}, \tag{3}$$

where $\theta_{i\cdot k}$ and $f_{i\cdot h}$ are the knee joint angle and the GRF of the heel, and C_x and C_y are the CoGRF in the lateral and sagittal planes, respectively. $\theta_{i\cdot(thre\_k)}$, $f_{i\cdot(thre\_h)}$, $C_{i\cdot(thre\_x)}$ and $C_{i\cdot(thre\_y)}$ are thresholds for shifting from the stance phase to the swing phase. The subscript ‘i’ indicates either the right leg or the left leg. In addition, the right and left legs are replaced with the numerical ‘1’ and ‘-1’, respectively. For instance, if the wearer moves its CoGRF to the right leg side, the numerical ‘1’ is substituted for the subscript ‘i’. Likewise, if the wearer moves it to the left leg side, the numerical ‘-1’ is substituted for the subscript ‘i’. This gait-intention estimator also has the role of safety mechanism. The system including the estimator does not start the forward leg-swing if any one of the inequalities (1), (2) and (3) are not satisfied. In contrast, the system starts the forward leg-swing in order to prevent the patient from falling over if he/she loses balance, that is, if the inequalities are involuntarily satisfied.

The system shifts from the swing phase to the double-limb stance phase when the following inequality is satisfied:

$$f_{(-1\cdot i)\cdot h} - f'_{(-1\cdot i)\cdot ho} > \alpha_{(-1\cdot i)\cdot ho}, \tag{4}$$

where $f'_{(-1\cdot i)\cdot ho}$ is the GRF of the heel off (HO) when inequalities (1), (2) and (3) are satisfied. $\alpha_{(-1\cdot i)\cdot ho}$ is the threshold in order to detect landing of the swinging leg. After that, the system starts the next leg-swing when inequalities (1), (2) and (3) are again satisfied during the double-limb stance phase.

B. Design of desired trajectories

Biped robots must be sufficiently robust against various disturbances for a stable gait. The stability of such a robot is maintained within the support polygon by controlling the position of the zero moment point (ZMP). Stability control is absolutely essential not only for biped robots but also for exoskeleton systems. Therefore, we proposed the design of desired trajectories to support sit-to-stand and stand-to-sit motions of complete SCI patients by using the CoGRF, because the ZMP is always equal to the CoGRF, not only in a static posture [9]. In this paper, we improve the design of the desired trajectories of the motion support in order to apply them to the gait support system.

1) Stance phase: HAL keeps the wearer’s stability based on the CoGRF during the stance phase. Four ground reaction force (GRF) sensors utilizing semiconductor type pressure sensors are installed in the toe part, the ball part, the heel part and the outside of the foot part on the sole. The weight of HAL and the wearer is measured by the pressure on the inner bags embedded in the plantar part of the shoes. The CoGRF is the representative point of the vertical vector in each GRF sensor. Each vector is calculated from the ground reaction force of the inner bag that touches the ground. The coordinate point of each sensor is set as shown in Fig. 4. The desired position of the CoGRF, C_{ref_y}, is located at the middle point of the stride length.

The hip joint angle, θ_{*h}, is solved based on the geometric calculation of the kinetic model shown in Fig. 4. In addition to the solution mentioned above, the desired angle of the hip joint, θ_{ref_*h}, is decided uniquely because the desired position of the CoGRF, C'_{ref_y}, is replaced with the current position of the CoGRF C'_y that is included as a parameter in

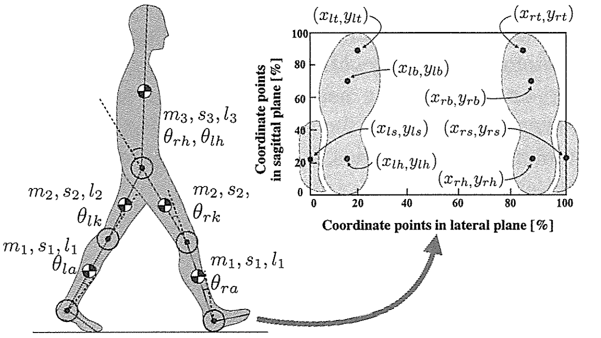


Fig. 4. Definition of system parameters and variables. m_i, l_i and s_i are the mass of link, the link length and the position of the mass, respectively. Subscripts 1, 2 and 3 indicate the lower thigh, the thigh and the trunk, respectively. The flexion of each joint angle is set as the positive direction, and each joint angle becomes 0 [deg] in the upright posture. x_i and y_i are the relative positions of the ground reaction force (GRF) sensors in the sagittal and lateral plane, respectively. Subscripts *rt*, *rk*, *rt*, *rs*, *lt*, *lk*, *lt* and *ls* indicate the sensor positions of the toe part, the ball part, the heel part and the outside of foot part on the right sole, and the left sole, respectively.

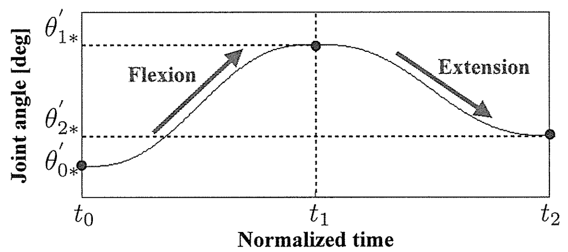


Fig. 5. Desired minimum jerk trajectory during the swing phase. Value θ'_{0_*} is the actual position of the desired trajectory when inequalities (1), (2) and (3) are satisfied. Values θ'_{1_*} and θ'_{2_*} are determined based on the gait of a healthy person in order to calculate the desired minimum jerk trajectories.

the geometric calculation. Thus, θ_{ref_*h} is calculated by:

$$\theta_{ref\_*h} = \frac{\pi}{2} - \theta_{*a} + \theta_{*k} - \cos^{-1}\varphi, \tag{5}$$

$$\varphi = \frac{1}{m_3 s_3}\Big\{(m_1+m_2+m_3)C'_{ref\_y} + (m_2 s_2 + m_3 l_2)\cos\left(\frac{\pi}{2} + \theta_{*a} - \theta_{*k}\right) - (m_1 s_1 + m_2 l_1 + m_3 l_1)\cos\left(\frac{\pi}{2} - \theta_{*a}\right)\Big\}, \tag{6}$$

where θ is the relative angle of each link. The desired angle of the hip joint, θ_{ref_*h}, as shown in (5) is updated at each control cycle based on the current status of the other joint angles. Disturbances can also be controlled in this framework.

The knee joints should be straightened through the stance phase to support the wearer’s weight on one leg. Therefore, the desired angle of the knee joint θ_{ref_*k} in the support phase is 0 [deg], thereby preventing the knee joint from bending due to the impact of the foot landing and the gravity.

2) Swing phase: It is necessary to provide an assist that is suited to the wearer’s physical characteristic so as not to give the wearer any uncomfortable feeling. In this paper, the minimum jerk trajectories shown in Fig. 5 are calculated based on the gait of a healthy person, and are provided to the swing phase during the gait support of HAL. The desired minimum jerk trajectories, θ'_{ref_*}, during the swing phase are given as follows:

$$\theta'_{ref\_*} = \begin{cases} \theta'_{ref1\_*} & (t_0 < t < t_1) \\ \theta'_{ref2\_*} & (t_1 < t < t_2) \end{cases} \tag{7}$$

where $\theta'_{ref_1\_*}$ and $\theta'_{ref_2\_*}$ are the desired trajectories for flexion and extension. The right leg and the left leg are denoted by an asterisk in the subscript, t_0, t_1 and t_2 are the starting time of the flexion [s], the finishing time of the flexion [s] and the finishing time of the extension [s], respectively. $\theta'_{ref_1\_*}$ and $\theta'_{ref_2\_*}$ are calculated by:

$$\theta'_{ref1\_*} = \theta'_{0*} + (15t_i^4 - 6t_i^5 - 10t_i^3)(\theta'_{0*} - \theta'_{1*}) \quad and \tag{8}$$

$$\theta'_{ref2\_*} = \theta'_{1*} + (15t_j^4 - 6t_j^5 - 10t_j^3)(\theta'_{1*} - \theta'_{2*}), \tag{9}$$

where time of the flexion t_i and extension t_j are equal to $(t - t_0)/(t_1 - t_0)$ and $(t - t_1)/(t_2 - t_1)$, respectively. Value θ'_{0_*} is the current position of the desired trajectory when inequalities (1), (2) and (3) are satisfied. Values θ'_{1_*} and θ'_{2_*} are the maximum flexion angle and the maximum extension angle. When heel contact (HC) occurs in the process of the swing phase, the desired trajectories from the end positions of the swing phase to the start positions of the stance phase are interpolated using a sigmoidal function. In contrast, the desired trajectories keep the angles of θ'_{2_*} when the HC does not occur during the swing phase. As such the trajectories can be smoothly calculated from the swing phase to the stance phase while avoiding discontinuity. In this research, the gait of a healthy person is captured by means of a MAC 3D motion capture system with twelve Raptor-4 Digital Cameras (Motion Analysis Co., USA) in order to determine parameters such as t_i, t_j, θ'_{1_*} and θ'_{2_*}.

C. Gait control

HAL controls each actuator by using a proportional and derivative (PD) control with gravity compensation so as to follow the desired trajectories mentioned above. The control law in each joint during the stance phase is described as:

$$\tau_{*h} = K_{Ph}(\theta_{ref\_*h} - \theta_{*h}) - K_{Dh}\dot{\theta}_{*h} + g(\theta), \tag{10}$$

$$\tau_{*k} = K_{Pk}(\theta_{ref\_*k} - \theta_{*k}) - K_{Dk}\dot{\theta}_{*k} + g(\theta) \quad \text{and} \tag{11}$$

$$\tau_{*a} = K_{Pa}(C_{ref\_y} - C_y) - K_{Da}\dot{C}_y + g(\theta), \tag{12}$$

where τ_{*h}, τ_{*k}, τ_{*a}, θ_{ref_*h}, θ_{ref_*k}, C_{ref_y}, $\dot{\theta}_{*h}$, $\dot{\theta}_{*k}$ and $\dot{C}_y$ are column matrixes. These variables have two elements that corresponded to each leg, respectively. Feedback gains K_{Ph}, K_{Dh}, K_{Pk}, K_{Dk}, K_{Pa} and K_{Da} are diagonal matrixes where feedback gains for each leg are diagonal elements. Likewise, the control law in each joint during the swing phase is also expressed by the PD control with gravity compensation using eq. (7).

III. Experiment

In order to verify the effectiveness of the proposed algorithm, a clinical trial consisting of a 10-meter walk on a treadmill is conducted with a complete SCI patient for eight days, two hours per day. The participant is a 66-year-old male, 160cm tall and weighting approximately 68kg (complete SCI at T10-T11, 8 years after injury). The clinical trial is performed in accordance with all procedures and approved by the Institutional Review Board. The patient had given informed consent before participating in this trial. In order to consider the fatigue of his arms, breaks are taken frequently depending on his physical condition during each trial.

As a preliminary step towards the clinical trial with the paraplegic patient, the proposed algorithm is applied to a healthy person who has similar physical parameters to the participant. Feedback gains of the PD control are adjusted through a preliminary experiment so as to perform the appropriate control without overshooting. Although the thresholds for the gait-intention estimator are also determined in the preliminary experiments, they are adjusted so as to swing the leg forward based on the instantaneous CoGRF when the patient intends to walk at the beginning of each trial session.

Figure 6 shows the experimental setting for the clinical trial with the 10-meter walk. In this trial, an audio-visual feedback system is applied in order to let the patient understand the position of the current CoGRF. Although his sensory and motor function in the lower body is completely impaired, he can induce the deviation of the CoGRF by using the handrails of the treadmill with both his arms. Thus, his intention related to the initiation of the forward leg-swing is conveyed to the intention estimator embedded in HAL. As a first step in the clinical walking trial, an unweighing system (Biodex, Unweighing System BDX-UESZ) is applied to support 20% of the patient's and HAL's weight. The belt

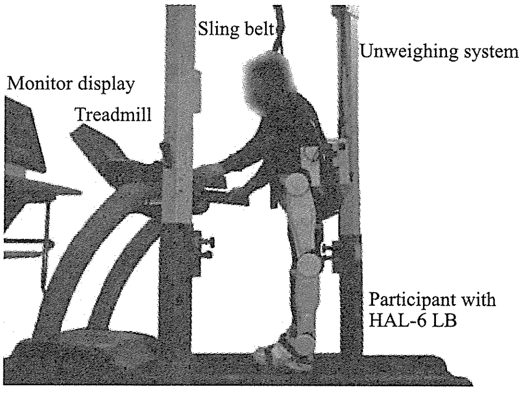


Fig. 6. Experimental setting for the clinical trial with a 10-meter walk on a treadmill. The audio-visual feedback system helps the patient to easily understand and induce the deviation of the CoGRF. The waist sling worn on his torso is connected to HAL to prevent misalignments of the joints of the patient and HAL during the gait support. HAL is connected to an unweighing system with a sling belt in order to eliminate the risk of falling.

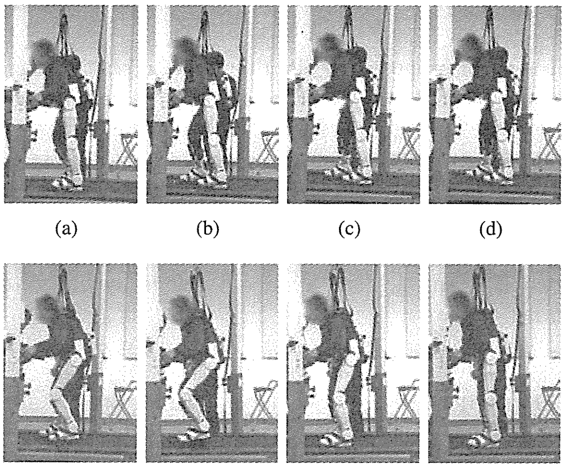


Fig. 7. Sequential photographs during a clinical trial session with a 10-meter walk on a treadmill. (a) and (b) Initiation of the swing of the right leg. (c) Detection of right heel contact (RHC). (d) Initiation of support for the double-limb stance. (e) and (f) Initiation of the swing of the left leg. (g) Detection of left heel contact (LHC). (h) Initiation of support for the double-limb stance.

speed of the treadmill is gradually increased so far as the wearer could continue to walk in a stable manner.

IV. Results

The results of the clinical trials with the 10-meter walk on the treadmill are depicted in Figs. 7, 8, 9 and 10. The sequential photographs as shown in Fig. 7 indicate that the patient could walk on the treadmill with the gait support of HAL. Figure 8 shows the joint angle of each joint, the CoGRF in the sagittal and lateral planes and the GRF of the heel parts. HAL initiates the swing of the right leg, when inequalities (1), (2) and (3) are satisfied. Furthermore, HAL detects the right heel contact (RHC) when inequality (4) is satisfied, and then initiates support of the double-limb stance. After that, HAL initiates the swing of the left leg when inequalities (1), (2) and (3) are satisfied during the double-limb stance phase. HAL then detects the left heel contact (LHC) when inequality (4) is satisfied and initiates support of the double-limb stance.

Figure 9 shows the CoGRF trajectory of the support polygon in the sagittal and lateral planes during the 10-meter walk on the treadmill for trial sessions on the first and the last two days. The thick line represents the mean value of the CoGRF during the 10-meter walk. The results in these graphs indicate that the CoGRF trajectory on Day 1 shown in Fig. 9 (a) deviates visibly from the mean value, whereas the trajectory on Day 2 shown in Fig. 9 (b) deviates less from the mean value.

The gait speed and the cadence during the 10-meter walk on the treadmill are shown for two days in Fig. 10. The gait speed shown Fig. 10 (a) increased to 6.67 [m/min] in only two days. In addition, the cadence shown in Fig. 10 (b) also increased to 20 [steps/min].

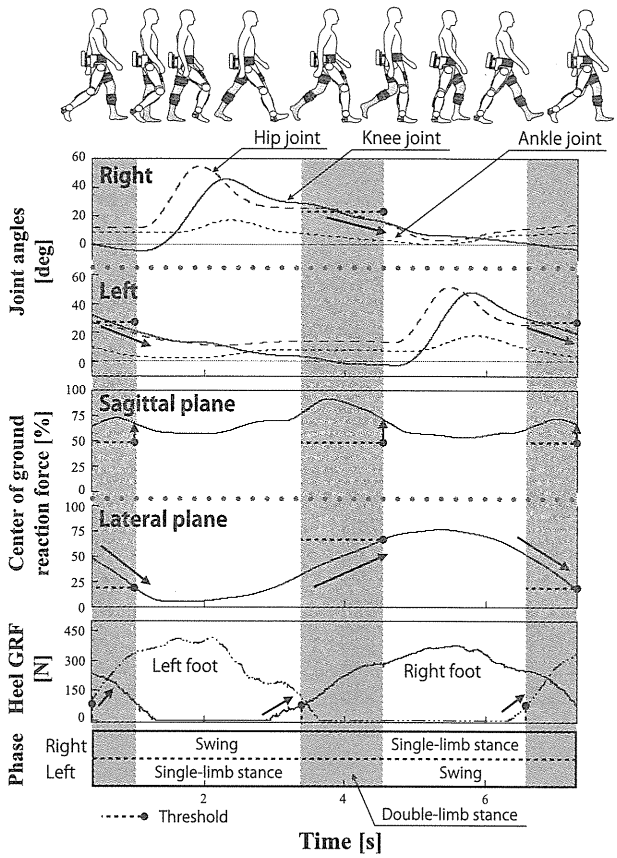
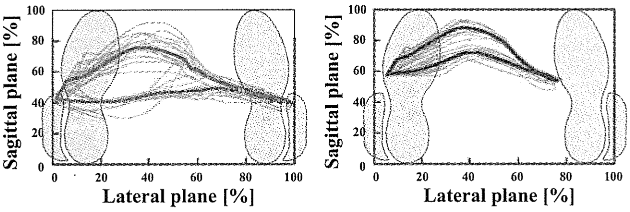


Fig. 8. Graphs showing the joint angle of each joint, the center of the ground reaction force (CoGRF) in the sagittal and lateral planes and the GRF of the heel parts during one gait cycle on Day 2. HAL initiates the forward leg-swing when the inequalities of the transition conditions are satisfied, and then controls the swing phase.

V. Discussion

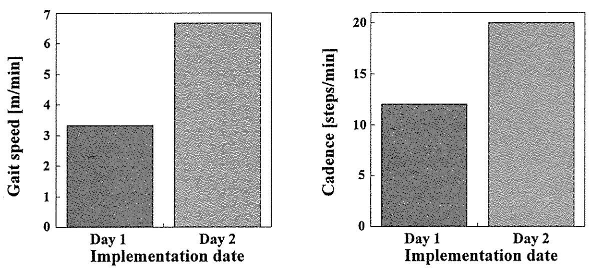
It is important that complete SCI patients walk using their own legs so as to improve the circulation of blood in their lower limbs and thus to enhance their QOL. An exoskeleton system that actively supports a patient's walk would be an ideal devices for a patient's active and healthy life. Therefore, the system should support the patient's gait while inferring the intention to initiate the forward leg-swing. The purpose of this study was to propose an algorithm that infers the intention related to the forward leg-swing in order to support the gait of complete SCI patients wearing HAL who have the ability to move their upper limbs by using walking aids. To this end, we focused on the deviation of the CoGRF instead of the BES of the leg muscles in order to infer the patient's intention, and verified the effectiveness of the proposed algorithm through a clinical trial with a 10-meter walk on a treadmill with a complete SCI patient.

The results shown in Fig. 8 indicated that the system could infer the wearer's intention and then successfully initiated the forward leg-swing in synchronization with the deviation of the CoGRF. The deviation of the CoGRF could be induced



(a) Day 1 (b) Day 2

Fig. 9. Results showing the CoGRF trajectory of the support polygon during the 10-meter walk for two days. The CoGRF in the sagittal and lateral planes indicates the representative point of the vertical vector detected by each GRF sensor. In this study, the CoGRF is calculated without consideration of the step length. The thick line is the mean value of the CoGRF. These results show that the trajectory of Day 2 deviates less from the mean value compared to the one of Day 1.



(a) Gait speed (b) Cadence

Fig. 10. Results of the gait speed and cadence during the 10-meter walk for two days. In Day 2, the gait speed and cadence of the SCI patient with HAL were increased.

by the patient using the handrail of the treadmill and both his arms.

In addition, the audio-visual feedback system was used so that the patient could easily understand the deviation of the CoGRF. The CoGRF trajectory on Day 1 (Fig. 9a) deviated visibly from the mean value. In contrast, the trajectory on Day 2 (Fig. 9b) deviated less from the mean value. The gait speed and cadence of Day 2 improved compared to Day 1 as shown in Fig. 10. These results suggested that the patient wearing HAL found his way for shifting the CoGRF in a short period while understanding the position of the CoGRF, and then he could intuitively walk. We learned that the complete SCI patient could improve his gait speed and cadence after a number of trials using the displayed current position of the CoGRF. Therefore, we need to regularly perform clinical walking trials with complete SCI patients for long periods.

Although this present system specializes in a straight walk for paraplegic patients on flat, it can build a generalized algorithm of the most basic legged-motions in their activity of daily living (ADL) by combining with the previous one that infers the intention related to the sit-to-stand and stand- to-sit motions [9]. We are currently developing the method that controls the gait speed and the stride length according to the wearer's posture, and examining a preliminary experiment in order to enhance the scalability of the system.

VI. Conclusions

This paper proposed an algorithm that infers the intention related to the forward leg-swing in order to support the gait of complete SCI patients wearing HAL. The effectiveness of the proposed algorithm was verified through a clinical trial consisting of a 10-meter walk on a treadmill. The results of the trial showed that the algorithm could infer the patient's intention to swing the leg forward based on the deviation of the CoGRF, and achieve a smooth gait in synchronization with it.

VII. Acknowledgments

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Exoskeletal Spine and Shoulder Girdle for Full Body Exoskeletons with Human Versatility

Stefan Roland Taal, *Student Member, IEEE,* and Yoshiyuki Sankai, *Member, IEEE*

Abstract—**Currently, wearers of full body exoskeletons are hindered in their ability to use their upper body as desired due to the rigid back parts used in these devices. In order to maximize their versatility the design and preliminary testing is shown of an exoskeletal spine mechanism, called "exo-spine", that allows the wearer to move all degrees of freedom of his spine and shoulder girdle. Based on the primary forces to be supported during lifting, identified as gravity forces from loads lifted in front of the wearer, as well as functional degrees of freedom, which is a control strategy used by our central nervous system, this mechanism can be actuated using only one motor to provide the required support. Experiments indicate a substantial, although not problematic amount of friction as well as further requirements for the control of the assisting force. Besides improving exoskeletons its basic structure and design principles may be successfully applied to rehabilitation as well.**

I. Introduction

VERSATILITY, the ability to move freely in all directions, in particular of our upper body, is indispensible for the kind of work that people do [1]. For exoskeletons to become successful in assisting human activities, they will need to enable their wearers to solve the problems they face with the degree of versatility that they would normally have. If not, even basic tasks as lifting items from the floor will require unnatural body postures, become undoable and/or require a much greater amount of effort.

Currently, the part of full body exoskeletons between the hips and shoulders is completely rigid. This restriction on both the wearer's spine (flexion, lateral flexion, and rotation) and, to a lesser extend, his shoulder girdle (abduction and elevation) thus leave the wearer with limited versatility. Moreover, since alltogether these parts contain 7 degrees of freedom (DOF), exoskeletons would require 7 extra actuators, using standard robotics technology, to regain this movability. This paper therefore presents a novel mechanical solution called "exo-spine" that, by maximizing the effectiveness of its actuation to the achievement of heavy work and lifting assistance, enables the required augmentation using only one motor.

This introduction will continue to set the specific context based on which the exo-spine is both required and possible. Subsequent sections will explore the mechanics, control method, as well as experiments to investigate the friction and controlability, and finally the discussion.

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S. R. Taal and Y. Sankai are with the Cybernics Laboratory, Department of System and Information Engineering, University of Tsukuba, 1-1-1 Tennodai, Tsukuba, 305-8573, Japan (email: Stefan@golem.kz.tsukuba.ac.jp).

A. *Spinal and Shoulder Movability in Exoskeletons*

Given the arrangement of DOF on the human body full versatility in exoskeletons is especially difficult to achieve in the upper body. Full arm actuation has been done, such as [2], although not yet in untethered, fully wearable types. As for the spine and shoulder, several devices exist that assist (parts of) the upper body; they can be grouped as follows.

Exoskeletons with an unlimited power supply include both wearable types with a tether as well as those fixed to a base [2-4]. Although wearability is restricted to the power supply, this group has fewer limitations on the amount of actuators. Two solutions for shoulder motion can be seen: free shoulders and arms with interaction at the hands [3], and full actuation using one motor per DOF [2] [4]. Another group consists of full body exoskeletons that carry their own power supply [5] [6]. With this extra limitation on the amount of actuators neither spine motion nor shoulder girdle motion has been implemented. More lightweight exoskeletal devices that attach to the arm are used for rehabilitation and force feedback systems [7] [8]. Their applications allow for a separate power supply and the required actuator forces are lower, such that full shoulder actuation is possible.

Comparing the above devices it can be concluded that the available power and actuators impose strong limitations on a battery powered exoskeleton. Moreover, the conventional solution of one actuator per DOF would require more motors than can be carried along.

B. *The HAL Robot Suit*

The current HAL (Hybrid Assistive Limb) suit, HAL-5, is a full body exoskeleton that carries its own power supply. It consists of frames interconnected by power units that each contain an electromotor and reduction gears and are positioned directly next to the hip, knee, shoulder (flexion) and elbow joints of the wearer to assist his movements [5]. Additional passive DoF are located at each shoulder, upper arm, and ankle joint. The suit is powered by batteries.

The system is controlled according to the intentions of the wearer, which are obtained by measuring the bioelectric signal (BES) on the skin above the main flexor and extensor muscles associated with each augmented human joint. Motor torques are calculated according to these signals. It is expected that similar control techniques and actuators will be used in versions that will contain the exo-spine.

C. Heavy Work and Lifting

Rosen *et al.* found that when performing daily living tasks the mean joint torques were at least an order of magnitude larger than those torques without the gravitational component [9]. In addition, HAL, like many augmenting exoskeletons, is meant to assist lifting during heavy work tasks, such that gravity forces will account for almost all required actuation. Furthermore, the weights of objects that are likely to be lifted with an exoskeleton are too high, and the sizes too large for the objects to be carried on one side while still being able to walk in a stable and balanced way.

Apart from gravity forces pulling and pushing forces may be found as well, such as seen in hospitals [10]. However, muscles at the main body joints from ankle to shoulder would all exert force in the same direction during both pulling and lifting, whereas pushing would be the opposite of lifting. Therefore, the kind of assistive forces the spine and shoulder girdle need most of the time are those that assist these parts to counter gravity forces from loads in the front. Instead of having as many actuators as the amount of DOF used for lifting it could thus be more effective to use a few actuators that focus on such lifting action only.

D. Functional Degrees of Freedom

To further combine multiple DOF into one it is possible to exploit a strategy, used by our central nervous system to control our high-DOF bodies in 3D space, called "functional degrees of freedom" (fDOF) [11]. An fDOF implies that in certain situations two or more muscles act based on the same control signal. For lifting, when first of all considering the static balances at the hip and the spine, and assuming there are no external moments on the lower back, it can be seen that the gravitational moments around the frontal axis at the hip and spine must be correlated. Furthermore, Thomas *et al.* have shown that during reaching tasks 94.7% of the peak-to-peak dynamic torques (i.e. excluding the gravitational components) at the ankle, knee, hip, spine, shoulder and elbow are determined by one parameter [12]. When considering only the hip, spine and shoulder the correlation will be even higher. Taken together it may be concluded that there is one fDOF that controls nearly all muscle torque of the hip and spine during lifting. Since HAL already uses hip motors that are controlled based on the BES of the hip muscles of the wearer, these signals can therefore be combined and used as a control signal for the exo-spine.

E. Applications for Spinal Cord Injury Patients

Spinal cord injury (SCI) patients have limited or no abilities to control the muscles that balance their pelvis, which even during sitting makes their upper body unstable [13]. They often solve this by leaning on an armrest or their knee with one arm, but doing so leaves them with only one hand to do most of their daily living tasks. Not only can the BES of the hips be used for the exo-spine, but similarly the BES of the upper back muscles of SCI patients may be effectively used to control a hip motor during sitting. Looking further ahead into this research, using the exo-spine and a hip motor as a hip and back support for SCI patients could increase the area they can reach with both hands when sitting in a wheelchair [14], as well as help them stand upright when such a back support would be attached to a lower body exoskeleton that assists their walking.

II. Design

This section will first describe the general design principles used followed by the design of a prototype based on these principles.

A. General Design

As mentioned, HAL uses BES based torque control of the motors to provide assistance; position control is completely left to the wearer, who can voluntarily change his BES to change both his own muscle torques and those of HAL's motors. The same principle will apply to the exo-spine. Only the assistive torque needs to be determined for the wearer to be able to move the exo-spine as desired. Furthermore, HAL's hip component is fastened to the wearer's pelvis, so that as long as the top of the exo-spine is attached to and can follow the wearer's shoulder girdle the shape of the exo-spine itself does not matter.

A further requirement follows from the position of the exo-spine behind the human spine. The exo-spine will have to become longer as it bends forward to ensure HAL's shoulders remain lined up with the wearer's shoulders.

As for HAL's shoulder girdle movement there are two simplifications that can be made. They are based on a principle first applied by Schiele and Van der Helm [7] where two passive joints are inserted, perpendicular to the active joint, between the actuator and the attachment with the wearer, such that any misalignment between, e.g. the shoulder's active joint and the wearer's shoulder does not create painful forces between HAL and the wearer. Using such a system HAL's passive shoulder joint (arm medial rotation) may be placed behind the wearer's shoulder instead of above. This opens up the space above the wearer's shoulder so that he can freely elevate his shoulders when needed, accommodated by the added passive joints between the actuator and the attachment with the wearer.

Shoulder abduction can be provided by the exo-spine by adding exoskeletal "shoulder blades" that make the same forward rotation as the wearer's collar bones, but behind the wearer, such that HAL's shoulders can move forward with respect to the top of the exo-spine.

To save energy and, in particular, to counter the effects of friction, which will be further explained from Section III.B, springs can be added that balance with the weight of HAL's upper body. This will relieve some of the actuator's required power during both up and down bending.

B. Prototype

In order for the exo-spine to bend forward into a convex shape, similar to that of the wearer's spine, as well as to extend simultaneously its basic mechanism follows the one shown in Fig. 1. Two types of parts, called "vertebra" and "link" are connected into a chain of in total five vertebras, including the base. The spine extends when bending forward as the instantaneous centers of rotation (ICOR) of all vertebras start in front of the exo-spine. Extension becomes slower as bending increases since the ICOR move closer to the vertebras (Fig. 1b). Despite the many parts the whole exo-spine bends forward as one single DOF.

Fig. 2 shows a drawing of the central vertebras (top) and links (bottom). (As in Fig. 1b numbers refer to the different vertebras; letters indicate the joints; X points to the front.) They are interconnected with rotational joints at A and rod ends, which provide 3 DOF motion, at joints B and C. This, and a parallelogram structure at each link that enables joint C to move sideways, allows the vertebras to rotate around their vertical axis. In addition, each vertebra can bend sideways (laterally) around the axis connecting B and C.

The full exo-spine is shown in Fig. 3: full bending and shoulder blades abducted (a), full side bending (b) and full rotation (c) (Height when straight is 350mm). When combined with HAL the base will be located just behind the 2nd lumbar vertebra of the wearer, L2, while the shoulder blades extend up to the top of his shoulder. The exo-spine can not hyperextend; this is blocked mechanically. Its neutral position is straight, without any lateral bending or rotation, similar to the human spine.

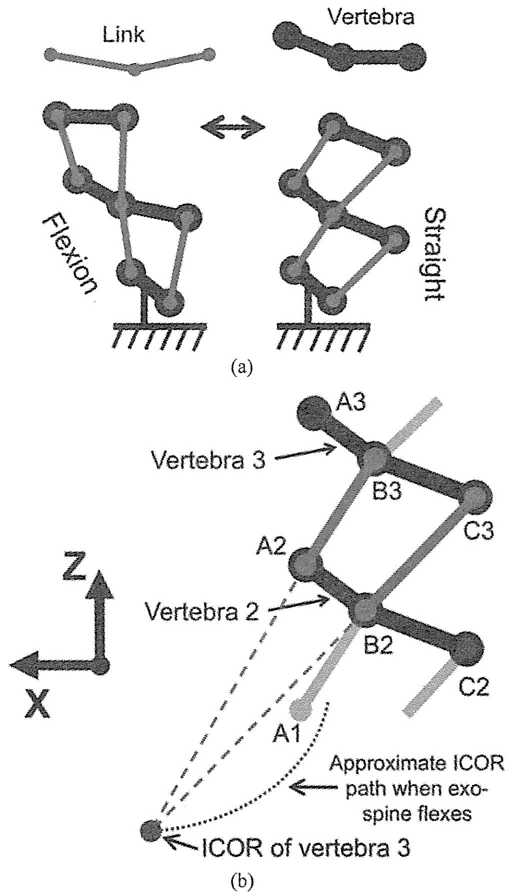


Fig. 1. Schematic side view of the vertebra-link mechanism of the exo-spine. As the mechanism bends each next vertebra rotates forward with respect to the one below (a). Moreover, the exo-spine as a whole extends when bending due to the fact that the instantaneous center of rotation (ICOR) of each vertebra starts in front of the spine.

III. Actuation

This section will describe the actuation method and primary control algorithm. Although verification of this algorithm is not included it will show how fDOF can be implemented into exoskeletons

A. Mechanism

The exo-spine is actuated using two cables that run over small pulleys in the back corners of the structure from the base to the top (Fig. 2). The cables are made of high strength Dyneema and pulling them generates a moment on the exo-spine that pulls towards the neutral position.

The cables are connected below the spine onto one pulley. When the exo-spine is bent laterally to one side the distance between the top and the base for the cable on the other side becomes larger such that only that cable actuates the exo-spine while the other becomes slack. This produces a torque that pulls back towards the neutral position. When the exo-spine rotates the pulleys of the vertebras and links move away from each other horizontally, so that the cables come into a zigzag shape. The tension on the cables then produces a torque that again pulls towards the neutral position. Based on the fDOF between the spine and shoulder during lifting, the two cables connect to a small lever at the top that in turn pulls the exo-spine's shoulder blades towards the zero abduction position. When lifting, assumed that it is in front

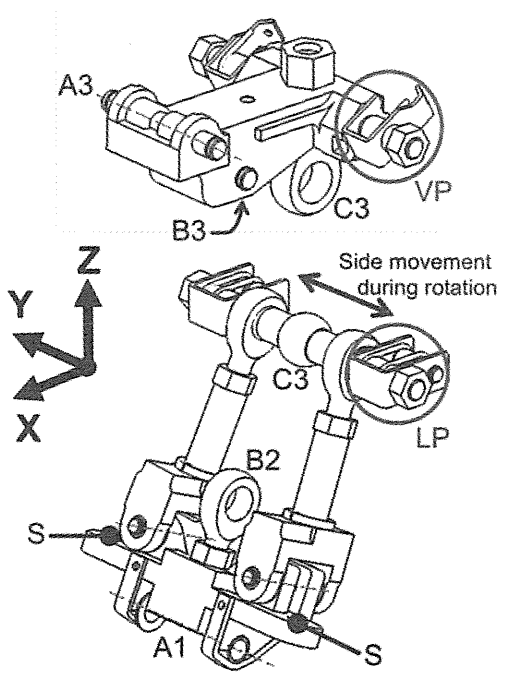
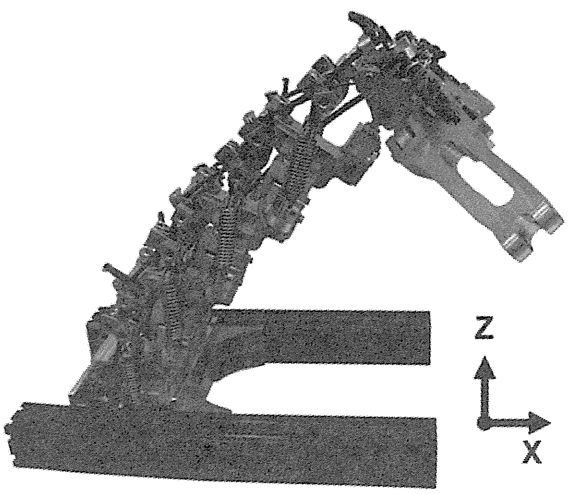
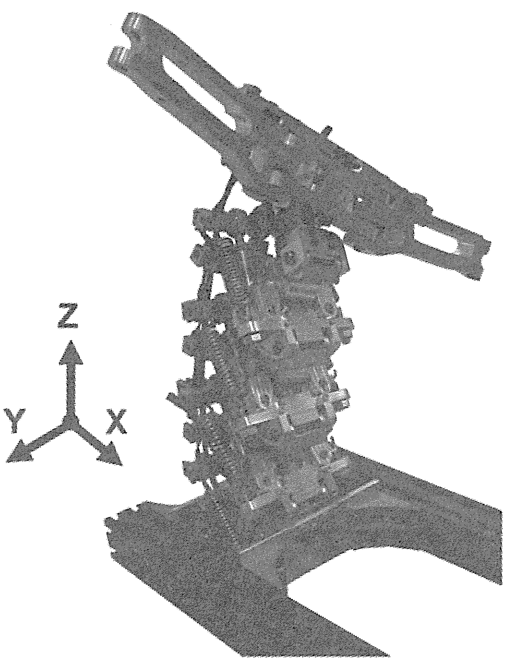


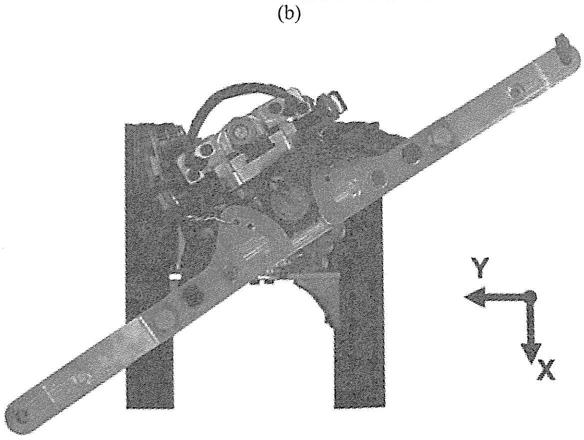
Fig. 2. CAD drawing of the actual vertebras (top) and links (bottom). Joints are indicated as: front (A), middle (B) and rear (C); the number indicates the vertebra to which they belong. These indications are as in Fig. 1b. The lower attachments of the springs are indicated by S, one vertebra pulley by VP, and one double link pulley by LP. All pulleys are located right above each other.



(a)



(b)



(c)

Fig. 3. Exo-spine with attached base (black) for testing. It is shown in full forward bending and shoulder girdle abduction (a), side bending (b) and rotation (c), but any combination of these is possible. Coordinate frames correspond with those of Fig. 1 and 2.

of the wearer, irrespective of the amount of bending, side bending and rotation of the exo-spine or abduction of the shoulder blades, the assistive torques will be counteracting forces that result from pulling as well as the gravity forces of the load on HAL's arms and pull toward the neutral position. Pushing however can only be done in the straight position as the cables can not produce any forward bending forces.

As mentioned above, only control of the top is important, the position of each vertebra is not controlled. This, however, can also lead to buckling, and thus increased friction. Although each vertebra has only a small range of motion (ROM) and buckling is limited to about 10mm deflection of the center, without countermeasures the exo-spine would always be buckled. Springs are therefore attached at the sides to both counter buckling (calculated based on the maximum load and deflection) as well as balance the weight of HAL laterally. This way, buckling is still possible, but will happen only occasionally. The springs are attached at "S" in Fig. 2 and connect to a short cable that crosses pulleys "LP" and is fixed next to "VP".

As for user safety, this can be ensured by blocking the cables at a certain length. For extra safety a backup cable runs through the center of the exo-spine.

B. Control

Forces on the cables are generated using a motor located below the base vertebra. Using the hip-spine fDOF as a basis for the control, the torque control signals of the hip motors added together, M_{hip}, become the control input signal for the exo-spine. Although likely possible, using the back muscle (erector spinae) BES would only add to HAL's setup time.

During usage the cable length is known (from the pulley angle), but the positions of the carried loads are not. Moreover, there will be a certain friction that reduces the required cable force, F_{cable}, when the exo-spine bends down, and increase the force when bending up. In addition, measuring the generated moment on the exo-spine, M_{spine}, is not possible due to friction as well as unknown forces from interactions with the wearer's body. However, assuming that

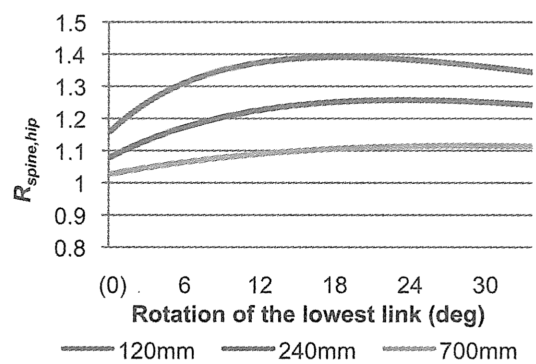


Fig. 4. Simulation results showing the ratio $R_{spine,hip}$ of the moment at the exo-spine to the moment at the hip versus the amount of bending of the exo-spine as measured by the rotation of the lowest link. This is shown for loads carried at different horizontal distances in front of the HAL's shoulder motor with the base of the exo-spine straight, and the shoulder girdle not abducted. As the controller can not measure the center of gravity of the load a certain distance must be assumed.

the friction is a linear function of M_{spine} and F_{cable}, it will be possible to do experiments to obtain two formulas, one for bending up and one for down, that give the ratio $R_{cable,spine}$, which is F_{cable} / M_{spine}, for a certain length of the cable below the base, L_{cable}.

To further calculate the required torque in the exo-spine, the ratio $R_{spine,hip}$, which is M_{spine} / M_{hip}, must be known. It is determined by the position of the center of gravity of the carried objects and HAL's arms with respect to the locations of the exo-spine's ICOR, which move as the wearer flexes (Fig 1b), and the center of rotation (COR) of the hip. That the center of gravity influences $R_{spine,hip}$ can be seen from the results of a SolidWorks Motion simulation comparing different horizontal distances from the load to the shoulder, as shown in Fig. 4. The further the load is held in front of the shoulders the lower $R_{spine,hip}$. A distance that is most likely found during usage must therefore be chosen.

With M_{hip} as the input signal the force F_{cable} becomes

$$F_{cable} = M_{spine} R_{spine,hip} R_{cable,spine}, \tag{1}$$

in which both ratios depend on L_{cable}, while $R_{cable,spine}$ also depends on whether the exo-spine bends up or down. It is possible to obtain this bending direction directly from the wearer's behavior. In addition, to save energy, when the exo-spine does not move the motor control should be in the "bending down" state, which gives a lower F_{cable} and combined with the friction will still be able to hold the load. When the wearer increases his hip BES for some short time while the exo-spine does not bend down he can be assumed to intend to bend up. As soon as there is no motion for some short time the wearer can be assumed to intend to hold still or bend down. A further compensation may be included to change $R_{spine,hip}$ according to the absolute angle of HAL's hip component, which is measured standard in each HAL suit.

Since feed-forward control is used and friction might change due to temperature or wear there will in addition be a "friction dial" that can be set by the user to let the controller assume a lower or higher friction. This will also be convenient for the user to set his own most comfortable setting based on his desired spine muscle activity. Since movements will be slow and not cyclic it is expected the feed-forward control will not result in unstable behavior.

IV. Experiments and Results

The exo-spine, yet without a motor for actuation, was attached to a base to examine the anticipated friction by measuring the forces during up and down movement, and its controllability by verifying the friction's linearity. For testing, and because of the high cable forces, this base was fixed to the forks of a manual forklift, while the cables were attached to a force sensor tight to the forklift base. The exo-spine was bent forward and stretched by lowering and lifting the forks, thereby releasing or pulling the cables. Motions of the exo-spine, obtained using a motion capture system, were recorded simultaneously with the force data.

In order to measure the cable forces at different loads the

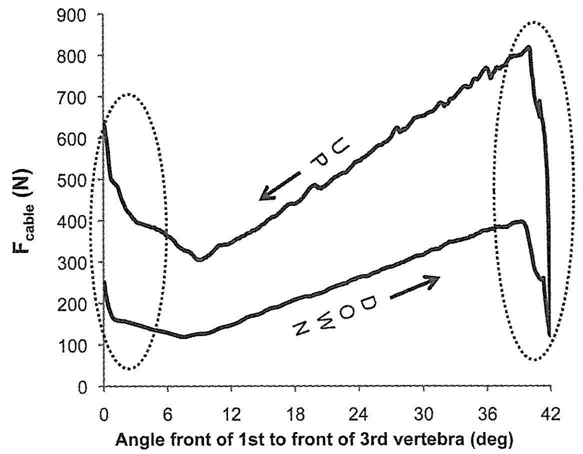


Fig. 5. Graph showing one up-down cycle of the cable forces, F_{cable}, vs. the angle between the 1st and 3rd vertebra and the vertical for a load of 11.2kg. In the left encircled area the neutral position was reached, in the right encircled part the center backup cable stretched.

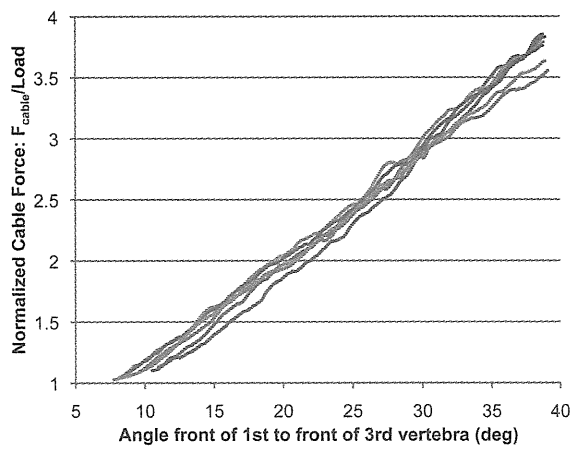


Fig. 6. Normalized cable forces, i.e. F_{cable} divided by the load, during downward bending of the exo-spine for 11.2, 14.3, and 18.0kg loads (twice per value). Important is not so much each individual line as is their closeness, implying linearity of the friction over different loads, as well as their spread, which might hinder effective control.

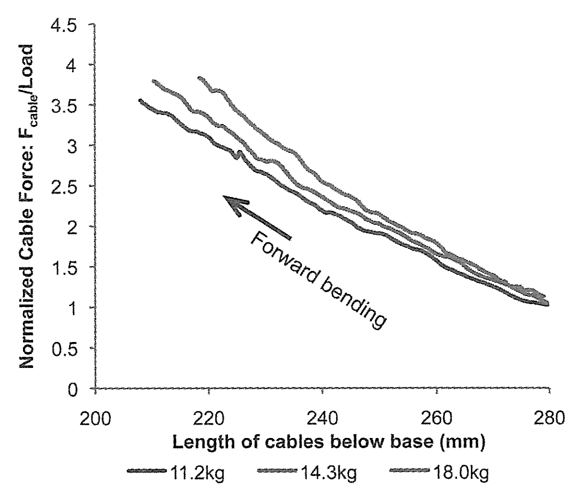


Fig. 7. Length of the cables below the base vs. the normalized cable forces. Increased loads show increased cable lengths due to stretching of the cables.

shoulder blades were locked at zero abduction and arms were attached for hanging weights. Weights were suspended at 37cm from the front of the shoulder blades. A few times, when the exo-spine buckled under loading the load needed to be released for the springs to pull the exo-spine straight again. No other adverse effects from buckling were found.

The ROM were measured to be 64mm abduction of the shoulder blades, 44deg forward bending (as in Fig. 3a), 33deg side bending (Fig. 3b), and 32deg rotation (Fig. 3c).

A. Friction

The exo-spine's friction behavior has been tested to verify the usability of the proposed control method. Fig. 5 shows the cable forces of one up-down cycle for a load of 11kg. At the left encircled part the exo-spine reached the extension limit; the right encircled part occurred when the center safety cable prevented further movement. Comparing the up and down going parts the effect of the friction can be seen.

Applying, e.g., twice as much load results in twice the values for F_{cable}. This can be confirmed from Fig. 6, which shows the normalized cable forces, i.e. F_{cable} divided by the load, during downward bending for 11.2, 14.3, and 18.0kg loads (twice per value) lying close together, indicating that the friction is a linear function of the load. This predictability of the friction is an important prerequisite for feed-forward control. On the other hand, the variability, as seen from the spread of the lines, shows it may not be possible to have accurate control of the assisting force.

In addition, although individual Dyneema fibers can not stretch it was found that, as each cable consists of 12 strands braided together, these strands become squeezed together under tension, which results in a small but significant lengthening of the cable that could distort L_{cable} measurements. This effect can be seen in Fig. 7, where increased loads show increased cable lengths.

V. Discussion

Even though the exo-spine has not yet been combined with HAL there are several indications of how it would perform. Its ROM, for example, can be compared with that of the human spine. Results of various studies are listed in [15] and comparing with these shows that the side bending and rotation ROM are around the average of those reported for the human spine. Although forward bending is about 10deg less, experiments will have to verify the full matching of exoskeleton and wearer before reaching conclusions.

Regarding the shape of the exo-spine, even though it is convex, its sharpest bending point is still at its base. For the human spine this is higher, around the lower thoracic spine. However, most of the exo-spine is not fixed to the wearer's spine and a small gap between the two just above the base can accommodate this difference. Similar effects will be seen for side bending and rotation, in which case differences can be accommodated by a slight S-shape of the exo-spine.

Although the friction is fairly substantial, the device will most not be moving and, owing to the friction, require less motor torque during those times. This also helps to save energy, probably more than offsetting the energy lost to the friction during lifting. As for the likely reduced accuracy of the feed-forward control due to the friction, it is quite likely the wearer will adapt his own back muscle force slightly and even unconsciously to maintain full balance.

From now on the exo-spine will be extended into a simplified full body exoskeleton and worn by several subjects to fully test its performance during lifting. When that is successful a specific control algorithm can be made and tested for SCI patients.

Overall the exo-spine is likely to provide a valuable improvement to the versatility of exoskeleton wearers and consequently to the usability of exoskeletons in general. Its basic structure as well as the usage of fDOF and focus on maximum effectiveness of a minimum amount of actuators could benefit the further design of both exoskeletons and rehabilitation devices such as back supports for SCI patients.

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