Patient preferences for reconstructive interventions of the upper limb in tetraplegia

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PATIENT PREFERENCES FOR RECONSTRUCTIVE INTERVENTIONS OF THE UPPER LIMB IN TETRAPLEGIA

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Chapter 1

Introduction and outline of thesis

Spinal Cord Injury

The first medical description of spinal cord injury (SCI) dates from 1550 BC. A papyrus manuscript found in Luxor, in Egypt, describes a male with a traumatic tetraplegia and his condition is referred to as “an ailment not to be treated.”[1] For many centuries this has been the case and the prognosis of a person with an SCI during the First World War was essentially the same as the ancient Egyptian. At the time of this war the mortality rate for SCI was 47- 65% during the first months, and 80% after three years.[2]

However, this situation changed during the Second World War. Special spinal units, devoted to the care of veterans with SCI, were established. The most well known unit is the National Spinal Injuries Centre in Aylesbury in the United Kingdom, which opened in February 1944 under the management of Sir Ludwig Guttmann, one of the founders of the International Medical Society of Paraplegia.[3] However, a little earlier, at the beginning of 1943 the Veterans Administration in the United States had also opened multidisciplinary centres for the care of veterans with SCI.[4] The aim of these specialised units was to provide comprehensive care and management for all aspects related to SCI. Active treatment of the physical consequences of an SCI, the prevention and treatment of primary and secondary complications, and the availability of antibiotics dramatically increased the prognosis of subjects with SCI.[5] In addition to dealing with the physical consequences of SCI, intensive physical, social and vocational rehabilitation is provided for individuals with SCI in order to keep them as independent as possible in the activities of daily living (ADL) and maintain participation in social activities. Providing this comprehensive treatment in specialised centres is the gold standard for the treatment of SCI, and has proven to reduce morbidity and mortality and to lead to better functional outcomes in subjects with SCI.[6-8]

The functional abilities of subjects with SCI are closely related to the level and extent of the spinal lesion.[9-11] Especially the motor level of the lesion is a good predictor of possible functional capacity.[12] In general, subjects with paraplegia and a low cervical (TH8) motor level of SCI can be fully independent in ADL. Subjects with a C7 lesion need some assistance, but can also perform many ADL activities independently. However, subjects with lesions above C7 will not become ADL independent, and do need assistance; the level of assistance will depend on the level of injury. Obviously, complications such as severe spasticity and contractures have a negative influence on potential levels of functional capabilities.

Subjects with an SCI suffer from many health problems such as pain, spasticity, pressure sores, urinary tract infections, etc.[13,14] However, despite these health problems, the satisfaction with life as a whole of subjects with SCI living in the community does not differ significantly from the life satisfaction of a population group, as demonstrated by Post et al.[15] The results of studies carried out by Post et al [14,15] and Francescini [16] showed that in SCI the levels of social and psychological functioning and the degree of autonomy are more important predictors of life satisfaction and quality of life than the seriousness of the injury. However, these studies also showed that subjects with tetraplegia, related to impairment of the upper extremities (UE), are less satisfied with self-care ability and also have an inferior degree of autonomy, which has a negative impact on satisfaction and quality of life. In this respect, treatment of the UE in subjects with a cervical SCI is of utmost importance.

Upper Extremity treatment

Thorough and repeated physical examination of subjects with SCI during the first weeks after the injury, especially those with complete injuries, makes it possible to predict motor recovery below the lesion level, and therewith their potential functional capabilities after rehabilitation.[17] Treatment of the UE should be directed at optimal functioning and functionality of the UE in the current situation, as well as the subjects potential future status. Therapy for the UE of subjects with tetraplegia comprises three stages: the acute stage, the sub-acute stage and the reconstructive stage.[18] The aim of therapy in the acute stage and the sub-acute stage is, respectively, to avoid complications, to achieve the best possible level of UE function within the constraints of neurological deficit, and to create optimal possibilities for further therapy in the reconstructive stage. During these two initial stages the corner stone of the therapy is intensive occupational therapy and physiotherapy and also several types of splints.[19,20] However, very little quantitative data about the effect of these measures on the development of UE function, functionality and complications is available in the literature.[21] Furthermore, uniformity between the various treatment centres in their therapeutic approach and assessment is difficult to achieve,[20] for example with regard to the necessity of tenodesis splints to shorten the finger and thumb flexors to improve a tenodesis grip during active wrist extension, [22-25] and the effectiveness of electrotherapy.[26-29]

In the third (reconstructive) stage, when no further neurological or functional improvement can be expected reconstructive interventions can be considered for certain carefully selected subjects with tetraplegia. Although the commonly accepted policy is not to consider these interventions until one year post injury, earlier application in well defined cases has recently been discussed.[30] The aim is to improve the UE function and, more importantly, the UE skills of subjects with tetraplegia. These interventions consist of one or more operations in which a combination of tenodesis, tendon transfers, stabilisation of joints, and/or implantation of Functional Electro Stimulation devices (FES) is carried out to achieve active elbow extension and/or improved lateral and palmar grasp. With FES, paralysed muscles are stimulated to a contraction, which is the function needed for instance to provide grasp. The choice of interventions depends on the actual status of the upper limb according to The International Classification for Surgery of the Upper Limb in Tetraplegia.[31]
An excellent historic overview of the development of reconstructive surgery until 1978, including the contribution of many pioneers in this field, is given by Moberg in his influential monograph about surgical rehabilitation of the UE in tetraplegia.[32] In 1978 the first international conference on this subject was held in Edinburgh,[33] and since then interest in surgical rehabilitation of the UE in tetraplegia has grown considerably. So far, eight conferences, the last of which was held Christchurch in 2004, have been attended by a growing number of participants. An increasing number of papers on surgical reconstruction of the tetraplegic arm have been published, and some excellent overviews and a recently published book provide a state of the art description of this therapy.[34-39] The development of the various FES techniques has been described by Triolo et al.[40,41] Only one system (the Freehand System™), has been used in a number of centres over the world on a relatively wider scale. This technique is usually combined with “conventional” surgery to achieve optimal results.[42] The results of a multi centre study are reported by Peckham et al.[43]

Reconstructive intervention of the UE in tetraplegia, with or without FES implants, is a very intensive therapy which requires a lot of motivation and determination from the individuals who are receiving this treatment. A series of operations is usually necessary, followed by immobilisation of the operated arm in a cast. After removal of the cast the arm is splinted, and an intensive therapy programme is started, in which the newly acquired functions are gradually trained to full usage. Before starting with the therapy the subjects must be well informed, and be aware of the intensity of the treatment and possible outcomes, and together with the treatment team the subjects formulate the treatment goals and planning. Other medical or social complications or problems should be dealt with before embarking on surgical UE rehabilitation, so that full attention can be paid to this treatment.

Rationale for thesis

In general, the results reported in the literature are good, although some critical remarks have been made about the methodology used in the studies and some authors mention that reconstructive UE interventions in subjects with tetraplegia are still controversial.[44,45] Most of the subjects who have had the interventions are satisfied with the results.[46,47] Moberg indicates that approximately 60% of the population with tetraplegia could benefit from reconstructive surgery, and Gorman deduced that approximately 10% of this population might be suitable candidates for a Freehand System.[48,49]

Related to the fact that, due to the impairment of the UE, subjects with tetraplegia are less satisfied with their self-care ability, and also have as an inferior degree of autonomy, one may assume that the tetraplegic population has a high degree of interest in reconstructive interventions of the UE. In this context the Hanson and Franklin study[50] is regularly cited in articles about surgical rehabilitation of the UE in tetraplegia. Their study focussed on 74 tetraplegic men with functional complete injuries (distribution of SCI levels was not described) from two Veteran Administration SCI centres. Their mean age was 37 years, and the time since injury varied from less than one month to over 20 years. The subjects were shown four cards with the captions: normal use of legs, normal control of bladder and bowel, normal feeling and use of sexual organs, and normal use of hands. They were asked to rank the items in order of importance on a scale ranging from 1 to 4. A total of 75.7 % gave the highest priority to return of UE function.

However, in actual clinical practice the interest in reconstructive interventions is not as high as might be expected in the treatment team, and many subjects who are excellent candidates for the procedure do not wish to undergo the treatment. This has raised questions about the actual importance of the treatment to improve UE function in subjects with tetraplegia, compared to the treatment of other impairments. Furthermore, questions have arisen concerning the decision-making process of subjects with tetraplegia with regard to reconstructive interventions of the UE, and especially what factors influence this decision. These questions form the basis of the present thesis.

Outline of thesis

Chapter 2 describes a survey among a large-scale population with a tetraplegic SCI. The aim was to investigate the relative importance of improvement of UE function in this population with long-lasting SCI, compared to the importance of improvement of other impairments. Compared to the Hanson and Franklin study the present survey did not ask the subjects to rank the impairments. Furthermore, the study sample was much larger than that investigated by Hanson and Franklin.

Chapter 3 describes the application of a surface FES system to improve hand function (Handmaster^{TM}) in a case series of 10 subjects with tetraplegia. This system is non-invasive and the application is less intense than reconstructive surgery and/or the implant of a FES system. The goal was to investigate whether UE skills improved with this system and to observe what factors determined the practical use of the system in daily life.

Chapter 4 describes an experiment with a choice-based method to establish the preferences of subjects with tetraplegia for improvement of impairments. Previous surveys were unconditional studies, which give a general impression about the impact of impairments and the (relative) importance of improvement in various impairments, but they can not be used to estimate the actual choice of subjects whether or not to undergo therapy aimed at improvement of impairments. In real life, choices are made between alternatives. For instance, choosing for therapy means choosing for procedures with a certain amount of discomfort and risk, but with the expectation of improvement in function, versus choosing not to undergo such procedures with the accompanying discomfort and to leave the situation unchanged. In order to investigate choices for therapy, choice-based preference elicitation methods, in which subjects are asked to make a choice between alternatives, are the gold standard.[51,52] This chapter describes a study based on such a method, namely the Time Trade Off method, to investigate the effects of improvement in the tetraplegic condition and improvement in separate impairments on the way in which subjects with tetraplegia valuate their health status.

Chapter 5 describes a study of the influence of treatment characteristics on the choice for reconstructive interventions of the UE in subjects with tetraplegia. Treatment procedures are complicated, and include various components such as the operation, the time spent in a cast, the hospitalisation period, etc. The effect of each element on the decision to undergo therapy is unknown. Multi Criteria Decision Analysis Techniques (MCDA) have been developed to study the effect of various elements on the decision-making.[53,54] In the study described in this chapter an MCDA technique is used to sub-divide reconstructive treatment of the UE in subjects with tetraplegia into the various components or treatment characteristics, and to investigate the effect of each characteristic on the choice for therapy. The method used was Conjoint Analysis, which has its origin in economic-market research to determine the preferences of customers for services or goods. This method is becoming increasingly popular in health research.

Chapter 6 deals with the perspective of the treatment team with regard to reconstructive interventions. In the previous studies, described in Chapter 2-5, the perspective of subjects with tetraplegia was the focus of attention and these subjects are advised and treated by multidisciplinary teams. Although the members of these teams have to work closely together, and are very coordinated, they all have their own experience, knowledge and opinions about the application of therapy. This not only has an implicit effect on the opinions and advice of the team as a whole, but also on the individual advice that team members give to their patients. It is important to be aware of this situation, and in the case of complex therapies the opinions of the team as well as the individual opinions with regard to the application of therapy should be made explicit. In the study described in this chapter another MCDA technique, the Analytic Hierarchy Process, was used to investigate the importance that an experienced tetraplegic UE treatment team attaches to various treatment characteristics, to compare two different treatment approaches to a specific clinical problem, and to compare the weighting of treatment characteristics by the treatment team with the weighting of these characteristics by a group of subjects with tetraplegia.

Finally, Chapter 7 discusses the methodological aspects and the clinical implications of the results of the various studies.

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Chapter 2

Survey of the needs of patients with spinal cord injury: impact and priority for improvement of hand function in tetraplegics

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Spinal Cord 2004; 42: 244-49.

Abstract

Objective: To investigate the impact of upper extremity deficit in subjects with tetraplegia.

Setting: The United Kingdom and the Netherlands.

Study design: Survey amongst the members of the Dutch and UK Spinal Cord Injury (SCI) Associations.

Main outcome parameter: Indication of expected improvement in quality of life (QOL) on a 5-point scale in relation to improvement in hand function and 7 other SCI-related impairments.

Results: 565 subjects with tetraplegia returned the questionnaire (overall response of 42%). Results in the Dutch and the UK group were comparable. A total of 77% of the tetraplegics expected an important or very important improvement in QOL if their hand function improved. This is comparable to their expectations with regard to improvement in bladder and bowel function. All other items were scored lower.

Conclusion: This is the first study in which the impact of upper extremity impairment has been assessed in a large sample of tetraplegic subjects and compared to other SCI-related impairments that have a major impact on the life of subjects with SCI. The present study indicates a high impact as well as a high priority for improvement in hand function in tetraplegics.

Introduction

Patients with spinal cord injury (SCI) above level Th1 suffer from impairments of the upper extremities.

The level and the extent of the lesion have great impact on the level of independence of the patient.[1,2.]

In this respect, therapy of the upper extremities in tetraplegics is of paramount importance. According to Murphy,[3] this therapy can be divided in three phases, the acute the sub-acute and the reconstructive phase. The aim in the first two phases (together referred to as the initial phase) is to prevent complications, to achieve optimal functioning within the limits of the neurological deficit and to create optimal conditions for the reconstructive phase.[4.5,6,7] In the latter phase, various options for surgical and functional electrical stimulation (FES) are available to improve positioning and stabilisation of the arm as well as key and palmar grasp function.[8,9,10,11,12.] Implanted FES devices are usually combined with augmentative and substitutional reconstructive surgery.[13]

According to Moberg, over 60% of the tetraplegic population could benefit from reconstructive surgery.[14] Gorman deduced that 11% of the tetraplegic population could be candidates for an implanted FES device (Freehand system).[15] Reconstructive surgery is widely advocated, and a number of papers that have been published describe its technical aspects and functional benefits. However, the benefits have not been clarified with good quality randomised clinical trials.[16] In a recent paper, Peckham et al. described the results of the Freehand system in a study of 51 subjects with C5 and C6 lesions with a follow-up of at least 3 years.[12] Compared to non-use of the system by these subjects pinch force, grasp abilities and independence increased significantly and user satisfaction was high.

Although the number of treatment options has increased in recent decades, clinical practice has shown that suitable candidates for reconstructive surgery or FES interventions often do not accept the treatment that is offered.

This led to debate about the importance of improvement in arm and hand function for the tetraplegic patient, compared to the other needs that they experience. Need assessment is gaining increasing interest as an important instrument in the development of treatment modalities and services. With regard to health care, needs are defined as the ability to benefit in some way from health care.[17] This depends on the number of people affected and the effectiveness of the available services. In addition to health-care needs, other categories of needs can be distinguished and could be taken into account in the assessment of needs, such as personal and social care, accommodation, finance, education, employment and leisure.

Two studies were identified in which impairment of the upper extremities in patients with tetraplegia was assessed in terms of the importance of treatment or needs to be addressed. In 1976 Hanson and Franklin studied the importance of loss of sexual function, compared to 3 other impairments in patients with spinal cord injury.[18] They included 74 tetraplegic men from two Veteran Administration SCI centres with functional complete injuries (distribution of SCI levels was not described). Their mean age was 37 years, and the time since injury varied from less than one month to over 20 years. The subjects were shown cards on which was written: normal use of legs, normal control of bladder and bowel, normal feeling and use of sexual organs and normal use of hands. The subjects were asked to rank the items in terms of importance on a scale ranging from 1 to 4. Of these subjects 75.7 % gave the highest priority to upper extremity function. The mean scores were 1.31 for improvement in hand function improvement, 2.50 for improvement in bladder and bowel function, 2.65 for use of legs and 3.54 for improvement in sexual function. This study is cited when the importance of hand function and reconstructive surgery for tetraplegics is discussed.[19,20] Ranking is a valuable method of assessment but it does not provide information about the relative importance of improvement in hand function, compared to improvement in the other items. In contrast other studies, in which upper extremity function was not included, reported high ratings for these impairments (e.g. bladder and bowel function, inability to walk and sexual dysfunction) in relation to the perceived difficulty of dealing with the consequences of SCI.[21] Unfortunately, their study population was relatively small, the subjects were recruited from two centres, and their needs were not assessed per level of lesion.

Cox et al. described the need for an outreach service for people with SCI living in the community in Queensland, Australia.[22] In this study, 54 subjects who were representative of the SCI population in Queensland were asked to rate the current level of need for 29 different items on a 5-point scale (no need, minimal need, some need, high need and very high need). Their results showed that only 17% indicated some need, high need or very high need for hand function/splinting therapy. Sixteen items had higher scores, 4 of which addressed physical impairments (physical changes, spasm, pain and sexuality). This study addressed a large number of topics, covering all the categories of needs mentioned by Kersten et al.[17] The results indicate, in contrast to those reported by Hanson and Franklin[18], a lower importance or less need for improvement of hand function. However, only 54 subjects were included in the study, 30 were tetraplegics whose data were not analysed separately.

Although a number of studies have reported on the impact of SCI on the lives of individuals (see reference 1-12 of the study carried out by Cox et al [22]), information about the impact of hand function deficit in individuals with tetraplegia is sparse. For this reason the present study was carried out, and the aim was to include a large sample of tetraplegic subjects for a nation wide survey in two countries. The importance of improvement in hand function, compared to seven other SCI-related impairments was investigated for the entire sample, as well as for separate levels of lesion.

Method

Survey design

In the present study, use was made of the database of a survey that was carried out as a part of the EU project Clinical Rehabilitation Using Electrical Stimulation Via Telematics, (CREST).[23]

The aim of the CREST project was to develop an FES system for incomplete paraplegics with marginal walking abilities. As part of the CREST project, a questionnaire was developed to assess the mobility needs in the target population for the CREST system. In addition to providing data on the mobility needs of SCI subjects with marginal walking abilities, the results of the survey also provided valuable information about other SCI-related problems, and these were used in the present study.

The CREST questionnaire was comprised of four sections, two of which were used in the present study (sections A and D). Section A contained questions about the respondent (e.g. age, gender, time since injury) and questions directed at classification of the level of lesion (e.g. paraplegia or tetraplegia, involvement of upper extremities, level of lesion, movement and/or sensation below the level of lesion). Section D addressed the needs and expectations of the subjects with regard to various aspects of SCI. The first question in this section focussed on coping with various impairments. The subjects were asked to indicate how well they felt they could cope with six impairments on a 5-point Likert scale. In the second question the subjects were asked to indicate the importance of a variety of impairments and disabilities in terms of improvement in quality of life (QOL) on a 5-point scale. See Table 1 for detailed information about section D.

Sample and execution of survey

The questionnaire was distributed among the SCI populations in the Netherlands and the United Kingdom via the SCI associations. All registered members were contacted by means of a letter explaining the purpose of the study, and enclosing the questionnaire and a pre paid reply envelope to maximise response rate. No reminders were sent.

Data analysis

The percentages of paraplegic and tetraplegic subjects in the Dutch and UK groups were calculated by combining the answers to the questions in section A about a paraplegia or tetraplegia, level of lesion and the involvement of the upper extremities. The subjects were defined as paraplegic if they stated that they were paraplegic and also gave a negative reply to the question about impairment of the upper extremities. The subjects were defined as tetraplegic if their answers concerning two or three of the following items were positive: tetraplegia, a cervical level of lesion and impairment of the upper extremities.

First the Dutch and the UK paraplegic and tetraplegic sub-groups were analysed. An impairment was considered to be important with regard to QOL if the subjects rating was either important or very important for the specific impairment in question 2-(Table 1). The percentages of subjects with these ratings was calculated for the Dutch and the UK paraplegic and tetraplegic sub-group separately.

Subsequently the scores per level of lesion were analysed for the items that were also investigated earlier by Hanson and Franklin[18], i.e. hand function, management of bladder and bowel function, feeling and function of sexual organs, and use of legs. In the CREST survey, 14 different standing and walking qualities were assessed. In the present study the standing and walking item with the highest score in the tetraplegic group was included, i.e. improvement in standing. The percentage of subjects per level of lesion who indicated a (very) important improvement in QOL in relation to improvement in the impairments was calculated.

For all percentages, 95% confidence intervals were determined.

Table 1 Topics addressed in section D of the questionnaire.

Section D question 1. How well do you think you are able to cope with the items listed below: Very well – well – adequately – poorly – very poorly	*Section D question 2.* In terms of quality of life, how important would improvement of the following items be for you: Very important - important - moderately important - not very important - unnecessary
Bowel management	Bowel management
Bladder management	Bladder management
Sexual function	Sexual function
Management of spasm	Management of spasm
Prevention of pressure sores	Prevention of pressure sores
Management of pain	Management of pain
	Hand function
	Standing time

Question 2 contained 13 other items concerning standing and walking related to the objectives of the project: Clinical Rehabilitation Using Electrical Stimulation via Telematics (CREST). These topics are not specified, as they are not of interest in the present study.

Results

The overall response was 42%; 426 of the 700 Dutch questionnaires (response of 61%) and 1122 of the 4800 UK questionnaires (response of 23%) were returned.

In 23 subjects in the Dutch group and in 50 subjects in the UK group it was not possible to determine the level of the lesion, and the data from these questionnaires were therefore not included in the analysis.

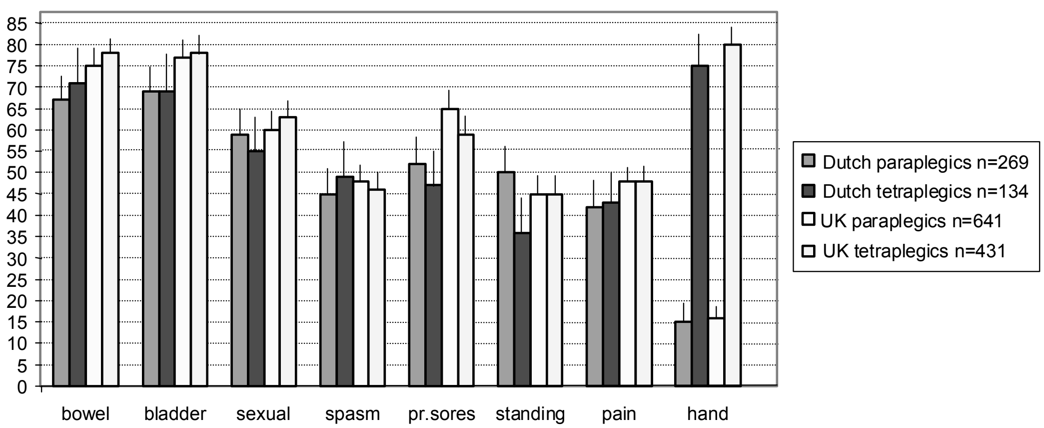
The demographic data for this sample of the SCI population is presented in Table 2.

Table 2 Population of CREST survey, divided into Dutch and UK populations

	Number	Female	Male	Mean time since injury (years)	Mean age (years)
Dutch-Paraplegics	269	98 (36%)	171 (64%)	12.2 (SD 9.9)	45 (SD14)
Dutch-Tetraplegics	134	42 (31%)	92 (69%)	13.9 (SD10.4)	43 (SD 13)
UK-Paraplegics	641	206 (32%)	435 (68%)	15.9 (SD12.2)	42.1 (SD 14)
UK-Tetraplegics	431	109 (25%)	322 (75%)	15.8 (SD 11)	43.1 (SD 11)

Figure 1 show for the Dutch and UK paraplegic and tetraplegic groups, the percentage of subjects who expected an important or very important improvement in QOL related to a possible improvement in different SCI-related impairments and disabilities.

Figure 1

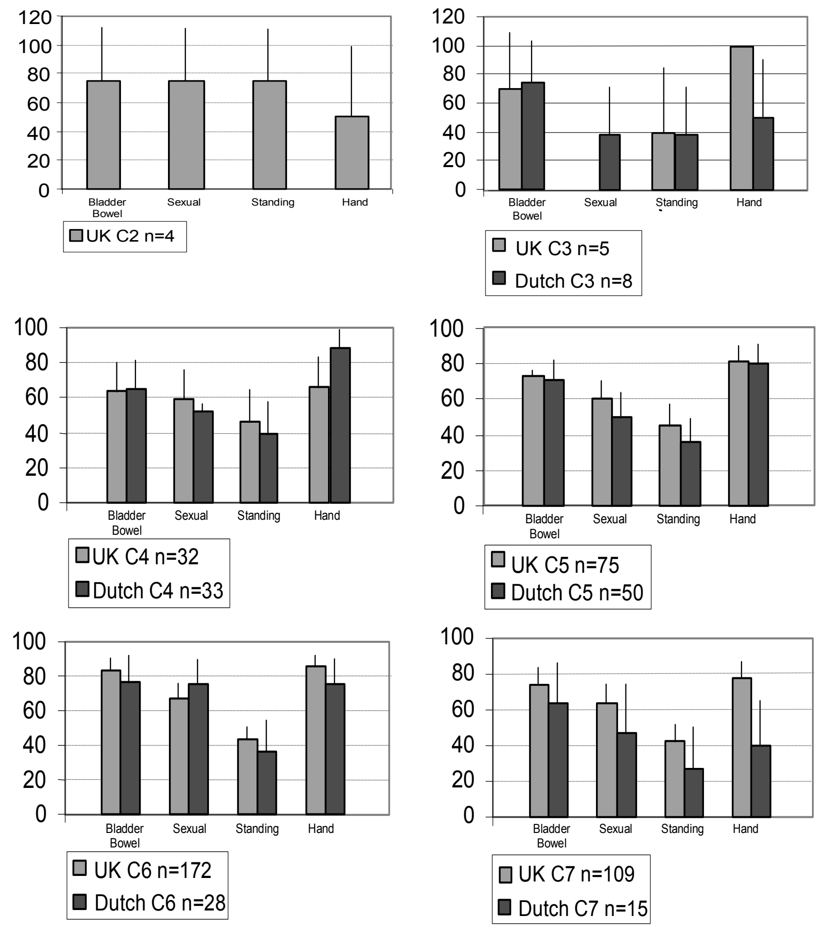


Y-axis shows the percentage and 95% confidence intervals of subjects in the Dutch and UK paraplegic and tetraplegic sub-groups who expected an important or very important improvement in quality of life if the impairments on the X-axis improved.(e.g. 80% of the UK tetraplegics expected an important or very important improvement in quality of life if hand function improved).

In addition to a high rating for improvement in bowel and bladder management the tetraplegic population also indicated that the improvement in hand function was equally important.

The results per level of lesion are shown in Figure 2. Especially in the C4, C5 and C6 groups and the C7 UK group, the improvement in hand function is important for the subjects, and comparable to improvement in bladder and bowel function. In the other groups the number of subjects was too small to draw statistically valid conclusions (wide range of 95% confidence intervals).

Figure 2 Results per lesion level



Y-axis shows the percentage and 95% confidence intervals of subjects indicating a (very) important improvement in quality of life if the impairment on the X-axis improved.

Discussion

One of the most devastating aspects of an SCI at cervical level is the impairment of arm and hand function, and this has great impact on the level of independence. So far, only 2 studies on the impact of SCI-related impairments and the needs of SCI patients have included upper extremity dysfunction.[18,22] Limitations of these studies are the relatively small size of the study population, a small number of other impairments or disabilities that were assessed, and the absence of either separate analysis of tetraplegics or analysis per level of lesion. As treatment modalities have been developed in order to restore some function of the upper extremities, it is important that the impact of upper extremity deficit on the lives of tetraplegic subjects is quantified, and that an awareness of the needs of these patients is generated. This was therefore the objective of the present study.

Exact comparison of our data with epidemiological data on SCI is difficult, because there are great methodological differences between the various epidemiological studies. Furthermore, because patients do not always know the exact level of lesion or confuse the level of lesion with the level of the fractured vertebra, the results per level of lesion must be interpreted with this in mind. In general, the demographic data of the present study population and the distribution of the levels of lesion are comparable to those reported in various epidemiological studies.[24, 25] Given the large sample size, response rate and apparently representative percentage of tetraplegics in the present study, it is arguable that the sample covers the spectrum of cervical SCI. Cox et al.[22] claim that their study population is representative of the SCI population in Queensland. However, they studied only 30 tetraplegic patients who were not analysed separately. Hanson and Franklin[18] do not report on the representativeness of their sample, and they only recruited subjects from two centres.

The first impression is that our results are remarkably comparable to the results reported by Hanson and Franklin.[18] In their study, 75% of the tetraplegic subjects ranked improvement in hand function as most important out of four possibilities. In the present study, 75% of the Dutch tetraplegic population and 80% of the UK population of the CREST survey indicated that an important to very important improvement in the quality of their lives was related to an improvement in hand function.

Cox et al.[22] reported lower scores for hand function in relation to the scores for other physical impairments, compared to the present findings. However, exact comparison is compromised by the fact that the size of their study population was substantially smaller, and only 30 subjects were tetraplegic. Moreover, they did not analyse the tetraplegic subjects separately.

Cox et al.[22] also described the issues most commonly reported in the literature as having an impact on the quality of life of SCI patients: pain, spasticity, pressure sores, mobility impairments, bladder management, finances, transportation, equipment, accessible housing, sexual function and employment. All the physical aspects were also included in the present study and compared to hand function deficit.

In general, the outcomes in the Dutch and UK tetraplegic populations were comparable. In the scores per level of lesion there was a difference in the C3 group, the C4 group, and C7 group. The C4 group had a higher score for improvement in hand function in the Dutch group, compared with the UK group. The scores on the other items in the C4 group were comparable.

The scores in the Dutch C3 and C7 groups indicated a lower priority for improvement in hand function. Scope for improvement in hand function is limited by poor upper limb control in the very high level tetraplegics (C3 and higher). Lower level tetraplegics (C7 and below) can be fully ADL independent with limited hand function. However, this finding is not reflected in the UK data. The small number of subjects in the C3 groups and the Dutch C7 group make it impossible to draw statistically valid inferences from these data.

In summary, the present study indicates a high priority for improvement in hand function, compared to other impairments in tetraplegic subjects.

Reconstructive interventions may be of benefit to patients who fulfil specific criteria. However, it is clear that eligible patients do not always whish to have this treatment. The apparent poor uptake of reconstructive options for restoring upper limb function is beyond the scope of this study. In this respect some remarks can be made about the method used to assess preference, as well as the multidimensional aspects of the evaluation of health states and the utilisation of health care services.

Preferences for health outcomes can be established in several ways. In non choice based methods that are not based on choice i.e. those used in the present study as well as in the studies carried out by Hanson and Franklin[18] and Cox et al. [22] use is made of rating, ranking or visual analogue scales. The advantage of these methods is that they are relatively easy to use. However, there are some theoretical drawbacks. Ranking makes it difficult to compare the weight of preference for the various items, because there may be a very small, in fact clinically unimportant, difference between the items which is not revealed. This is illustrated by the fact that in contrast to the findings of Hanson and Franklin,[18] other studies have indicated that bowel and bladder dysfunction is one of the most disabling factors of SCI. In the present study, as well as in the study carried out by Cox et al.[22] the items were separately scored on a 5-point scale. By offering the subjects a list containing all the items there may have been some implicit ranking, but this remains uncertain. More importantly, a positive response has no negative consequences, which may result in positive answer bias. In methods to assess preference that involve no actual choice, no trade-off can be observed and exact comparison between the preferences assessed in this way is not possible. Therefore choice-based methods to assess preference valuation are more appropriate to obtain a theory-based preference weight, because these methods actually involve a choice in terms of a trade-off between various possibilities.[26,27,28,29] The valuation of health outcomes is complex because physical, psychological and social factors are involved, and the actual utilisation of health care depends on a great variety of factors[30]. Andersen describes a model that was used to assess the utilisation of health care services, in which environmental factors, population characteristics, health behaviour and outcomes all play a role.[31] In this respect, multi-criteria decision-analysis, taking all these factors into account, is needed to provide information about actual willingness to receive reconstructive interventions[26,28.].

Finally the main outcome parameter in the present study was the concept in improvement of quality of life (QOL) related to improvement in impairments. Although QOL is the primary aim of rehabilitative treatment, it is a very complex concept. The definition of QOL is multidimensional and in addition to health, many other aspects contribute to the QOL experienced by an individual, and should be taken into account in QOL assessment. Impairments are only one attribute of QOL, and are correlated less with QOL than level of activity and participation.[32,33,34] These aspects must be kept in mind when interpreting the results of the present study. A high percentage of subjects indicating improvement in QOL if a certain impairment could be improved is an indication of the burden imposed by that specific impairment. However, actual improvement or cure of the impairment does not necessary result an improvement in QOL.

Conclusion

The present study is the first study in which the impact of impairment in hand function has been assessed in a large sample of tetraplegic subjects. In addition, analysis was performed at the level of lesion and compared to other SCI-related impairments. This study is unique in its explicit assessment of the issues that are involved in living with consequences of SCI. The results of the present study indicate a high impact and a high priority for improvement in hand function in tetraplegics, comparable to that for bladder and bowel dysfunction, which is known to have great impact on the lives of SCI patients.

This study is a first step in investigating the patient's perspective with regard to the potential for reconstructive interventions. Further research is needed to illuminate the decision-making process in patients who are contemplating participation in such reconstructive interventions.

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Chapter 3

Use of the Ness-Handmaster^{TM} to restore hand function in tetraplegia: clinical experiences in 10 patients

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Abstract

Objective: To explore possible functional effects of the Handmaster in tetraplegia and to determine suitable patients for the system.

Patients: Patients were selected if they had a cervical spinal cord injury between C4 and C6, motor group 0-3. Important selection criteria were a stable clinical situation and the absence of other medical problems and complications.

Design: Ten patients were consecutively selected from the in- and outpatient department of a large rehabilitation hospital in the Netherlands. Each patient was fitted with a Handmaster by a qualified therapist and underwent muscle strength and functional training for at least two months.

Methods: Functional evaluation comprised the performance of a defined set of tasks and at least one additional task as selected by patients themselves. Tasks were performed both with and without the Handmaster. Finally, patients were asked for their opinion on actual Handmaster use as well as their willingness to future use.

Results: In 6 patients a stimulated grasp and release with either one or both grasp modes (key- and palmar pinch) of the Handmaster was possible. Four patients could perform the set of tasks using the Handmaster, while they were not able to do so without Handmaster. Eventually, one patient continued using the Handmaster during ADL at home.

Conclusion: Based on our clinical experiences we conclude that the Handmaster has a functional benefit in a limited group of patients with a C5 SCI motor group 0 and 1. Suitable patients should have sufficient shoulder and biceps function combined with absent or weak wrist extensors. Though functional use was the main reason for using the Handmaster, this case series showed that therapeutic use can also be considered.

Introduction

Patients with a spinal cord injury at level T1 and above suffer from sensori-motor deficits of their upper extremities, which impacts greatly on their level of independence. The initial therapy of the upper extremities in tetraplegia combines intensive functional training with use of orthoses. The therapy aims at preservation of joint mobility, optimal function of the innervated muscles and learning of compensatory movements. Orthoses, e.g. writing splints and adapted aids are used to obtain an increased level of independence given the impairment status of the patient.

When no more progression can be expected continuing this approach, augmentative therapeutic options can be considered. Much experience has been gained during the last few decades with reconstructive arm-hand surgery.[1,2,3,4] In patients with C6 lesions and motor group 3 and higher, according to the international classification of the upper limb in tetraplegia[5], there are usually "motors" available for tendon transfer in order to create active grasp function as well as elbow extension.

Unfortunately, surgical reconstruction of grasp function in patients with motor group 2 and 1 is more complicated and fewer options are possible. In cases of absent active muscle function below the elbow, a satisfying surgical reconstruction of grasp function is not possible.

An interesting method in these patients may be the use of functional electrical stimulation (FES). In the last decades several research groups have been working on the development of FES systems for the upper extremities.[6,7,8] At present, four FES systems for the restoration of grasp function of tetraplegic patients can be mentioned: the Bionic Glove,[9] the Fesmate,[10] the Freehand system[10] and the Handmaster[11].

The Bionic Glove (marketed as Tetron Glove by Neuromotion, Edmonton, Canada) is a surface FES system in which self adhesive surface electrodes placed over motor points of the muscles to be stimulated are connected with a fingerless glove on which a stimulator is mounted. Active wrist movements are detected by a wrist position sensor and result in stimulation of finger and thumb flexors and extensors. The system is developed to be used in patients with a C6-C7 spinal cord injury. The first multi centre trial, which concerned nine patients with SCI, with the bionic glove showed improvement of hand-grasp force in all nine patients and improvement in the performance of standardised handfunction tests in four patients [9].

The Fesmate (NEC Medical Systems, Tokyo, Japan) uses percutaneous indwelling electrodes in selected muscles connected to an external stimulator. Depending on the level of the spinal cord injury the stimulation is controlled by various types of switches activated by hand- mouth- or head activity. Some case reports are published about the successful use in tetraplegic patients[12].

A hybrid approach, reconstructive surgery combined with FES, is used in the Freehand system (NeuroControl, Cleveland, USA). FES is applied via implanted epimysial electrodes on selected muscles whereas the electrode leads are connected to a subcutaneous receiver/stimulator[13]. A range of surgical procedures may be undertaken to enhance the effects of FES in the Freehand system. Over 80 systems are implanted world wide and several clinical reports indicate good results with the system on the level of impairment- disability- and handicap reduction.[14,15,16,17.]

A different, but also hybrid, approach (i.e. splint and FES) is used in the Handmaster. The device is designed to be used in C5 tetraplegic patients as well as in hemiplegic (stroke) patients. So far, only three small conference contributions have been published on preliminary results of the Handmaster in tetraplegia.[18,19,20] The Handmaster was introduced in our rehabilitation hospital at the end of 1995 and in this paper we aim to describe the clinical findings in the first 10 SCI patients treated with the Handmaster. Description of the results is focused at the actual functional benefit and at determination of potentially suitable patients for the system.

Methods

THE HANDMASTER[21]

The splint and control box

The Handmaster (figure 1) contains an external control unit connected by a cable to a below elbow splint. The splint contains a body with a front spiral end and a wing which pivots about the body and can be opened by lifting a release handle.

Figure 1 The Handmaster^{TM}

Five surface electrodes are attached in the splint and correspond with the motorpoints of the flexor digitorum superficialis (FDS), extensor pollicis brevis (EPB), flexor pollicis longus (FPL), extensor digitorum communis (EDC) and thenar muscles. The stimulus parameters are: pulswidth range of 0.01-0.5 milliseconds which can be adjusted in ten intervals by the patient. The frequency is 18 hertz for functional modes and 36 hertz for muscle restrengthening mode. The maximum output of the stimulation unit is 60 milliamps and can be adjusted by the therapist.

Three exercise modes and two grasp modes can be selected on the control unit. The exercise modes provide repetitive stimulation of the muscles in order to improve strength and muscle condition. The functional modes provide a key- and palmar grasp stimulation pattern. After activation of the selected grasp via a trigger button on the control unit, a stimulation sequence is started in which the hand is opened via stimulation of the extensors. After a preset and adjustable delay, the flexors are subsequently stimulated in order to obtain the selected grasp. The stimulation of the flexors is maintained until a push on the trigger button activates the extensors in order to release the object. The stimulation of the extensors is stopped after a preset duration. The palmar grasp mode requires stimulation of the EDC and EPB for hand opening, followed by stimulation of the FDS, FPL and thenar muscles. The key mode requires stimulation of the EPB and FDS for acquisition, followed by stimulation of FDS, FPL and thenar muscles. The stimulation amplitude can be adjusted by the therapist while fitting the Handmaster.

The patient can increase or decrease the stimulation intensity by adjusting the pulse width on the control unit.

Fitting procedure

Excitability of the relevant muscles is confirmed prior to preparing a splint for the patient. Three splint sizes are available in which interchangeable wrist inserts with different sizes can be used in order to individually fit the splint. A so-called clinical unit, which is an open version of the basic frame of the splint, is used to determine the motor points of the relevant muscles (FDS, EDC and EPB). In the newer versions of the device NESS introduced a new fitting technique using different panels containing standard electrode configuration. The thenar electrode and the FPL electrode remain permanently in place. After determination of the localisation of the motorpoints the exact position of the electrodes can be copied in the Handmaster splint. Star springs are put into prepared holes of the splint in order to connect the electrodes with the stimulation circuit of the splint.

ASSESSMENT OF EXPERIENCES

Patients

Patients admitted to the in- and outpatient department of the spinal unit of the rehabilitation centre Het Roessingh with a stable spinal cord injury level C4-C6 and motor group 0 to 3 according to the International Classification of the Upper Limb in Tetraplegia were selected for treatment with the NESS Handmaster.

Patients were excluded if they had severe spasticity of the upper extremities, contractures of the elbow and shoulder that prevented positioning of the arm, skin defects and infection of the upper extremities, pacemaker implant or other implants which could be disturbed by the electrical field of the Handmaster, pregnancy, haemorragic diathesis, received handsurgery on the side to be fitted with the Handmaster, malignancy or other interfering medical problems. An informed consent was obtained from all patients and the project was approved by the local medical ethics committee.

Training

Following the fitting procedure the patient was instructed to use the exercise modes in order to improve strength and condition of the stimulated muscles. After an exercise period of two weeks the patients continued with a training period. The training period lasted from 6 to 12 weeks depending on functional progress being made. The training was stopped if patient and therapist did not expect any additional functional gain.

Functional Assessment

Functional performance was assessed using four tasks as selected by the rehabilitation staff to test the key and palmar grasp modes. Patients were free to use either the key or the palmar grasp mode to fullfill the tasks. These tasks were: pouring water from a can, opening a jar, opening a bottle and taking a video tape out and putting it into a video player. In addition the patients were asked to select at least one other task. Criteria for these tasks were the unability or great difficulty to perform the tasks independentely and the expectation to improve the performance with the Handmaster.

The performance of the tasks was recorded on video tape. The performance was judged by an experienced panel of a physiotherapist, an occupational therapist and a rehabilitation physician. The necessary objects for the tasks were put on a table in front of the patient. The patients sat in their wheelchairs in front of the table with the arm fitted with the Handmaster, switched off, placed on the arm rest of the wheelchair. The performance was considered successful if the apprehension of the object (starting the stimulation, proper positioning of the upper extremity and acquisition of the object with the selected grasp), the functional task itself (if required lifting of the object and carring out the nessessary manipulations to fullfill the task and the release of the object (after placing it back on the table in the starting position) could be done independently. If one of these aspects could not be done without assistance the performance was considered unsuccessful.

Finally subjective user information was collected by asking patients' opinion on actual Handmaster use as well as their willingness to future use.

Results

Fitting

Ten patients with a SCI level C4-C6 volunteered to participate in the pilot study. The relevant clinical data and the general results are listed in table 1.

In 3 patients the splint could not be fitted, either due to inability to stimulate the key muscles or to anthropometric (splint size was too small) problems. In the other seven patients the splint could be fitted properly.

Training

Two patients could obtain a proper palmar grasp and four patients a palmar as well as a key grasp. In one patient serious finger flexion contractures prevented opening of the hand. For this patient, the Handmaster was used as a therapeutic device to treat these contractures. At the end of the training period the contractures of the meta carpo phalangeal joints were reduced from 50 to 10 degrees, measured with a hand held goniometer. Prolonged use of the Handmaster as a training device appeared not possible due to the discharge of this particular patient and the practical problems of continuing in the trial on an out patient basis.

Compliance

One patient was not motivated to continue with the Handmaster training after the fitting procedure and another patient stopped training period after four weeks and was not motivated to undergo the evaluation. The other 4 patients completed the training period.

Side Effects

No medical or technical problems were encountered during the study.

Functional Results

The functional results are summarised in table 2. All 4 patients who completed the training period were able to perform several tasks with the Handmaster, while they were unable to do so without the Handmaster. A few of the selected tasks by the patients could be performed with other splints as well but the selection of these tasks by the patients indicated that they were not satisfied by nor had difficulty with the performance. Two patients were able to use the key- as well as the palmar grasp mode for functional tasks, while two patients were only able to use the palmar grasp because of inability to obtain a proper stimulated key grasp in one patient and pain during the key grip stimulation sequence in the the other patient.

Table 1 Relevant subject information and general results

Gender age	Fitted hand	Level of injury	TSI	Int. Class.	Hand status	Funct. training	Overall result
Male 21	Right	C6	1 yr	3-CU	1	Yes	Disliked rigid splint; received hand surgey
Male 29	Right	C6	6 yr	3-CU	1,3	Yes	Disliked rigid splint; received Freehand
Male 32	Right	C4 (ZPP C5);L:C6	1 yr	1-O	5,7	Yes	Improved shoulder function
Female 65	Left	C5 (ZPP C6);R:C6	½yr	1-O	1,2,4,6	No	Therapeutic use to reduce finger contractures
Male 33	Right	C6	2 yr	3-Cu	1	No	Fitting not possible
Male 41	Right	C6	1 yr	2-O	1,3	No	Muscles not excitable
Male 23	Left	C5	1 yr	1-O	2,3,4,6	Yes	Actual daily use combined with conventional splint
Female 20	Left	C4 (ZPP C6);R:C5	1 yr	1-O	2,3,4,7	No	Withdrawn during training period; improved shoulder function
Male 22	Left	C5	2 yr	1-O	2,3,4	No	Not motivated after fitting
Male 43	Right	C4 (ZPP C5);L:C5	3 yr	0-O	2,4,6	No	Muscles not excitable

Table includes information regarding the hand which was fitted with the Handmaster, the level of spinal cord injury (Z.P.P = zone of partial preservation),TSI: time since injury in years; Int Clas.: the international classification for surgery of the upper limb in tetraplegia. Actual hand status refers to the actual grasp function which patients had prior to fitting and the way it was achieved: 1=tenodesis grasp;2=eating splint;3=writing splint;4=typing splint;5=cock up splint;6=adapted cutlery or tools;7=O.B.apparatus.

Three of these patients were able to don and doff the splint independently and one of them indicated that he would use the system at home. With some difficulty we managed to get the Handmaster reimbursed by his health insurance company. After discharge from clinical rehabilitation he continued to use the device at home for several ADL activities such as brushing teeth, shaving and pouring coffee. Both other patients who could handle the splint independently had good wrist extension and both indicated a strong interference of this function with the rigid Handmaster splint. Eventually these 2 patients were selected for other therapies (tendon transfer and a Freehand FES system respectively). Finally the patient who could not don and doff the Handmaster independently experienced no additional benefit of the Handmaster because of this inability and the unsuccessful completion of the tasks he found important to achieve.

In two patients, shoulder movement before Handmaster training was only possible when assisted by a therapist or with a supportive apparatus. In both patients, shoulder movement could be performed unassisted after the training period, resulting in a better use of the arm with conventional splints. We believe that this improvement is a secondary benefit related to the extended training possibilities with the arm and hand using the Handmaster.

Discussion

This article describes our first clinical experiences with one FES system, the Handmaster, in a group of ten SCI patients with level C4-C6 and motor group 0 to 3. The number of patients who had functional gain appeared to be limited due to the heterogeneous population. The Handmaster is primarily designed for patients with C5 lesions and we also included C6 patients. In six patients we achieved a stimulated grasp. Positive results concerning handling objects with the grasp function provided by the Handmaster were found in four patients. One C5 patient decided to use the system on a daily basis at home during ADL. Though the Handmaster is initially designed to improve hand function in tetraplegia, it was found that three patients gained therapeutic benefits (improved muscle strength and reduction of finger contractures) from training with the Handmaster.
Whereas functional gain was the main treatment goal, actual use of the device during ADL by the patient was the most important outcome in the evaluation of the system.

Table 2. Functional task performance in four subjects

		Performance											
	Task	Subject 1			Subject 2			Subject 3			Subject 7		
		w/o	splint	hndm.	w/o	splint	hndm.	w/o	splint	hndm.	w/o	splint	hndm.
1.	pouring water from a can	-	-	+	-	-	+	-	-	-	-	-	+
2.	opening a jar	-	-	+	-	-	+	-	-	-	-	-	-
3.	opening a bottle	-	-	+	-	-	+	-	-	+	-	-	-
4.	putting a tape in a VC	-	-	-	-	-	+	-	-	+	-	-	-
5.	cutting meat	-	-	+	-	-	+						
6.	handling a hammer	-	-	-	-	-	+						
7.	putting on socks				-	-	+						
8.	writing				-	+	+				-	+	+
9.	handling a credit card				-	-	-						
10.	handling a zipper from coat				-	+	-						
11.	handling CD							-	-	-			
12.	bruching teeth							-	+	-	-	+	+
13.	drinking coffee without straw							-	-	-			
14.	dry shaving										-	-	+
15.	pouring coffee										-	-	+

Functional training was conducted in four patients. Tasks 1 - 4 were selected by professionals. Tasks 5 - 15 were selected by patients. W/O refers to performance of the task without any device; splint refers to performance with an orthosis; hndm. refers to performance with the Handmaster. A minus sign (-) indicates unsuccessful completion of the task, a plus sign (+) successful completion. No sign after tasks 5-15 indicates that the particular task was not selected by the patient and was not evaluated

In the clinical trials with the Handmaster reported by Florence, 20% of the C5 tetraplegics showed good grasp and release with the Handmaster and an additional 40% were possible candidates after correction of contractures and other problems[20].

The C5 patients using the Handmaster in the study by Florence developed functional grasp and release, independence in the use of the switches and independent ability to don and doff the device. Furthermore Florence reported the use of the stimulated grasps in ADL and various activities.

In our report six out of ten patients had a C5 level of SCI or partial innervation of C5. In four of these patients a stimulated grasp was possible, two of them showed improvement of functional handling of objects and one was able to don and doff the device independently and continued using it at home. Florence et al. did not report the actual number of patients using the Handmaster neither did they report about the environment where it was used (in hospital or at home).

Aito[19] described 16 patients with a C5-C6 lesion in whom the Handmaster was tested. Only six patients completed this study. The device was well accepted by these patients and almost all the functions tested with ADL scales and the Frenchay hand function test improved. Though comparability of the study population (e.g. level of lesion) could not be confirmed, these results are comparable to our findings: four out of ten patients completed the study and showed improvement of hand function with the Handmaster.

Conclusion

Our preliminary conclusions are that the Handmaster has a functional benefit for a limited group of C5 patients, motor group 0 and 1. In our case series, half of the patients fitted with the Handmaster actually started functional training and four completed this with improved performance of several tasks in a test situation in the rehabilitation centre. Only one C5 patient decided to continue the use of the Handmaster at home after the training period. However, the functional gains provided by the Handmaster were important for this patient as they reduced his dependency. This demonstrates the importance of the evaluation of the actual use of FES devices.

In regard to our patients, successful functional use of the Handmaster seems to depend on a number of factors. Stimulation of the muscles as well as fitting of the orthosis must be possible. Arm function, especially shoulder and elbow function, must be sufficient to stabilise and position the arm. Active wrist extension, however, can interfere with Handmaster use. Independent donning and doffing is important for actual use at home and depends on the function of the opposite arm which is also important for bimanual activities with the Handmaster. Furthermore the motivation of the patients is of paramount importance. This may reflect on the tasks the patients hope to achieve with the system. It is remarkable that the patient in our series who continued using the Handmaster at home succeeded only in one of the tasks defined by the rehabilitation professionals and in all four tasks defined by him. Besides functional use of the Handmaster therapeutic use in arm and hand function training programs can also be considered.

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Chapter 4

Choice - based evaluation for the improvement of upper extremity function compared to other impairments in tetraplegia

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Abstract

Objective: To assess preference for reconstructive treatment of upper extremities in tetraplegic subjects.

Design: Survey.

Setting: Two specialized spinal cord injury centers in the Netherlands.

Patients: A Consecutive sample of 47 individuals with tetraplegia in a stable condition.

Interventions: Not applicable.

Main outcome measure: The quality weight of five tetraplegic health states determined with the Time Trade Off technique and expressed as a single value (the "utility") on a scale between 0 (worst possible situation) and 1 (best possible situation).

Results: The response rate was 92 %. The utility of tetraplegia was 0.57 (SD 0.30). The utilities of tetraplegia without impairment in one of the following functions were: for sexuality 0.69 (SD 0.33), for standing/walking 0.69 (SD 0.33), for bladder and bowel function 0.63 (SD 0.31), and for upper extremity function 0.65 (SD 0.32). The differences between these utilities and the utility of tetraplegia were significant ($p < 0.05$). No significant differences were found between the utilities of the impairments. Improvement of a specific impairment contributes between 14 and 28% to the potential overall gain in the tetraplegic health state utility.

Conclusions: The combination of impairments determines the low utility of the tetraplegic health state. No priority for improvement of any one of the investigated impairments was found. This emphasizes the need for the meticulous selection of patients for treatment of specific conditions. Further research should aim to determine crucial factors in the decision making process of patients for specific interventions.

Introduction

A number of studies have reported on the relationship between the level of Spinal Cord Injury (SCI) and possible self-care and mobility.[1-8] Rehabilitation therapy aims at achieving optimal independence within the constraints of neurological deficit. In this respect, adequate therapy of the upper extremities in individuals with tetraplegia is very important. According to Murphy, therapy of the upper extremities can be divided into 3 phases: the acute phase, the sub - acute phase, and the reconstructive phase.[9] Reconstructive surgery or, more recently, the application of neuroprostheses, can be considered in select cases during the third phase.[10,11] The results of these procedures have been reported in a number of studies.[12-19] Moberg indicates that approximately 60% of the population with tetraplegia could benefit from reconstructive surgery. Gorman deduced that approximately 10% of this population might be suitable candidates for functional electrical stimulation (FES) implants.[20, 21] However, Harvey et al. report that the benefits of reconstructive surgery, although widely advocated, have still not been supported by good quality randomized clinical trials.[22] Moreover, Forner Cordero et al. stipulate that these interventions are still controversial.[23]

Clinical practice has shown that suitable patients for reconstructive upper extremity procedures often decide not to undergo these procedures. In this respect it is relevant to know how important improvement of upper extremity function is for individuals with tetraplegia. A study conducted by Hanson and Franklin, with 74 men with tetraplegia, found that 75% of the men ranked hand function first out of 4 impairments as the most important impairment they wanted improved.[24] Snoek et al. studied 564 individuals with tetraplegia and found that 75% indicated that improvement of hand function would be very important in terms of improving their quality of life[25]. The same percentages were found for improvement of bladder and bowel function. For five other major impairments studied, 40% to 60% of the study population indicated that improvement would be important in improving their quality of life. These studies indicate that upper extremity impairment has great impact on quality of life and is a high priority for improvement of this condition in individuals with tetraplegia.

Some methodological arguments can be raised against the way in which data were collected in both the Hanson and Franklin and Snoek et al. studies. The ranking method used in the study by Hanson and Franklin[24] revealed a true order, but the relative difference in weights between the impairments could have been either very small or very large. This could have important practical implications; because the order suggests that hand function was the most important impairment to be addressed, whereas all four may be almost equally important. The study carried out by Snoek et al.[25] did show the relative difference between the various impairments. However, the number and severity of problems could be over - estimated because the subjects expressed their desire to improve one specific impairment without comparison with other impairments.

In order to evaluate the importance of improvement of upper extremity function in individuals with tetraplegia precisely, a sophisticated method of preference elicitation is needed. Preference elicitation methods enable subjects to express their needs more realistically and with a relative weight. Methods that allow such analysis, e.g. the Standard Gamble (SG) technique and the Time Trade Off (TTO) technique, have been developed in the field of health economics. Because these methods are based on the principle of trading off possibilities, they are referred to as choice based preference elicitation methods, and are considered to be the gold standard in preference valuation.[26-28]

The SG method determines the quality weight of a present, impaired, health state by comparing a specific number of years in this health state to a gamble with a probability to live the same number of years in perfect health but a complementary probability of immediate death. The risk the subject is willing to take to obtain perfect health is then used to determine the quality weight of the present, impaired, health state. For example, if 10 years in the present situation are equal to a chance of 70% to obtain perfect health and 30% of immediate death, the quality weight of the present, impaired, health state is 0.7.

The TTO method determines the quality weight of a present, impaired, health state by comparing a specific number of years in this health state to the willingness to trade life time for a perfect health state. The amount of time a subject is willing to trade is then used to calculate the quality weight for the present health state. For example, if an individual is willing to trade 2 out of 10 years to obtain a perfect health state (10 years in the present health state are equal to 8 years in a perfect health state) the quality weight for the present health state is 0.8. The quality weights of health states determined with these methods are called health state utilities which can be defined as the level of subjective satisfaction that people associate with a particular outcome or health state. The utilities are expressed on a scale from 0 (worst imaginable state or death) to 1 (perfect health), and have cardinal measurement properties (For a detailed description of these techniques, as well as extensive methodological details see Johannesson et al., Dolan, and Torrance).[26,29,30] Recent publications have shown that the TTO measures people's utilities for health states better than the Standard Gamble[28]

The main objective of the present study was to determine the utility of the health state of individuals with tetraplegia and to compare this utility with the utility of a tetraplegic health state without impaired upper extremity function as well as three other major impairments respectively. The TTO method for determining health state utility was utilized in this study. The second objective was to evaluate the effect of subject characteristics as well as functional status on the preferences for upper extremity improvement.

Methods

Study Design

The study was a cross-sectional study, involving two SCI centers in the Netherlands. Both centers have an extensive hand function program, which includes traditional therapies and more invasive surgical therapies. The present study focussed on individuals with tetraplegia in a stable condition, who had an SCI for at least 2 years. After this period no further improvement in motor and functional recovery can be expected.[31] The subjects were included in the study in 2002. The discharge records of the centers were reviewed from December 1999 backwards in time, and the first 30 subjects who met the selection criteria were identified in each center. The selection criteria were that the subject was either a first admit or a re-admit, had been injured for at least 2 years, had or had not a history of reconstructive surgery of the upper extremity, had an SCI with a neurological level above T1, and had an ASIA impairment level A to D.[32] These selection criteria represent a heterogeneous group of individuals with tetraplegia. The criteria were chosen in order to be able to access the utility for the tetraplegic health state with and without impaired upper extremity function in a broad sample of individuals with tetraplegia. Those that agreed to participate were invited to visit the center and data were collected in one single session by an experienced SCI physician and trained therapists. The study was approved by the Medical Ethical Committee of both centers and all subjects gave their written informed consent.

Measures: determinants

The following general subject characteristics were recorded: age, gender, time since injury, marital status, and level of education. Perception of general health and quality of life were assessed on a 5-point scale: perfect, very good, good, reasonable, poor (1-5). Surgical procedures for the upper extremities and SCI - related complications of the upper extremities (e.g. spasm, pain, oedema and contractures) were also recorded.

Functional deficits can be measured according to the level of impairments of structure and function, the level of activity limitations and the level of restriction in social participation, as defined in the International Classification of Functioning, Disability and Health (ICF)[33]. Reaching or gripping represent the integration of strength, sensation, range of motion, etc., and therefore occur at the individual level rather than at the level of the organ system. For this reason, reaching and gripping are on the ICF level of activities. However, this level includes a broad range of activities, from basic activities such as grasping and moving objects to complex activities such as dressing or grooming. It is useful to make a distinction between basic activities and complex activities. Another influential model of rehabilitation outcomes has been developed by Nagi and has been discussed by Marino and Stineman in their review of functional assessment in SCI [34]. The concept of functional limitation in Nagi's disablement model is comparable to that of basic activities in the ICF.

In the present study, impairment was assessed by determining the motor level on both sides as well as impairment scores according to the guidelines of the American Spinal Injury Association (ASIA).[32] Upper extremity activities were assessed at the level of functional limitation with The Grasp Release Test (GRT). The GRT was designed to assess use of the Freehand system, but the developers mention limited use in other populations with tetraplegia.[35] Although neither psychometric nor normative data on the GRT are available it is the only hand function test that is specifically designed for individuals with tetraplegia.[36] The test was administered according to the instructions in the manual.[37] In the present study the total of the correct manipulations of six objects was calculated over three sessions with both hands.

Assessment at the level of activities was based on the Short form Quadriplegia Index of Function, which was developed because of difficulties that had been experienced in administering and scoring the Quadriplegic Index of Function (QIF).[38,39] The short form is significantly less redundant (6 versus 37 items), has a simplified scoring system and yield results comparable to the QIF.[40] The outcome of the short - form QIF is presented as the total score of the 6 items.

Outcome Measure

Utility scores for present tetraplegic health state, present tetraplegic health state without impaired upper extremity function, present tetraplegic health state without impaired bladder and bowel function, present tetraplegic health state without impaired sexual function, and tetraplegic health state without impaired standing and walking respectively were determined using the TTO technique. After a detailed explanation of the objectives of the study and the abstract nature of the study, the following situation was described to the subjects:

"Imagine you have one year to live. You have a choice between living this year in the present health state or you can take an imaginary drug that will cure a specific condition. However, the disadvantage of this imaginary drug is that you will only live for less than 1 year"

It was systematically assessed how many months the subjects were willing to trade for a cure of all their SCI - related health problems or a cure of only one of the following conditions: bowel and bladder dysfunction, paralysis resulting in walking dysfunction, sexual dysfunction and upper extremity dysfunction, in this order.

The health state utility of the tetraplegic condition was calculated, using the following formula:

$$U\ (\text{tetra}) = \frac{12-X}{12}$$

U (tetra) is the utility of tetraplegic health state; X is the number of months of the hypothetical life - year a subject is willing to trade to cure tetraplegia.

For example: if a subject indicated that he would not trade any time for improvement of the tetraplegia, the utility would be 12/12= 1. If this subject indicated that he would trade 4 months of the hypothetical year to cure the tetraplegia or expressed the opinion that this

situation was equal to living one year with the tetraplegia uncured (8 months cured condition equals 12 months in present condition) the utility would be 8/12= 0.66.
For the utility of the tetraplegic health state the end - points of the scale are defined as worst possible health state (tetraplegic condition) versus best (perfect health) possible health state. However, for the tetraplegic health states without the impairments the definition of the end - points of the scale are different, i.e. tetraplegic health state with the impairment and tetraplegic health state without the impairment. In order to compare the data on improvement of the impairments with the utility of the tetraplegic health state (U(tetra)) must be taken into account for the data found for the improvement of separate impairments.[41] The impairment-related data was transformed to the 0-1 scale (worst versus best possible health state) using the following formula:

$$U(\text{tetra-imp}) = \frac{12}{12-X} * U(\text{tetra})$$

U(tetra-imp) is the utility of the tetraplegic health state with the impairment cured; X is the number of months a subject is willing to trade for cure of the impairment.
For example: assume that a subject is willing to trade 3 months of the hypothetical life-year for improvement of upper extremity function. In the following equation, tetraplegia with the impairment is referred to as (Tetraplegia+imp) and tetraplegia with the impairment cured is referred to as (Tetraplegia-imp). For this subject: 9/12* (Tetraplegia-imp) = 12/12* (Tetraplegia+imp). This is equal to: (Tetraplegia-imp) = 12/9*(Tetraplegia+imp). Expressed as a utility, U(tetra-imp), the utility of the tetraplegic condition with cured upper extremity function is 12/9*U(tetra).

Data analysis

Differences between the utility of the tetraplegic health state and the utilities of the tetraplegic health state without each impairment were assessed with the Wilcoxon signed rank test. This test was also used to assess the differences between the utilities of the health states without the impairments. The following formula was used to calculate the contribution of improvement of a single impairment to the potential overall improvement in the tetraplegic health state:

$$\frac{U(\text{tetra-imp}) - U(\text{tetra})}{1 - U(\text{tetra})}$$

Spearman correlation coefficients were calculated between the utility of the tetraplegic health state without impaired upper extremity function and ASIA impairment level, short form QIF, GRT, quality of life (QOL), age, motor level, time since injury, general health, and marital and educational status. The Wilcoxon test was used to assess the differences in the utility of the tetraplegic health state without impaired upper extremity function between genders, subjects with and without hand surgery, and subjects with and without complications of the upper extremities. Multivariate regression analysis of the utility of the tetraplegic health state without impaired upper extremity function was performed to assess a model of determinants that could predict the utility for the tetraplegic health state without impaired upper extremity function.

Additionally two subgroups were defined and analyzed. The purpose was to investigate in an explorative way the effect of severely impaired upper extremity function with relatively less severe impaired function on the utility of the tetraplegic health state without impaired upper extremity function. The first subgroup contained subjects with motor complete lesions (e.g. ASIA A and B) at or above level C6. The second subgroup contained subjects with motor incomplete lesions and/or best motor level at C7 or below. Differences between the health states in the subgroups were assessed with the Wilcoxon test. Differences between the subgroups were determined with a Mann-Whitney-U test.

Finally Spearman correlation coefficients were calculated between the status of having a motor complete lesion at or above C6 and the utility of the tetraplegic health state without impaired upper extremity function, operation of the upper extremity, complications, general health state, QOL, marital status and educational level.

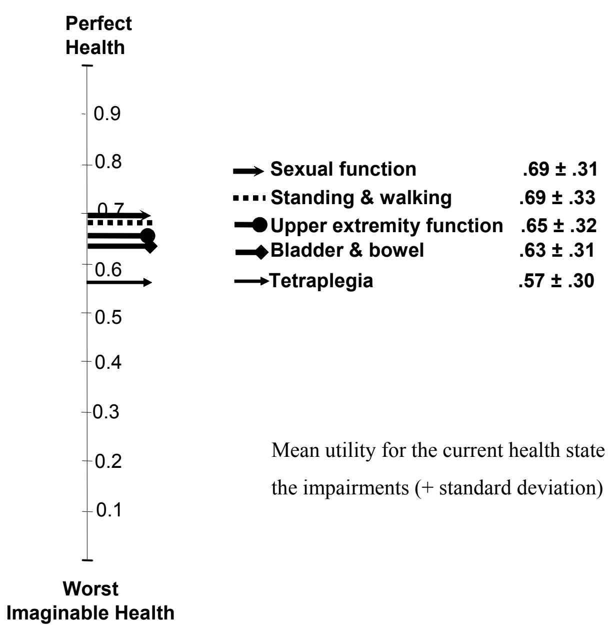
SPSS version 11.5 was used for the all the statistical analysis, and a p-level <0.05 was considered to be significant.

Results

Fifty-five out of 60 subjects were willing to participate in the study (response rate of 92%). Eight subjects who participated were excluded from analysis because of unreliable data due to inconsistent responses on the outcome measures. Table 1 shows the demographic and clinical characteristics of the remaining 47 subjects. Noticeable are the high percentages of subjects who had surgery (46%) and had complications of the upper extremity (45%). Distribution of ASIA impairment levels was: 44% ASIA A, 31 % ASIA B, 9% ASIA C and 16% ASIA D. Distribution of lesion levels of the right/left arm was: C3 2%/2%; C4 2%/6%; C5 19%/14%; C6 34%/39%; C7 24%/24%; C8 16%/9%; T1 3%/6%. The distribution of the lesion levels of the present study population was similar to demographic data reported in other studies.[42,43]

Figure 1 shows the mean utility of the current tetraplegic health state (0.52) and the utility of the tetraplegic health state without sexual dysfunction (0.69), without standing and walking dysfunction (0.69), without upper extremity dysfunction (0.65), and without bladder and bowel dysfunction (0.63). The Wilcoxon test showed a significant difference ($p<0.005$) between the utility of the tetraplegic health state and the utility of this health state with one of the impairments cured. No significant differences were found between the utility of tetraplegia without impaired hand function and the utility of tetraplegia with one of the other impairments cured.

Figure 1



Mean utility for the current health state (tetraplegia) and utilities for the tetraplegia without the impairments (+ standard deviation) for the study population.

Table 1 Characteristics of the study population and two sub-groups

	study population n=47	**BML ≤ C6 and motor-complete* n=23**	**BML≥ C7 and/or motor incomplete[†] n=24**	**Difference between the subgroups╝**
mean age	42 (sd═ 13)	35 (sd 8)	48 (sd14)	p=0.002
mean TSI[‡]	11 (sd 9)	10 (sd 5)	11 (sd11)	p=0.28
male	38 (81%)	20 (87%)	18 (75%)	p=0.30
female	9 (19%)	3 (13%)	6 (25 %)	p=0.014
operation[‖]	22 (46%)	15 (65%)	7 (29%)	p=0.18
complications[¶]	21 (45%)	8 (35%)	13 (54%)	p=0.00
mean BML[**]	6.5 (sd 1.1)	5.6 (sd 0.56)	7.4 (sd 0.97)	p=0.00
mean WML[††]	6.1 (sd 1.2)	5.5 (sd 0.67)	6.8 (sd 1.3)	p=0.00
mean GRT[‡‡]	371 (sd 259)	195 (sd 121)	548 (sd 240)	p=0.00
mean QIF[‖‖]	14.8 (sd 18.7)	9.9 (sd 6.9)	19 (sd 6.1)	p=0.00
mean general health[¶]	2.7 (sd 0.8)	2.8 (sd 0.8)	2.6 (sd 0.7)	p=0.271
mean QOL[¶]	2.8 (sd 0.7)	2.9 (sd 0.7)	2.8 (sd 0.7)	p=0.50

*: Sub-group with motor-complete lesions C6 and above (n=23); †: subgroup with motor-incomplete lesions and/or best motor level below C6 (n=24); ‡: Time since injury; ||: number of subjects who had reconstructive arm-hand surgery; ¶: number of subjects with complications of upper extremities; **: best motor level; ††worst motor level; ‡‡: grasp release test; ||||: quadriplegia index of functioning; ¶¶: mean general health score and mean quality of life score (1[perfect] – 5 [poor]); ═ standard deviation; ╝ difference between subgroups determined with Mann-Whitney test

The contributions of the improvement of one impairment to the potential overall improvement in health state were 14% for improvement of bladder and bowel function, 19% for improvement of hand function and 28% for improvement of standing and walking and sexual function.

Table 2 shows the potential determinants for the utility of the tetraplegic health state without impaired upper extremity function. Significant correlations were found for ASIA impairment level and QIF score. The Mann-Whitney test showed a significant difference between the operated and the non-operated subjects. However, multivariate regression analysis did not result in a significant model for the utility of tetraplegia without impaired upper extremity function.

The characteristics of both sub-groups are also presented in Table 1, and the utility of tetraplegia and the utility of tetraplegia without the impairments are shown in Figure 2. Table 1 shows that hand function and ADL function (GRT and QIF scores) are, as expected, significantly different in these two groups. Further these groups differed significantly in mean age, number of subjects with surgeries and best and worst motor level.

Figure 2 shows the difference between the utility of the tetraplegic health state and the utility of the tetraplegia without the impairments in both sub-groups.

In the sub-group of motor-complete subjects with lesions at or above C6, significant differences were found between the utility of tetraplegia and the utility of tetraplegia without the impairments ($p<0.02$) and between the utility of tetraplegia without impaired upper extremity function and tetraplegia without bladder and bowel dysfunction ($p<0.05$).

In the sub-group of subjects with motor incomplete lesions and /or lesions at C7 or below, a significant difference was only found between the utility of tetraplegia and the utility of tetraplegia without impaired standing and walking ($p<0.02$). In this sub-group no significant differences were found between the utility of tetraplegia without impaired upper extremity function and tetraplegia without one of the other impairments.

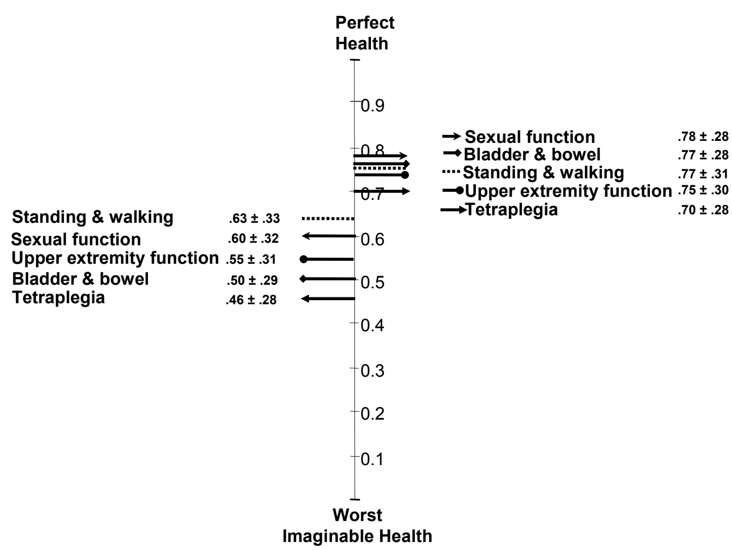
A significant difference in the utility of tetraplegia without impaired upper extremity function was found between the subgroups ($p<0.03$). Further the utility of tetraplegia ($p<0.008$) as well as the utility of tetraplegia without bladder and bowel dysfunction ($p<0.002$) and sexual dysfunction ($p<0.04$) differed significantly between the subgroups.

Table 2 Bi-variate relationships between utility of upper extremity function and the determinants

Determinant	**Spearman correlation coefficient**
ASIA impairment*	0.392; p=0.008
mean QIF score	0.313; p=0.03
mean GRT score	0.229; ns
quality of life	-0.091; ns
age	0.127; ns
best motor level	0.248; ns
worst motor level	0.200; ns
time since injury	-0.268; ns
general health	0.096; ns
marital status	-0.012; ns
educational level	-0.184; ns
	Mann -Whitney test
operation	p = 0.02
gender	p = 0.47
complications	p = 0.31

*: American Spinal Injuries Association Impairment Classification; ns: non significant; For other abbreviations see footnotes of table 1

Figure 2



The mean utility for the tetraplegic health state and the utilities for the tetraplegia without the impairments (+ standard deviation) in two sub-groups. On the left is the group with motor-complete lesions at or above C6 (n= 23). On the right the group with lesions below C6 and/or motor-incomplete lesions (n=24).

Having a motor complete lesion at or above C6 was significantly correlated with the utility of tetraplegia without impaired upper extremity function (correlation coefficient -0.376, $p<0.01$) and with reconstructive surgery (correlation coefficient -0.361, $p<0.01$). No significant correlations were found between motor complete lesions at or above C6 and complications, general health, QOL, marital status and educational status.

Discussion

The present study focused on the valuation of the present health state (tetraplegia), expressed as health state utility, by individuals with tetraplegia as well as their valuation of the tetraplegic health state without impairment of the upper extremities compared to the tetraplegia without three other major impairments respectively. The difference between the utility of the tetraplegic health state and the utility of the tetraplegic health state with an impairment cured indicated the preference for improvement of that specific impairment. The results showed that the health state of a subject with tetraplegia was determined by the combination of various impairments. Also, the utility of the tetraplegic condition (0.57) was low. On average, subjects were willing to trade 5.2 months of a hypothetically last life-year for a cure of the tetraplegic condition. A significant difference was found between the sub-group with high-motor complete tetraplegia (utility 0.46) and the subgroup with motor-incomplete or lower levels of tetraplegia (utility 0.70). However, even individuals with incomplete or lower level tetraplegia were willing to trade time (in the present study 3.6 months of the hypothetical year) to regain full health.

Although, levels of social and psychological functioning have been shown to be more important predictors of life satisfaction than the seriousness of the injury, the tetraplegic condition is related to lower satisfaction with self-care ability, as well as an inferior degree of autonomy.[44-46] These aspects may explain the low utility of the tetraplegic condition.

A significant difference was found between the utility of the tetraplegic condition and the utility of the tetraplegic condition with one of the impairments cured. This demonstrates that solving a major impairment is important for individuals with tetraplegia. However, cure of bladder and bowel function, or upper extremity function, or walking or sexual function, only contributes to 14-28% of the potential gain in utility. Many problems remain unchanged and the subjects were less willing to trade life time for cure of these impairments separately (between 1 and 1.8 months of the hypothetical year).

The specific focus of the present study was the impact of loss of upper extremity function and the effect of improvement of upper extremity function on the utility of the tetraplegic health state. The results of the present study did not indicate a higher preference for improvement of upper extremity function, compared to three other major impairments that were investigated. These results put the previously mentioned unconditional studies on the impact of upper extremity impairment and the importance of treatment of this condition in individuals with tetraplegia into perspective. The study by Hanson and Franklin[24] and the study carried out by Snoek et al.[25] indicated a considerable impact of upper extremity deficit on the lives of individuals with tetraplegia and a high preference for treatment of this condition compared to other impairments. The present study, however, demonstrated no significant preference for a tetraplegic health state without impaired upper extremity function compared to tetraplegia without three other impairments respectively.

The relationship between subject characteristics and the utility of tetraplegia without impaired upper extremity function was extensively assessed. In general, the significant higher utility of the tetraplegic health state without upper extremity impairment in the high-complete subgroup indicated a higher preference for improvement of upper extremity function in individuals with motor complete lesions at or above C6. This may be related to the lower level of ADL compared to the other subgroup (see the QIF scores). Also the utilities of the tetraplegic condition and the utilities of tetraplegia without bladder and bowel and sexual impairments were significantly higher in the high-complete subgroup. This indicates an overall higher preference for improvement of impairments among severely injured individuals. It may be that these individuals had not been able to adjust to their injury. However, we did not find a significant relationship between adaptation to injury (i.e. general health and QOL) and the utility of tetraplegia without upper extremity dysfunction.

Significant correlations were found between ASIA impairment levels and QIF scores and the utility of tetraplegia without upper extremity impairment. Furthermore, significant differences of this utility between subjects with and subjects without a history of reconstructive hand surgery were found. Since subjects with a history of reconstructive hand surgery had already invested in improvement of hand function, therefore, they may have been less willing to trade time for improvement of upper extremity function. This would result in a lower utility for the tetraplegic health state without upper extremity impairment. It is interesting and important to note that QIF scores as an indicator of functional activities were significantly correlated with the utility of tetraplegia without upper extremity impairment. However, all other determinants, which were investigated, showed no significant correlation or difference. Therefore, it was not possible to construct a multivariate regression model that predicted the utility of the tetraplegic health state without upper extremity impairment.

Based on the results of the present study it was also not possible to establish a profile of characteristics for a potential subject who would be interested in undergoing reconstructive interventions with the aim to improve upper extremity function.

This study showed that decisions concerning reconstructive procedures should be based on the individual assessment of the subjects, realistic functional goals and expected improvement in autonomy and QOL. As QOL depends on a variety of factors [47,48] meticulous consideration and discussion about what the subject wants to achieve is essential in order to avoid raising false hopes and disappointment following technically successful interventions.[23]

The results of the present study illustrated the importance of using appropriate methods when assessing the expected use of therapy and correlate well with actual practice. For instance, the results were in accordance with the findings of Gorman et al. and Rushton et al.who investigated the potential number of candidates for functional neurostimulation devices for the lower and upper extremities.[21,49] Only a small percentage of the suitable candidates were interested in participating in a further selection process and actually receiving the therapy. The present authors had the same experience in a case-series study addressing the use of a Handmaster FES device.[17]

Although the results of the present study did correlate well with actual practice, a few methodological considerations should be mentioned. One general disadvantage of the TTO method is that the choice is hypothetical and does not resemble a real clinical situation. With regard to impaired upper extremity function, treatment of this condition does not mean that a patient has to trade life-time against improvement of upper extremity function. However, when patients are confronted with the question and the choice to invest a fair amount of time, energy and discomfort related to invasive treatment of the upper extremity in order to improve (and not cure) elbow extension and grasp strength, which, in turn, is expected to result in better functional abilities. These benefits have to be gradually discovered after therapy, and are not a certainty at the start of the treatment procedure. In this respect, the actual willingness to undergo these therapeutic interventions should be assessed with methods that incorporate the necessity to make a trade-off. Studies have demonstrated that choice-based preference elicitation methods reveal actual preferences and that TTO reflects patient preferences better than other choice-based methods.[27,29]

The intention of the present study was a tetraplegic population based evaluation of preferences for health states. The present study population enabled this as well as a comparison with previous unconditional studies about preferences in subjects with tetraplegia. However, the sample of the present study also has limitations.

The first limitation is that the study population has been injured for a relatively long period of time; therefore, the subjects may have adapted to the present situation and may have been less willing to trade time for improvement of impairments.[44,45,48] As a result, the health state utilities may be under estimating preferences for persons who have been injured for a shorter period of time.

A second limitation is that the study population was heterogeneous as it contained a great variety of lesion and impairment levels and contained a fairly high number of individuals who had surgery for upper extremity improvement. Individuals with different lesion and impairment levels might have different expectations about the effect of improvement of upper extremities, which could result in different utilities. Also the number of subjects who had surgery may have influenced the results of the utility analysis because surgery had a significantly negative correlation with utility for tetraplegia without upper extremity impairment.

Conclusion

In conclusion, the present study showed that, in general, subjects with long lasting SCI a combination of impairments determines the low utility of the tetraplegic heath state. Although the improvement of major impairments results in significant improvement of the utility of the tetraplegic health state compared to improvement in overall condition, the study population was less willing to trade time to improve a single impairment. No differences were found between the utility of the tetraplegic health state without impaired upper extremity function and the utility of the tetraplegic health state without three other major impairments respectively.

Using the TTO method enabled for the explanation of the discrepancy between patients available for surgical treatment, their self reported importance of improved upper extremity function, and the low rate of patients that proceed to surgical treatment in a broad sample of individuals with tetraplegia. Future studies in specific populations with SCI would further clarify the findings. Further research could also focus on identifying crucial factors in the decision-making process of the choice to undergo reconstructive interventions or not.
In the design or further development of special treatment programmes for specific SCI impairments, choice-based preference research is a useful tool that can reveal important information about interest in and possible use of these treatment programmes.

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Chapter 5

Decision for reconstructive interventions of the upper extremities in tetraplegia: the effect of treatment characteristics

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Submitted

Abstract

Objective: To assess the effect of treatment characteristics on the decisions made by subjects with tetraplegia concerning reconstructive interventions for the upper extremities.

Design: Survey.

Setting: Seven specialized spinal cord injury centres in the Netherlands.

Patients: A sample of 49 individuals with tetraplegia in a stable condition.

Interventions: Not applicable.

Main outcome measure: Importance and the relative weight of 7 treatment characteristics on the decision to undergo reconstructive surgery determined by means of Conjoint Analysis.

Results: All 7 characteristics contributed to the decision to undergo surgery ($p< 0.01$). The relative weights were: for type of intervention 0.14 (95% confidence interval (CI) 0.05-0.23), for number of operations 0.15 (95% CI: 0.05-0.25), for inpatient rehabilitation period 0.22 (95% CI: 0.10-0.32), for outpatient rehabilitation period 0.08 (95% CI: 0.02-0.14), for risk of complications 0.16 (95% CI:0.06-0.26), for results of elbow function 0.1 (95% CI:0.02-0.18), and for results of hand function 0.15 (95% CI: 0.05-0.25). In 40.8% of the subjects one characteristic had a relative weight of 0.30 or more.

Conclusions: Non-health outcome factors related to the intensity of treatment are as important or even or more important than the potential outcome of hand or elbow function in the decision to undergo reconstructive therapy. Inpatient rehabilitation period was the most important factor, and a substantial number of subjects focus on only one characteristic in their decision-making process.

Introduction

Subjects with a Spinal Cord Injury (SCI) at cervical level have impaired upper extremity function, and the degree of impairment is related to the level of their independence in the activities of daily living (ADL)[1-4]. Therapy for the upper extremity (UE) is most important to achieve the best possible level in ADL. Therapy for the UE of subjects with tetraplegia comprises three stages: the acute stage, the sub-acute stage and the reconstructive stage [5]. The aim of the acute stage and the sub-acute stage is, respectively, to avoid complications and to achieve the best possible level of UE function within the constraints of neurological deficit. When no further neurological or functional improvement can be expected, reconstructive interventions can be considered for carefully selected subjects with tetraplegia in order to improve their UE function and, more importantly, their UE skills. The available interventions comprise reconstructive surgery with or without implantation of functional electrical stimulation (FES) devices [6-14].

In general, subjects with tetraplegia are satisfied with the results of reconstructive interventions [15,16]. However, in clinical practice, many eligible candidates for these interventions decide not to have them. This has raised questions about the importance of improvement in UE function for subjects with tetraplegia. Two previous studies show that approximately 75% of subjects with tetraplegia consider UE dysfunction to be the most important or one of the most important impairments to be improved [17,18]. However, preference-based elicitation methods were used in these studies with a non-choice judgement task, which is an approach with known methodological shortcomings [19-21]. Therefore, an additional study was carried out, in which a choice-based method was used to elicit preference, namely the time trade-off method [22]. The aim of this study was to obtain data on the valuation of different health states by subjects with tetraplegia. The health states which were evaluated were the current tetraplegic health state of the subjects, and their current health state with the absence of a major impairment: a tetraplegic health state without bladder and bowel dysfunction, UE dysfunction, sexual dysfunction and standing and walking dysfunction, respectively. For all tetraplegic conditions the absence of one of these major impairments improved the value of the health state significantly, compared to the current tetraplegic health state. No differences were found between the four health states in the absence of one of the impairments. In this respect, it can be argued that there is no single most important impairment to be treated in tetraplegia, and the decision to treat

impairments is based on individual considerations. It is important to realise that not only health outcome, but also non-health outcomes and the treatment process should be taken into consideration when investigating preferences with regard to health care [23,24].
The aim of the present study was to assess the effect of non-health outcome factors in relation to effectiveness of the intervention on the decisions of subjects with tetraplegia concerning reconstructive UE interventions. The method used in the present study was Conjoint Analysis (CA). This method to elicit preferences for certain aspects under study has been developed, tested and found to be suitable to investigate factors "beyond health outcome" in health interventions [25]. The information obtained in the present study will provide better understanding of the decision-making process of subjects with tetraplegia concerning reconstructive UE interventions. Given the situation that suitable candidates decide not to have potentially beneficial treatment, the results of the present study can be important to achieve optimal clinical practice in individual cases, as well as in the development of treatment programs.

Methods

Conjoint Analysis (CA)

Traditionally, "conjoint analysis" has been a collective term, covering both the theory and methods of a variety of different paradigms that can be used to design, implement and analyse individual response data experiments. Responses can be based on evaluative rankings or ratings (judgment) of a set of multi-attribute alternatives or based on choices between a set of alternatives. CA was popularised as a tool for the practical analysis of consumer judgment data by Green and Roa [26]. The axiomatic theory that underlies the design and analysis of rank-order judgment experiments was introduced by Luce & Tukey [27] and is summarised by Krantz et al. [28]. During the 1990's CA was introduced in the elicitation of patient preferences in health care. For an extended overview of the method and the application of CA in the context of health care the reader is referred to literature [23-30]. For a brief description of CA, see also Appendix A.

Identifying attributes and levels

Based on the literature, the expertise of the local rehabilitation team and current clinical practice in the Netherlands, a draft version of the attributes and levels of reconstructive UE therapy for subjects with tetraplegia was formulated by the principal author (a rehabilitation/SCI physician) in collaboration with co-workers (2 hand therapists and 1 hand surgeon) of the local rehabilitation team. This draft version was reviewed by the other authors. The second version was presented to 5 (international) experts in the field of UE treatment in tetraplegia (3 SCI physicians, one hand surgeon and one orthopedic surgeon/SCI physician). The comments made by these experts were incorporated in a third version which, after slight modification by the authors, was used for a pilot test with 6 SCI subjects. The only amendments that were made after this pilot test were minor changes in the phrasing of one attribute in order to improve clarity. The fourth, and final, version was used for the present study.

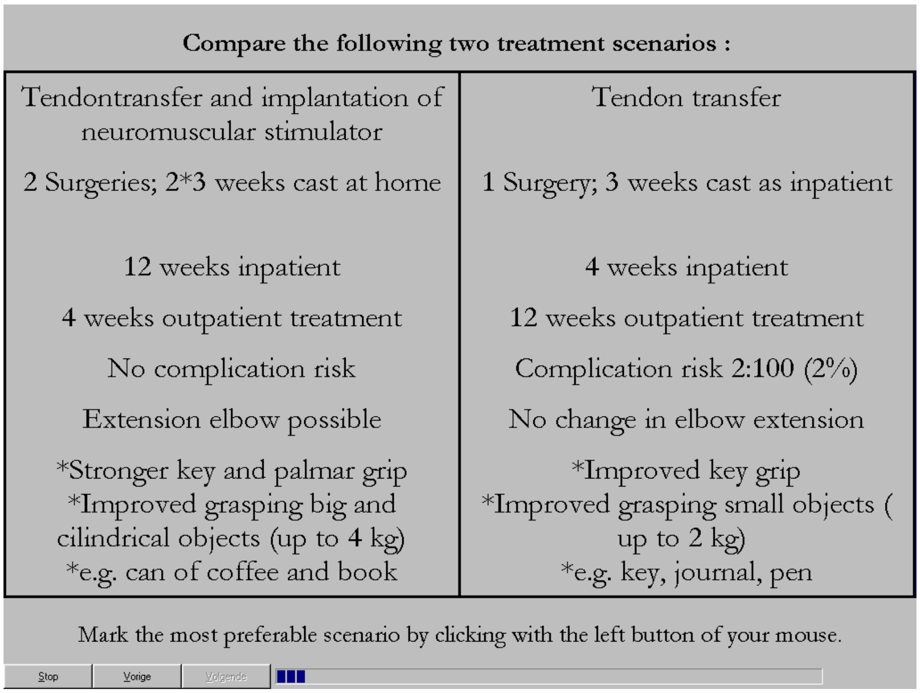
The CA questionnaire

The choice-based conjoint analysis software package by Sawtooth Software™ * was used to design the CA questionnaire. The subjects were presented with a set of 17 pair-wise comparisons of two scenarios which were randomly composed for each subject. They were asked to select the scenario they would prefer most if they would consider undergoing an operation to partially restore their UE function. The random selection of pair-wise scenarios was presented to the subjects according to the minimal overlap method included in the software. With this method all options are presented at least once in combination with the other levels. This method makes it possible to calculate the contribution of all attributes and levels to the decision-making process. The order in which the attributes were presented to the subjects in the scenarios was fixed, and the two scenarios were presented horizontally. For an example of a choice set see Figure 1.

Internal validity and consistency

Three fixed questions were included to test the consistency and validity of the design. The first fixed question presented a very positive scenario compared to a very negative one. The second and third fixed questions presented the current scenarios offered for the intervention with tendon transfers and FES, but the scenarios were presented in a different order (referred to as the mirror set). The subjects were expected to choose the positive scenario, as well as the same scenario twice in the mirror set. If not, they were considered to be inconsistent in their answers, and their results were not included in the final dataset. Finally, the subjects were asked to rate 5 different scenarios with a score between 0 (worst treatment scenario imaginable) and 100 (best treatment scenario imaginable). The 5 scenarios represented the best and worst scenario according to the subject's results in the initial CA questionnaire, a randomly selected scenario, and both scenarios which were presented in the mirror set. If the subjects rated their personal worst scenario better than their personal best scenario, they were thought to be inconsistent in their answers, and their results were not included in the final dataset. If the response to the mirror set in the initial CA questionnaire was inconsistent, but the scores for these two scenarios were equal in the rating questions the results were included again in the dataset.

Figure1.Example of scenario set



Research setting and patient selection

Seven rehabilitation centers in the Netherlands, specialized in the treatment of spinal cord injuries (SCI) contributed to the study. The study was approved by the local institution ethics committee. The physician who had the most contact with outpatients selected subjects who were eligible for participation in the study. The inclusion criteria were a motor complete C5, C6 or C7 SCI, according to the guidelines of the American Spinal Injury Association (ASIA) [31], with at least one arm classified as motor group 1 to 4 according to the International Classification for Surgery of the Upper Limb in Tetraplegia [32]. Subjects had to be medically and neurologically stable, at least one year after the initial injury, and possible candidates for surgical reconstruction of elbow extension and palmar and/or lateral grasp function. Subjects were excluded if they had previously undergone surgery to improve UE function, or if they had been extensively informed about these interventions and had declined treatment in the past 5 years. After consent had been given by the subject, one of the authors (JvT) visited the subject at home to obtain the necessary data: gender, age, time since injury, and SCI and UE classification according to the guidelines were established. Possible UE interventions were briefly described with a standardized power-point presentation. The purpose and practical aspects of the CA interview were explained, and preference data were collected. Based on the instructions provided by Sawtooth Software™ , a minimum of 50 subjects were necessary for the present study in order to be able to draw valid conclusions [33].

Data-analysis

The aim of the present study was to determine the importance of the attributes in the decision concerning reconstructive interventions, to calculate the relative importance of the attributes, and to calculate the preference for each level within an attribute. Furthermore, we were interested to find out whether subjects had distinct preferences for certain attributes when deciding about therapy. The logit logistic regression analysis statistical software included in the CBC Sawtooth Software™ package was used to analyze the data of the random scenarios. This analysis of pair-wise comparisons of sets of random scenarios resulted in regression coefficients for each level of the attributes. These coefficients were used to calculate the importance and relative importance of the attributes and the preference for the separate levels within the attributes. The difference between the level with the maximum coefficient (max [coefficient $Level^{a\text{-}n}Attr^{A}$]) of each attribute and the level with minimum coefficient of each attribute (min [coefficient $Level^{a\text{-}n}Attr^{A}$]) was tested for significance with a t–test. The t-value was calculated by dividing the difference between these coefficients by the pooled standard error (provided by the software). A p-level of < 0.05 was considered to be significant and the attribute was then considered to be important in the decision to undergo therapy. The relative importance of each attribute was calculated with the following formula:

$$\text{Relative Importance Attr}^{A} = \frac{(\max[\text{coefficient Level}^{a\text{-}n}\text{Attr}^{A}] - \min[\text{coefficient Level}^{a\text{-}n}\text{Attr}^{A}])}{\Sigma\,(\text{range Attr}^{A\text{-}N})}$$

where Attr^{A} is the attribute which is being investigated. The numerator represents the range of coefficients of the levels of the attribute and the nominator represents the summed ranges of the coefficients of the levels of all attributes.

The preference for each level within an attribute (the proportion or relative preference for a specific level of an attribute, compared to the other levels of the same attribute) was calculated with the formula:

$$\text{Proportion Level}^{a}\text{Attr}^{A} = \frac{\text{Exp (coefficient Level}^{a}\text{Attr}^{A})}{\Sigma\ \text{Exp (coefficient Level}^{a\text{-}n}\text{Attr}^{A})}$$

The numerator represents the exponent of the coefficient of a level of an attribute, and the nominator represents the summed exponents of all coefficients of all levels within the attribute.
Using the Hierarchical Bayes module of the Sawtooth Software^{TM} package, the relative importance of the attributes was calculated for each subject in order to determine whether the subjects had distinct preferences for certain attributes. Subjects with a relative preference of 0.30 (30%) or above for a specific attribute were considered to have a distinct preference in comparing the treatment scenarios.
Additionally, a sub-group division was made, a so called “balanced sub-group”, including subjects with no distinct preference for any of the attributes. The importance and relative importance of the attributes and the proportions of the levels were also established for this sub-group.

Results

A final set of seven key attributes were defined; (1) type of intervention, (2) number of operations and preferred location of time spent in a cast, (3) rehabilitation time as inpatient in rehabilitation centre, (4) rehabilitation time as outpatient, (5) risk of complications, (6) effect of the intervention on elbow function, and (7) effect of the intervention on hand function. The range of levels of the attributes reflected as much as possible the actual range of these factors in the available treatment options. The final set of attributes and levels is presented in Table 1.

A total of 58 patients were selected in the 7 rehabilitation centres. Five selected patients were either unwilling to be interviewed after they were contacted by the research assistant, or could not be reached. Data were obtained from 53 subjects, whose characteristics are presented in Table 2.

Table2 Demographic data of the study population

Male	Female	Mean Age (sd)	M0 R/L*	M1 R/L*	M2 R/L*	M3 R/L*	M4 R/L*	M5 R/L*	TSI¶ 1-2 Y	TSI¶ 2-5 Y	TSI¶ 5-10 Y	TSI¶ > 10 Y
41	12	39 (10)	1/2	14/12	12/11	8/6	15/13	4/7	1	10	13	29

sd: standard deviation;* number of arms at the right (R) and left (L) side classified as motor group M1 to M5 according to the International Classification of the Upper Limb in Tetraplegia. Eight of the subjects with one arm classified as M4 had bilateral M4 classification, and one had the other arm classified as M5. In all other subjects with one arm classified as M4 or M5, the opposite arm was classified as M1, M2 or M3.
¶ Time since injury in years

After checking for consistency, data on four subjects did not fulfill the validity and consistency criteria described in the Methods section, so these data were excluded from further analysis. 40.8 % of the remaining 49 subjects showed a distinct preference for one attribute, and 59.2 % (29 subjects) were in the balanced sub-group.

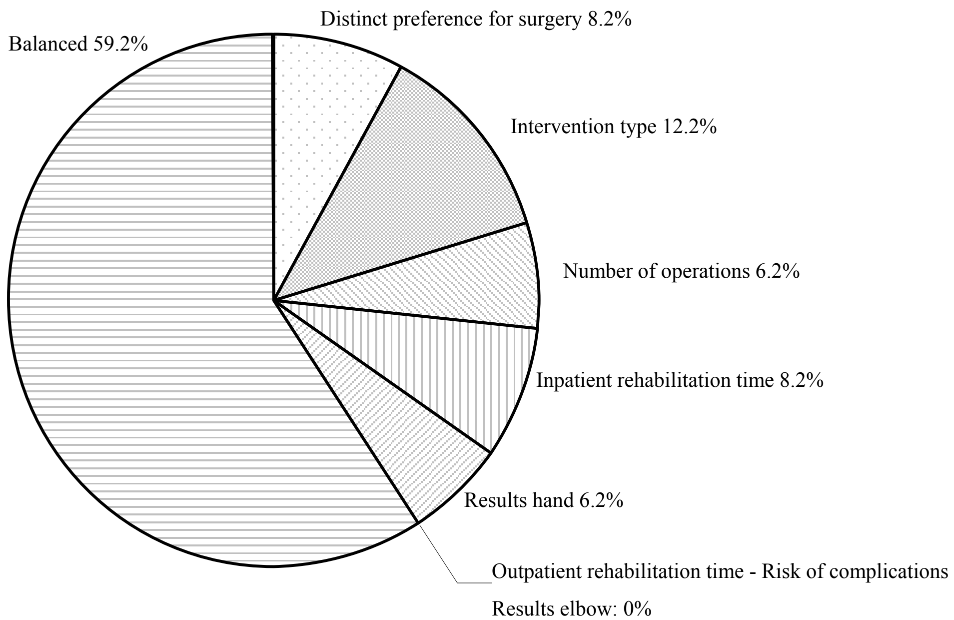
Figure 2 shows the distribution of distinct preferences. 8.2% of the subjects declined the implantation of FES devices, and none of the subjects had a distinct preference for outpatient rehabilitation time, risk of complications and results of the elbow.

Table1 Attributes and levels

1.Intervention	a. Tendon transfer
	b. Tendon transfer + FES system implantation
2.Number of operations & time +location spent in a cast	a. 1 operation; 3 weeks cast as inpatient
	b. 1 operation; 3 weeks cast at home
	c. 2 operations; 2*3 weeks as inpatient
	d. 2 operations; 2*3 weeks at home
3.Rehabilitation period as inpatient	a. none
	b. 4 weeks
	c. 8 weeks
	d. 12 weeks
4.Rehabilitation period as outpatient	a. none
	b. 4 weeks
	c. 8 weeks
	d. 12 weeks
5.Risk of complications	a. none
	b. 1 in 50 (2%)
	c. 1 in 20 (5%)
	d. 1 in 10 (10%)
6.Functional result elbow	a. Active extension after intervention
	b. No active extension (no intervention)
7.Functional result hand	a. Moderately improved key grip
	b. Moderately improved key and palmar grip
	c. Very much improved key and palmar grip

The short statements concerning the last two attributes were described in slightly more detail to the subjects. Active elbow extension was described as the possibility to extend the elbow against gravity, overcoming slight resistance. Moderately improved grip was described as considerably stronger than in the pre-operative situation, making it possible to pick up objects such as a plate, cutlery, videotape, ADL equipment, etc. Very much improved hand function was described as very much stronger grip than in the pre-operative situation, making it possible to pick up heavier objects such as like tools, phone books, etc.

Figure2



Percentage of subjects of the study population (n =49) with a distinct preference for a certain attribute (relative preference of 0.3 or higher for that specific attribute) and percentage of subjects with balanced preferences.

Between 6.2 % and 12.2 % of the subjects had a distinct preference for one of the other attributes.

In the present study, 3072 different scenarios were possible (multiplication of levels for each attribute: 2x4x4x4x4x2x3). The 49 subjects generated data on 833 random choice tasks (multiplication of number of subjects by number of random choice sets: 49x17), and the balanced sub-group data on 493 random choice tasks (29 subjects and 17 choice sets). The results of the logit analysis are shown in Table 3. In the entire study population, as well as in the balanced sub-group, all attributes significantly contributed to the decision to undergo reconstructive intervention therapy (for all attributes $p < 0.01$).

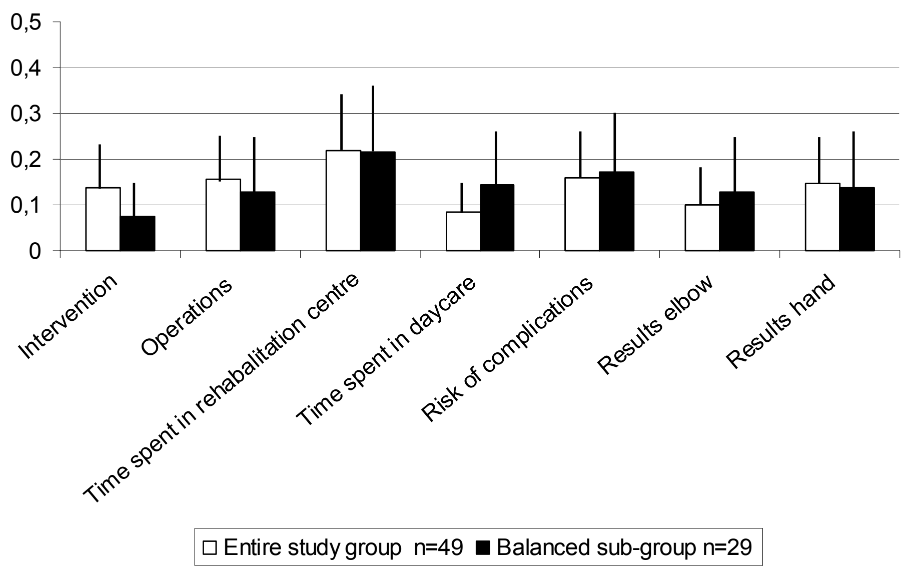
Table 3 Results of logit analysis

	study population						balanced sub-group					
attribute levels*	Effect†	S.E.‡	Dif.¶	Pld.SE.╝	T╓	p═	Effect†	S.E.‡	Dif.¶	Pld.SE.╝	T╓	p═
intervention												
-tendon transfer	0.28	0.04	0.57	0.06	9.82	< .01	0.19	0.05	0.38	0.08	4.91	<.01
-tendon transfer+FES	-0.28	0.04					-0.19	0.05				
no. op.and time/loc in cast												
-1 op; 3 wks cast; inpatient	0.33	0.09	0.65	0.12	5.32	<.01	0.30	0.12	0.67	0.17	4.04	<.01
-1 op; 3 wks cast; at home	0.24	0.08					0.25	0.11				
-2 op; 2* 3 wks cast; inpatient	-0.32	0.09					-0.37	0.12				
-2 op; 2*3 wks cast; at home	-0.25	0.09					-0.18	0.11				
inpatient rehabilitation												
-none	0.53	0.10	0.91	0.13	7.10	<.01	0.62	0.13	1.11	0.17	6.50	<.01
-4 weeks	0.16	0.09					0.22	0.11				
-8 weeks	-0.31	0.09					-0.36	0.12				
-12 weeks	-0.38	0.09					-0.49	0.12				
outpatient rehabilitation												
-none	0.14	0.09	0.34	0.13	2.70	<.01	0.32	0.13	0.73	0.17	4.28	<.01
-4 weeks	-0.04	0.09					-0.02	0.12				
-8 weeks	0.10	0.09					0.12	0.12				
-12 weeks	-0.21	0.09					-0.41	0.12				
complications												
none	0.32	0.09	0.66	0.12	5.41	<.01	0.46	0.12	0.89	0.16	5.46	<.01
-1 in 50 (2%)	0.02	0.09					-0.09	0.12				
-1 in 20 (5%)	-0.01	0.09										
-1 in 10(10%)	-0.33	0.09					-0.43	0.19				
effect elbow												
-active extension	0.21	0.04	0.41	0.06	7.00	<.01	0.33	0.06	0.66	0.08	8.04	<.01
-no active extension	-0.21	0.04					-0.33	0.06				
effect hand												
-moderately impr. key grip	-0.32	0.07	0.61	0.10	6.40	<.01	-0.40	0.09	0.71	0.13	5.56	<.01
-moderately impr. key + palm. grip	0.03	0.07					0.09	0.09				
very much impr. key + palm. grip	0.29	0.07					0.31	0.09				

*For exact description of attributes and levels see Table 1. † Coefficient in logit regression analysis; ‡ =standard error; ¶ difference between coefficients of levels with maximum and minimum effect per attribute; ╝ pooled standard error; ╓ t-value; ═ p-level.

Figure 3 shows the relative importance of the attributes and their 95% confidence intervals in the entire study population, as well as in the balanced sub-group. In both groups the inpatient rehabilitation period is the most important factor in deciding about reconstructive interventions. In the entire study population the type of intervention, the number of operations, the time spent in cast and, the risk of complications are of the same order of importance as functional outcome at hand level, and only the outpatient rehabilitation period is less important than both functional outcome attributes. In the balanced sub-group type of intervention had less weight and the outpatient rehabilitation period had more weight in the decision concerning therapy, compared to the entire study population.

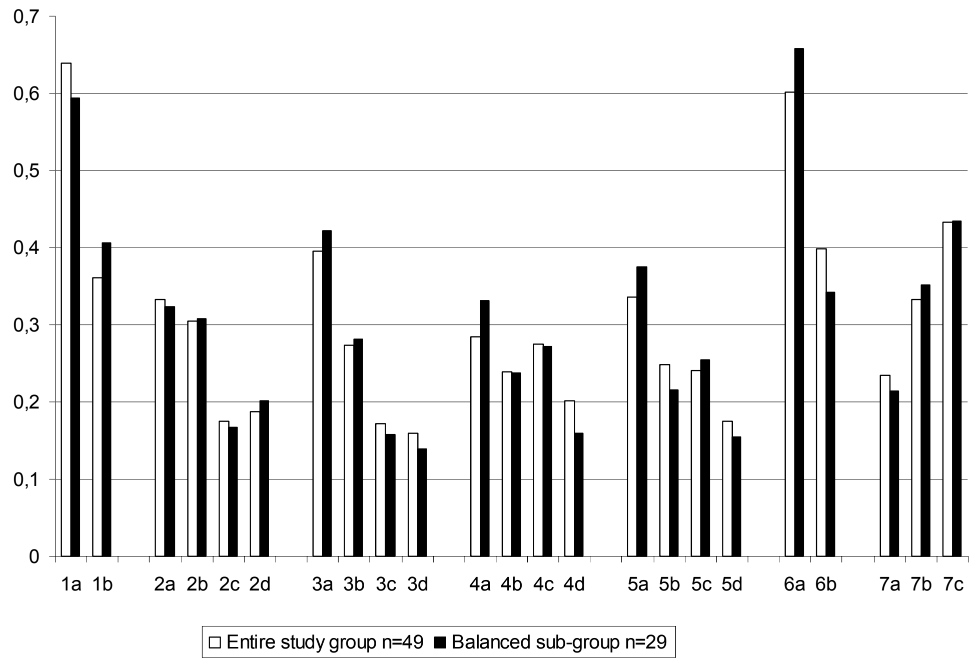
Figure 3



Relative importance and 95% confidence intervals of attributes for the entire study population and the balanced sub-group.

Finally, Figure 4 shows the preferences for each level (proportions) within the attributes. In general, the distribution over the levels is logical, and the best or most attractive levels have the highest proportion of preference.

Figure 4



Proportion or relative attractiveness of the levels (for a description of the levels see Table 1) .

Discussion

The aim of the present study was to measure the effect of treatment characteristics (attributes) on the decisions made by subjects with a tetraplegia concerning reconstructive UE interventions in a study population with a stable SCI.

All attributes investigated in the present study contributed significantly to the decision to undergo reconstructive UE intervention and must therefore be taken into account when subjects are informed about these therapies or in the development of therapy programs. In this respect, it is important to note that over 40% of the subjects focused on one specific treatment characteristic. In clinical practice these subjects will miss a lot of the explanation about the other aspects of the treatment. It is important to be aware of this, and it is worthwhile to find out whether the individual patient makes a "balanced choice" and, if not, on what aspect is the focus of their attention.

In the entire study population, as well as in the balanced sub-group, inpatient rehabilitation period was the most important attribute in the choice of a treatment scenario. Increase in the inpatient rehabilitation period has a substantial negative effect on the preference for treatment. More in general, attributes related to the intensity or "burden" of therapy are equally important, or even more important than functional outcome characteristics in deciding about therapy. An interesting point is that, although scientifically proven and favoured by professionals as a very rewarding procedure [34], the potential benefits of active elbow extension seem to be less important for a considerable number of potential recipients with tetraplegia of surgical UE reconstruction. This feature should be given special attention when informing patients about possible interventions. Although none of the 95% confidence intervals of the relative importance of the attributes contains the zero level, the width of the intervals indicates a large inter-individual variation in the relative importance of the attributes. As expected, the relative importance of the attributes in the balanced sub-group shows more equilibrium.

Looking at the proportions (relative attractiveness) of the levels of the attribute (see Figure 4); tendon transfer is more preferable than FES implants. However, only 8.2 % of the subjects absolutely rejected the implantation of devices (these are the subjects with a distinct preference for an intervention in Figure 1). Furthermore, it is interesting to note that in the balanced sub-group the type of intervention is less important, and the 95% confidence interval contains the zero level. This is in contrast with reports in the literature [35, 36], and also contrary to the clinical expectations of the authors, that more subjects would reject the implantation of foreign objects. One operation is understandably preferable to two operations, but the location in which the post-operative period, with the operated arm immobilised in a cast, is spent does not seem to be an important factor. This might be associated with the uncertainty that patients experience directly after surgery because of a temporary limitation in independence due to immobilisation, in most cases, of the dominant arm, which implies that they require additional ADL assistance. The length of outpatient treatment was found to be relatively irrelevant, except for the longest period of 12 weeks, which was less appreciated. Patients take a post-operative rehabilitation period into account. During the survey the subjects who were given treatment scenarios with very short rehabilitation periods often indicated that, although they preferred this option, they did not really expect this to happen. Some patients added up the inpatient and outpatient period in order to estimate the total treatment time. They were obviously not concerned with the location of the treatment, but more with the total burden of the treatment. Retrospectively, it might have been better to cluster the attributes of inpatient and outpatient periods under the more general attribute of total treatment time, and to access the relative importance of inpatient and outpatient periods separately. However, due to our design this was not possible in the present study. For the attribute "risk of complications" the proportions for 2% and 5% are equally attractive. The inclusion of risk as an attribute in CA experiments is still under debate, because of the difficulty subjects have in estimating risk accurately [37].

Some methodological points have to be discussed in more detail.

Obviously the classifications of the UE function of the subjects in the study population represent a range of upper extremity functions and functional capabilities [1-3, 5, 38, 39]. However, the main objectives of surgical interventions for all subjects with an arm classification of M1 to M4 are an active elbow extension and restoration of one or two grasp functions [5-14]. The aim of the present study was not to compare full treatment scenarios, but to focus on the effect of treatment characteristics on the decisions made by subjects concerning interventions to restore elbow extension and one or two grasp functions. In this respect, the sample is adequate for the purpose of this study, and there were sufficient subjects to make it possible to draw valid conclusions of the CA.

An appropriate choice of attributes and levels is crucial in a CA study. Although the attributes and levels were based on reports in the literature, developed by an experienced rehabilitation team and reviewed by international experts, there will always be an element of "local flavour." This depends on the clinical situation in which the attributes and levels are established and in which the study is carried out. For instance, the levels of the attribute inpatient rehabilitation period in the present study will not be appropriate for the current situation in the USA. In this respect, the results of the present study are fully applicable to those centres and countries with similar methods of clinical practice and partly applicable to those with different methods of practice.

In general, CA has been proved to be a valid method with which to investigate the influence of health outcome and non-health outcome factors in the preference for health care [25]. Content validity in the present study can be assumed based on the method used to establish the attributes and levels as well as the fact that all attributes significantly contributed to the decision to undergo reconstructive surgery. The logical distribution of the proportions of the levels indicates the internal validity of the present study. Only four subjects showed inconsistency in their preferences, and these subjects were excluded from the analysis. However, the exclusion of inconsistent subjects or non-traders is a topic of discussion in which is stipulated that future research should consider the extent to which inconsistent respondents are behaving rationally and explore issues related to non-traders [37]. In the present study, non-trading occurred only in subjects with a distinct preference for an intervention; 8.2 % rejected the implantation of FES devices. Subjects with a distinct preference for certain attributes were identified, and a sub-group with "balanced choice" was analysed separately.

The practical experience of the authors with CA is that, in general, the subjects enjoyed participating in the study, and the subjects in the pilot study made very useful comments. The preparation of a CA experiment demands considerable time and energy, and the way in which the subjects were interviewed at home is time-consuming and expensive. A mailed or web-based questionnaire would be less expensive and more practical. However, we thought it was very important to provide the subjects with sufficient knowledge about augmentative reconstructive therapy before starting the presentation and the weighting of treatment scenarios. Because weighting in CA is essentially an implicit cognitive operation considerable cognitive burden is associated with multi-criteria decision methods. Good explanation of the aims and voting behaviour was therefore regarded as essential. In this respect we preferred the subjects to have personal contact with an experienced researcher who explained the treatment in general before the CA questionnaire was administered. Furthermore, the inclusion criteria could be checked by the author who made the home visit.

Obviously, the results of the present study cannot replace the contact between the treatment team and the patient in explaining the options for each individual patient, and the associated pros and cons. However, in this process the results of the present study can be taken into account in order to optimise the information given to a patient, and at the same time be aware of the patient's views with regard to the various aspects of therapy. In the development of treatment protocols and when discussing existing treatment protocols the results of the present study can also be taken into account.

Conclusion

In conclusion the present study demonstrates the applicability of CA in rehabilitation and spinal cord injury research to study the effect of health outcome and non-health outcome factors on the decision to undergo therapy. With regard to reconstructive UE interventions in subjects with tetraplegia non-health outcome factors indicating the intensity or burden of the treatment are as important or even important than outcome on hand or elbow function in decisions concerning therapy. Inpatient rehabilitation period was the most important factor. Over 40% of the subjects focused on only one treatment characteristic in deciding about therapy. The results of the present study can be used in the discussion about UE treatment with individuals with tetraplegia, as well as in the preparation or adaptation of treatment protocols.

Acknowledgement

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***Address for the Conjoint Analysis software program used in the study:**

Sawtooth Software, Inc.
530 West Fir Street
Sequim, WA 98382-3209
United States of America

Appendix A

Conjoint Analysis (CA) is a technique to establish which factors influence the demand for or decision concerning a good or a service (for instance reconstructive hand surgery), as well as the relative importance of these factors. These factors are indicated as attributes, and they can be presented to subjects in various levels. A CA experiment has 5 stages.

In the first stage the attributes are identified (in the present study the treatment characteristics of reconstructive interventions for the upper extremity. The attributes must be relevant and comprehensive, in order to avoid missing important information. However, the number should be limited in order to ensure that the response tasks (stage four) manageable.

In the second stage levels are assigned to the attributes. The levels should be plausible, actionable and tradable.

In the third stage hypothetical treatment scenarios are designed, combining different levels of attributes.

In the fourth stage response tasks for the scenarios are established. This can be done by ranking or rating the scenarios or by making a discrete choice between sets of scenarios. In discrete choice experiments the subjects are given a series of sets of different scenarios and asked which one they prefer. This pair-wise comparison has a strong psychological theoretical background. Discrimination in psychology is regarded as a basic operation of judgement and of generating knowledge in general. In fact, subjects are making choices between alternatives constantly in daily life. Either all possible (pairs of) scenarios can be compared (full factorial design) or a selection of scenarios is presented (factorial design). In the latter case, however, not all possible interactions between attributes can be estimated. In general, subjects are able to compare between 16 and 25 sets of scenarios before becoming bored or tired. There are various methods to establish scenarios as well as sets of scenarios, and to reduce the number of scenarios for inclusion in the questionnaire, while it is still possible to infer preferences for all possible scenarios. For these procedures special software, catalogues and expert opinion are used.

In the fifth and final stage the data are analysed. Data-analysis, using regression techniques such as logit procedures, enables the decomposition of overall preferences for alternative scenarios into the effects of the specific attributes and their levels on the preference for a specific treatment scenario. If an attribute contributes significantly to the decision concerning a good or a service the attribute is considered to be important. The relative importance of the attributes and levels are indicated by their relative size or proportions.

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Chapter 6

A multi criteria decision analysis of augmentative treatment of upper extremities in persons with tetraplegia

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Abstract

Purpose: To support the evaluation by a rehabilitation team of the performance of two treatment options that improve the arm-hand function in subjects with a C6-motor group 2 tetraplegia.

Method: The analytic hierarchy process, a technique for multi-criteria decision analysis, was used to quantitatively support a rehabilitation team and potential recipients in comparing a new technology (Functional Electrical Stimulation) with conventional surgery.

Results: Performance was measured by functional improvement, treatment load, risks, user-friendliness and social outcomes. Functional improvement after FES was considered better than conventional surgery. Yet, the overall rating of the rehabilitation team for conventional surgery was slightly higher than FES (56% versus 44%). Compared to the rehabilitation team potential recipients gave greater weight to burden of treatment and less weight to functional improvement.

Conclusions: Evaluation of new technology has to be more comprehensive than the evaluation of functional improvement alone. Actual patient's preferences may differ from preferences of the rehabilitation team.

Introduction

The field of rehabilitation has become increasingly complex. The demand for rehabilitation treatment increases, but the resources for rehabilitation are scarce. The allocation of rehabilitation resources to potential recipients is also often complex and many factors need to be taken into consideration. A specific decision that rehabilitation teams have to make is to allocate the appropriate assistive technology to potential recipients, and the multi-disciplinary nature of rehabilitation requires that rehabilitation professionals make such decisions in teams. These teams include physicians, nurses, and members of the various different therapy services [1]. All parties involved must carefully consider the various factors that underlie the acceptance of the technology by the recipient [2].

This study focuses on a multi-criteria decision method to support the evaluation of the importance of treatment characteristics and the performance of various different treatment approaches in a specific clinical situation. In the present study a rehabilitation team and a group of subjects with a C6 level tetraplegia evaluated the importance of the treatment characteristics of reconstructive interventions of the upper extremities (UE). The rehabilitation team evaluated the performance of two different interventions for the UE for subjects with a C6 level tetraplegia base on the treatment characteristics.

In individuals with tetraplegia due to a cervical spinal cord injury (CSCI), the motor level is related to the level of independence in the activities of daily living [3-5] Therefore, therapy of the upper extremities is very important. For subjects who meet the selection criteria, reconstructive surgery of the upper extremities can partially restore elbow extension and grasp function [6-8]. More recently, the implantation of Functional Electrical Stimulation (FES) devices has been introduced to improve upper extremity function. In the FES system (Freehand system™ [A]) electrodes are surgically placed onto the paralyzed hand muscles that are responsible for grasp and release. These electrodes are connected to a subcutaneous receiver-stimulation unit, which interprets voluntary signals from motions such as shoulder elevations, and transfers the appropriate stimulation wave-forms via the electrodes to the target muscles. FES implants are usually combined with conventional surgical procedures in order to optimize functional abilities [9, 10].

To judge eligibility for surgery, subjects are classified according to the International Classification of the Upper Limb in Tetraplegia [11, 12]. This classification scores the number of functional muscles below the level of the elbow with at least a strength grade of 4/5, using a manual muscle test. The muscles are classified into 9 separate motor groups (groups 0 - 9). In addition to motor function, sensory function is also tested with the 2-point discrimination test of the pulp of the thumb. In subjects with motor group 0, according to this classification, no muscle below the elbow has a strength of grade 4/5, and FES is the only option to enhance hand function. In motor group 1 only the m. brachio radilais has a strength of grade 4/5, and in motor group 2 both this muscle and the m. extensor carpi radialis longus has a strength 4/5. In subjects with motor group 3 also the m. extensor carpi radialis brevis have a minimum strength of grade 4/5, and in motor groups 4 to 9 more muscles per group have this strength.

For subjects with C5 lesions-motor group 1 and especially for subjects with C6 lesions-motor group 2, limited surgical procedures as well as reconstructive surgery combined with FES implants can be considered. These subjects have to choose between these two treatment options if they are willing to undergo a reconstructive procedure. To support this decision, the rehabilitation team is asked for advice. In order to be able to give the correct advice, it is essential that the team clearly understands its preferences for the treatment options.

Decision-making by rehabilitation teams is likely to be negatively influenced by lack of time, lack of procedural guidelines, if alternative opinions are disregarded, or if there is a dominant team member or leader [1]. It is beneficial for teams to develop strategies to enhance their teamwork, and to develop guidelines to standardize their decision processes. The analytic hierarchy process (AHP), a technique for multi-criteria decision analysis, can support team decision-making [13], and it can support rehabilitation treatment teams in evaluating the performance of new medical technology. The aim of this study is to support, with the AHP, the evaluation by a rehabilitation team of conventional upper extremity reconstructive surgery and reconstructive surgery combined with FES. Moreover, an additional study was carried out to compare the preferences from the perspective of potential recipients of reconstructive interventions with the preferences, with regard to treatment requirements, of a rehabilitation team.

Materials and methods

A decision is a choice between two or more alternatives and the choice for an alternative is generally based on multiple criteria or requirements. Saaty's analytic hierarchy process (AHP) is a technique for multi-criteria decision analysis. This technique supports decision-makers when they have to choose between alternatives and it can be used to support individual decision-making as well as group decision-making. The AHP structures group discussions, makes the disagreements among the group members explicit, and supports a quantitative comparison between the alternatives. It helps to quantitatively estimate how well the alternatives fulfill a number of performance requirements. These performance requirements can be both quantitative and qualitative [13]. The AHP has been implemented in a group decision support system: Team Expert Choice [B]

We applied the AHP to evaluate the effectiveness of FES in enhancing the hand function of subjects with C6 tetraplegia. An expert panel compared the effectiveness of surgery including an FES implant with conventional surgery for a specific group of potential recipients. These recipients were subjects with a C6 level tetraplegia who were classified as motor group 2 according to the International Classification of the Upper Limb in Tetraplegia. The recipients can keep sufficient balance, are psychologically adjusted to their injury, are capable of learning how to use the revised hand function, and their target muscles can be stimulated by electrical wave-forms. These subjects can undergo conventional surgery to improve elbow extension (posterior Deltoid to Triceps transfer).

To improve the hand function of these subjects, both conventional surgery and reconstructive surgery combined with an FES implant can be considered. Conventional surgery is the active transfer of the m. brachio-radialis to thumb or finger flexors, which can be eventually combined with tenodesis of thumb or finger flexors. This therapy results in one active and one tenodesis grasp of either palmar or lateral grasp. Surgery combined with FES implants result in a stimulated lateral and palmar grasp function. For an extensive review of the possibilities the reader is referred to the literature [6-10].

The expert panel included two rehabilitation physicians, two occupational therapists, two physiotherapists and one social worker, as well as a person with a C6 complete tetraplegia. These panel members were selected on the basis of their knowledge about the treatment of the tetraplegic arm-hand or the psychosocial effects involved. All professional members belonged to the same SCI treatment team and had a considerable experience (varying between 8 and 24 years) in treating patients with SCI and a special interest and expertise in treatment of the UE. The person with tetraplegia had sustained his injury over 20 years ago, has undergone reconstructive UE surgery, and is active as a counsellor for people who have recently sustained an SCI. Due to practical reasons a nurse of this team could not attend the evaluation.

The panel members were seated at a u-shaped table with a facilitator facing them. The hardware consisted of a laptop on which Team Expert Choice was installed, a projection system, a radio`-frequency receiver, and individual wireless keypads for the panel members. The panel members first defined the appropriate group of potential recipients, FES and reconstructive surgery. A brainstorming session followed, in which the panel members listed performance requirements fort assessing the treatment options. The panel members had 10 minutes in which to formulate these requirements, which they, subsequently, read out in the group. The facilitator entered these requirements in Team Expert Choice and they were projected on a screen.

> *In the present study, the objective is to choose, out of two alternative arm-hand treatments, the treatment with the highest performance. Some of the main performance requirements are, for example: safety of the treatment, influence on the quality of the hand function, and ease of using the hand.*

In the next step, each of the main requirements was divided into several sub-requirements. All requirements were discussed in the group to ensure that the main requirements as well as each group of sub-requirements were mutually exclusive, clear, comprehensive, and of importance within the same order of magnitude. They were revised until the group had no further comments, additions, modifications or omissions with regard to the requirements. The expert panel compared then the importance of the requirements. First, the importance of each pair of two main requirements was compared on a 9-point scale, on which a score of 1 indicated equal importance of the requirements. If one of the requirements was considered to be more important than the other, this requirement was assigned a score ranging from 2-9 depending on the level of importance. An example of a pair-wise comparison of the importance of two main requirements is:

Which requirement is more important with regard to the performance of the hand treatment, and to what degree?

Safety is a requirement that is

(1) equally (3) slightly more (5) strongly more (7) very much more (9) exceedingly more

important than the quality of the hand function.

[2, 4, 6, 8 represent intermediate values]

The importance of each pair of sub-requirements that related to the same main requirement was subsequently compared. Likewise, the performances of the two treatment options were compared with regard to each sub-requirement. In this case, the comparison focused on which treatment option was preferred with regard to the sub-requirement, and to what degree. For the comparisons between treatments, the 9-point scale ranges from indifference to extreme preference.

Using their hand-held radiographic keypads, the panel members gave their scores for each pair-wise comparison. Individual scores were projected on a screen, which enabled the panel members to discuss their scores. During the discussions, the panel members could alter their scores. No actual consensus was forced. Group scores were the geometric averages of the final individual scores for the pair-wise comparisons.

The AHP software uses the group scores for the pair-wise comparisons to calculate the weighting factors according to an eigenvector method. This eigenvector method can be interpreted as being a simple averaging process, by which the weights are the average of all possible ways of comparing the importance of the requirements or the preference for the treatments. Accordingly, the weights that were calculated represent the relative importance of the main and sub-requirements, and the relative preference for the treatments with regard to each sub-requirement. These weights were used to calculate an overall weighted preference for the two treatment alternatives. (See references 14 and 15 for a more in-depth explanation of this mathematical approach). The software illustrates these weights by means of graphs.

> *For example, 2 decision-makers are convinced that safety and ease of use are equally important (score = 1), and two other decision-makers consider safety to be much more important than the ease of use (score = 5). The group scoreis therefore 3, indicating that safety is slightly more important than the ease of use. Let's assume further: the safety of treatment 1 is preferred slightly more than the safety of treatment 2. On the other hand, treatment 2 is preferred slightly more than treatment 1 with respect to the ease of using the hand. The treatments are equally preferable with respect to their influence on the quality of the hand function. In this example, treatment 1 is safer than treatment 2, but the hand will be more difficult to use. Since safety weights stronger in this evaluation than ease of use, the results indicate that treatment 1 is preferred. Overall, this treatment is therefore considered to perform better than treatment 2.*

An additional exploratory study was performed to investigate whether the results obtained during the session with the rehabilitation team were in accordance with the needs of potential recipients. In other words, do potential recipients have the same values as the rehabilitation team with regard to the requirements of surgery combined with FES and conventional surgery? Eight rehabilitation, centers specialized in SCI care in the Netherlands, selected 34 persons with a C6 tetraplegia to participate in this formal study. Criteria for the inclusion of subjects were: C6 motor group 2 CSCI, time since injury >1 year (stable neurological condition) and not recently informed about reconstructive surgery. Patients were excluded if they had either received reconstructive surgery or had declined treatment within the previous year. The subjects were individually interviewed by a research assistant, and asked to assess pair-wise the relative importance of each pair of the main requirements that had been defined by the expert panel. The subjects made a total of 10 pair-wise comparisons. Due to the combination of this study with other questionnaires, the available time was limited and the subjects were not asked to value the sub-requirements. ANOVA analysis was performed to compare the importance of each main requirement, as rated by the members of the expert panel (n = 8) and the persons with tetraplegia (n = 34).

This additional study involving subjects with SCI was approved by the Roessingh Rehabilitation Centre Ethical Committee.

Results

In the evaluation of reconstructive surgery including an FES implant, compared with conventional surgery, the expert panel considered 19 sub-requirements to be relevant. These requirements were related to five main requirements: ease of use, social acceptance, improved arm-hand function, minimal risks, and minimal load of the treatment (Figure 1). Figure 1 and Table 1 show detailed quantitative results of the weighting according to the expert panel. Figure 1 shows the weighting factors (w) of the main requirements and the sub-requirements. These weighting factors represent the relative importance of these requirements. Table 1 shows the preferences (p) for the treatment options, for each sub-requirement separately. A high weight indicates a strong preference of the expert panel for the effectiveness of the specific treatment option in fulfilling the corresponding sub-requirement.

Figure 1 Evaluation structure with importances of (sub-)requirements

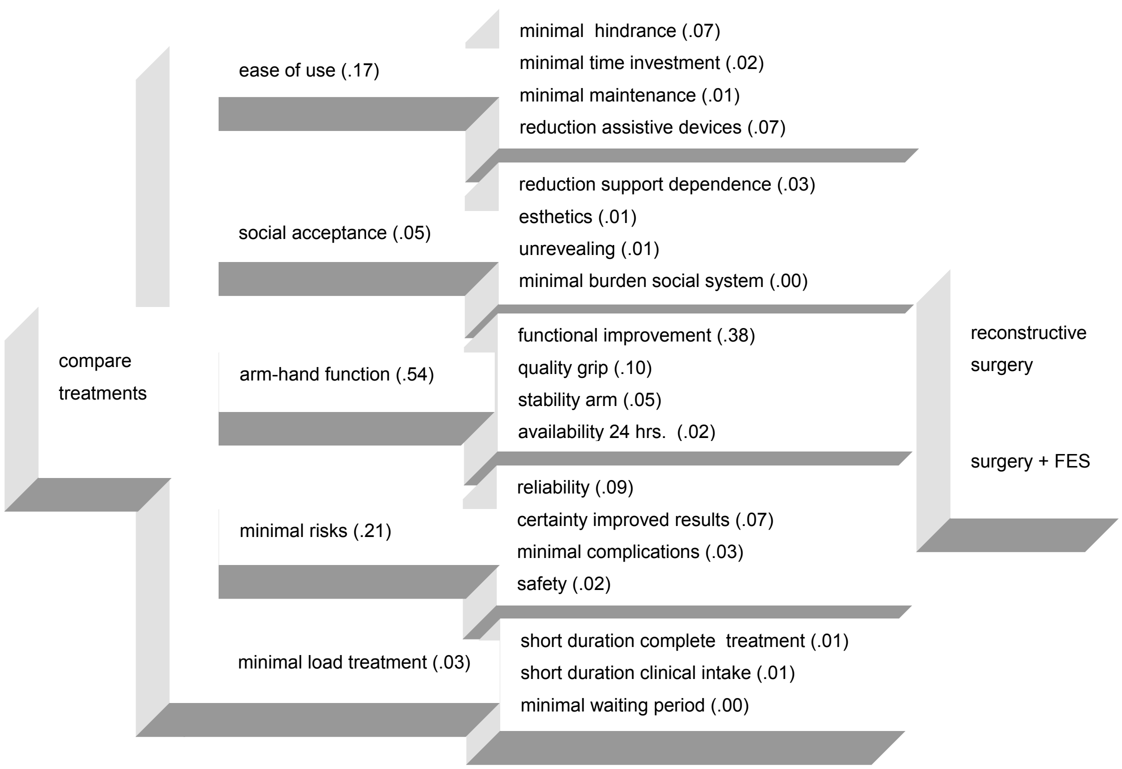


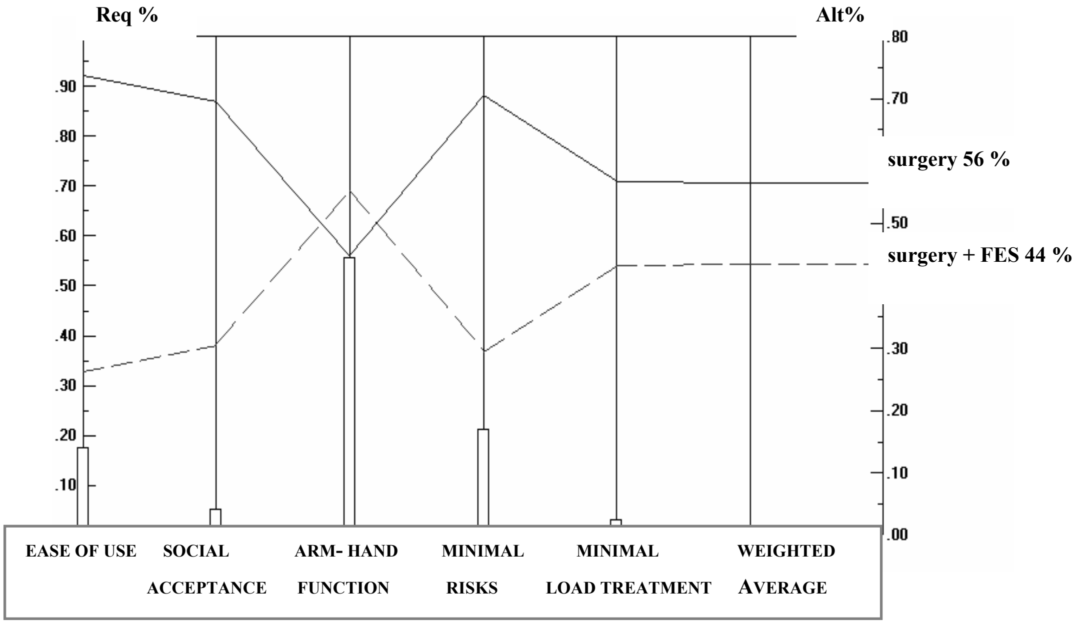
Table 1 Relative priorities with regard to sub-requirements

	EASE OF USE				SOCIAL ACCEPTANCE				ARM-HAND FUNCTION				MINIMAL RISKS				MIN. LOAD TREATMENT		
	hindrance	time investment	maintenance	assistive devices	dependence	esthetics	unrevealing	social burden	functional	quality grip	stability arm	availability	reliability	certainty results	complications	safety	duration treatment	duration intake	waiting period
FES	.12	.11	.11	.46	.38	.12	.11	.16	.52	.78	.50	.10	.18	.48	.15	.34	.33	.52	.31
Surgery	.89	.89	.89	.54	.62	.88	.89	.84	.48	.22	.50	.90	.82	.52	.85	.66	.67	.48	.69

In summary, the most important main requirements associated with a treatment option, according to the rehabilitation team, are functional arm-hand results (w=0.54), risks (w=0.21), and ease of use (w=0.17). In general, surgery combined with FES is preferred for its improvement of the arm-hand function. For example, the quality of the grip is considered to be superior if treated by FES. In contrast, conventional surgery without the implantation of a FES device scores better on most of the remaining sub-requirements. For example, after surgery the improved hand function is available 24 hours a day, the revised arm-hand function hinders the person with tetraplegia less, can be used in less time, requires less maintenance, and is less revealing.

Figure 2 shows an overview of the final weighting factors of the main requirements (in bars), the weighted preferences for the treatments in fulfilling these requirements (in lines), and the overall weighted preference for the treatments (end of the lines). The overall preference of the panel was 44% for surgery combined with FES versus 56% for conventional surgery.

Figure 2

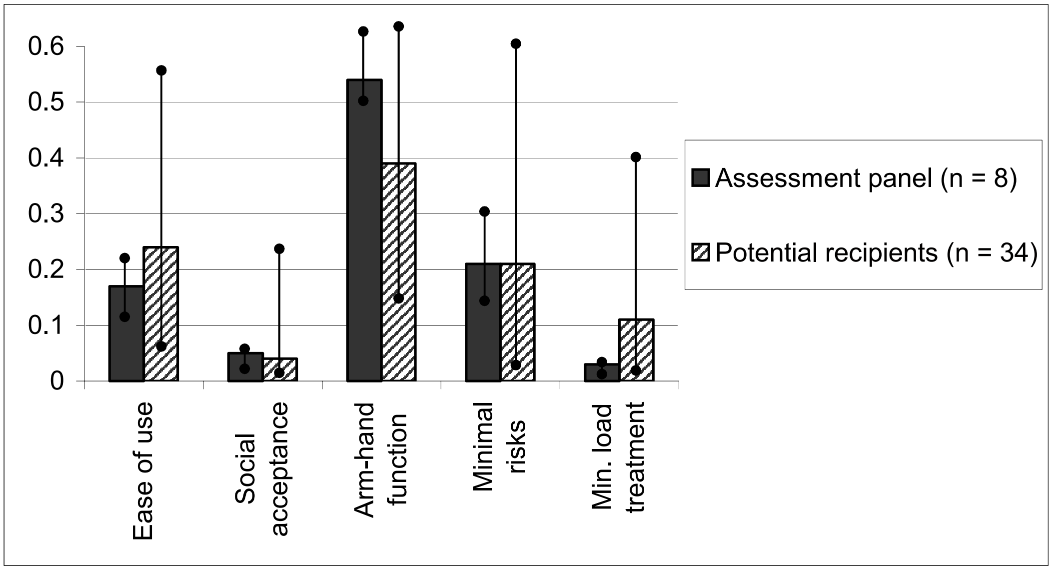


Importances of main requirements (in bars) and preferences for surgery with FES and for conventional surgery (lines).

The panel preferred surgery combined with FES for its improvement of the arm-hand function and this improvement is considered to be the most important requirement. Nevertheless, the overall (average-weighted) preference for conventional surgery is slightly higher than the preference for surgery with FES. This overall preference for conventional surgery is explained by, in order of decreasing influence on the overall outcomes, by the greater ease of use of the arm-hand function after surgery, the lower risks involved, the greater social acceptance and the lesser load of reconstructive surgery.

An important determinant of less ease of use after surgery with FES is that the FES system may hinder the person with tetraplegia. The FES equipment has to be put on and taken off every day, and has to be transported during the day. An important cause of the higher risks involved in the FES treatment is that, in addition to the normal complications of reconstructive surgery, failure of the FES system may necessitate surgical repair and the implanted parts may become infected and subsequently have to be removed [10].

Figure 3 Importances of the main requirements as rated by two groups



In the additional study, 34 potential recipients rated the importance of the main requirements.

Figure 3 shows the mean scores for importance of the main requirements as rated by the expert panel and the 34 potential recipients. The ranges of the importance scores for importance in both groups are also indicated in the figure. ANOVA analysis showed that the means of the scores for importance differ significantly between the two groups with regard to improvement of the arm-hand function ($p = 0.005$) and regarding the load of the treatment ($p = 0.01$). However, substitution of the expert panel scores for importance with the recipient scores for importance would not change the mean overall preference into a preference for surgery combined with FES rather than conventional surgery. Each recipient would have a slight preference for conventional surgery.

Discussion

Clinical trials about the application of new treatment technology generally focus only on the functional effects and/or safety of the new technology. However, besides functional outcome and safety, more treatment characteristics need to be considered in evaluating the performance of the treatment. A lack of knowledge about the performance in all aspects of assistive technology may result in the inappropriate allocation of treatment, which is likely to decrease patient satisfaction, and increase the costs of health care.

In the present study an experienced rehabilitation team in the field of upper extremity treatment for tetraplegia and a person with tetraplegia compared the performance of reconstructive surgery with FES with the performance of conventional surgery for subjects with a specific tetraplegic condition. This multidisciplinary team formulated technical, medical and social performance requirements. In more comprehensive panel evaluations, the amount of treatment options can be increased by adding, for example, the option of no medical intervention. Yet in this first evaluation we included two comparable treatment options that raise questions about the difference in performance with regard to each of these performance requirements and therefore would benefit from an in-depth discussion about all these requirements. The systematic procedure offered by the AHP helps to prevent important deficiencies in team decision-making such as failure to carry out all elements of the decision-making process, isolation from alternative opinions and dominance. Although such evaluations are still likely to take several hours, particularly when controversial technology is introduced such panel evaluations are important.

The results of [laboratory-based] assessments indicate that the FES system is able to enhance grasp and pinch better than conventional surgery [10]. In line with these results, the expert panel preferred surgical therapy combined with a FES implant above conventional surgery for its functional improvement of the arm-hand of “C6 motor group 2 persons with tetraplegia”. However, the overall preference for surgery with FES is rated slightly lower than the preference for conventional surgery. This is due to the greater ability of conventional surgery to meet other requirements, in particular with regard to the ease of using the hand after surgery and the low risks involved in this treatment. Moreover, if actual recipients values had been taken into consideration the balance would shift even more towards a preference for reconstructive surgery. This is supported by the experiences of the expert panel in rehabilitation practice. These results underline the need to evaluate rehabilitation technology more comprehensively, and not just to simply evaluate functional performance of technology. Functional outcomes alone cannot predict the acceptability of or satisfaction with assistive technologies.

The opinions of users and professionals from a variety of disciplines are needed to determine all the relevant performance requirements. The panel, as a whole, needs to be a well-balanced representation of individuals with relevant, state-of the art knowledge about each of the domains of rehabilitation. Each panel member can contribute with arguments that support the judgments in his or her specific domain. For example, the person with tetraplegia in the expert panel was not familiar with the performance of FES. However, he could contribute to the panel discussions in particular by explaining why certain performance requirements were more important than others.

The question that remains is whether a rehabilitation team should speak for the patient in respect with defining the requirements of treatment options and their relative importance's [16, 17.] This question is raised because, compared to the potential recipients, the expert panel rated the load of the surgery combined with FES to be less important and functional improvement of the arm-hand function to be more important. This is also observed in other studies [18,19] The comparison between the outcomes of the panel and outcomes of the subjects with tetraplegia can only be considered as a first exploratory pilot. Even though the subjects with tetraplegia were supported by the AHP, they did not experience the panel discussions, and they were not familiar with both types of treatment. In order to learn the opinions of potential recipients who have to make a choice of treatment, only potential recipients and not actual recipients of FES or conventional surgery were included. Bias in their opinions due to lack of experience is limited since they were only asked to rate the importance of the main requirements and not to judge the performance of the treatments. Furthermore, the potential recipients were not free in selecting the main performance requirements, because the expert panel did, in order to facilitate comparison between the two groups. Future research will compare the outcomes of the expert panel with the outcomes of actual recipients who have gained experience with the FES system or surgery to restore their arm-hand function.

The results of this study indicate the technology for which this specific rehabilitation treatment team had a slight preference when considering UE interventions for subjects with C6-motor group 2 tetraplegia in a specific clinical setting. Prior to the evaluation, the panel members did not receive a meta-analysis of the literature on these the treatment options. This evaluation was based on the panel's existing knowledge of the relevant literature, and the multidisciplinary knowledge that has been acquired in the treatment of persons with a

C6 tetragplegia in the specific treatment facility. One should note that FES is a relatively new treatment option, and experience needs to be gained with this treatment. Growing experience, an increasing body of literature on the performance of this treatment, and improvements of the FES systems [20] may influence the preferences for FES. According to our results, the impending improvement in the user-friendliness of the FES system is likely to be an important factor that can increase the preference for the FES system. In the early stages of clinical implementation, objective measurements of various aspects of the performance of new versus more established treatment options is limited. In future evaluation the AHP offers the possibility to integrate the results of well-designed studies on the performance of various different treatment options on one or more of the performance requirements, such as UE function or complication risk. Due to these factors, the outcomes of this panel evaluation can not be generalized to other treatment teams or to other circumstances. The essence of such panel evaluations is to reveal and discuss the arguments that support the preference of a treatment team in its own specific circumstances. This particular preference shapes the advice given by treatment teams or individual care-givers to patients.

The outcomes can be used as guidance in sharing information with individual patients. The importance of the requirements and preferences for the treatments can subsequently be attuned to their specific needs and characteristics. Our results show that the individual potential recipients have a relatively wide range of opinions about the importance of the performance requirements. In a quick screening procedure for a specific patient, the minimal requirements of the treatment options can be discussed. In clinical practice the option of no intervention at all should be included in this discussion. No intervention at all would be a disadvantage in the arm-hand function area, but would have advantages with regard to treatment load and risks. If a patient wants to be treated and a certain treatment option fails to meet the minimal requirements of this patient that specific treatment option should not longer be considered. For instance, if a patient does not want to consider implanted devices at all then surgery with FES implants does not need to be discussed. In order to choose between the acceptable treatment options, detailed discussions should take place between the rehabilitation team and the patient to determine the importance of the performance requirements for the patient and to compare the various treatment options.

Potential FES recipients, as well as rehabilitation professionals, have a lack of knowledge about the various factors that underlie the acceptance of assistive technology. [2] Comprehensive evaluations of rehabilitation technology, such as described in this study, are designed to reduce this lack of knowledge that is required in order to allocate the appropriate rehabilitation technology to potential recipients.

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[A] The Freehand system was developed by the Cleveland FES Center, departments of Orthopedics and Biomedical Engineering, Case Western Reserve University, Cleveland Veterans Affairs Medical Center, and MethroHealth Medical Center, Cleveland Ohio USA. It was available from The Neuro Control Corporation, 8333 Rockside Road, Valley View Ohio 44125 USA. Since 2003 this corporation has stopped the delivery of the system and to date no other firm has taken over this activity.

[B] TeamEC 2000 is commercially available at Expert Choice, Inc. 5001 Baum Boulevard, Suite 650, Pittsburgh, Pennsylvania 15213, USA. System requirements: 32 MB RAM and Pentium CPU, Windows 95, 98, Me, NT4, 2000 and XP.

Chapter 7

Practical implications for treatment of the upper extremity and use of preference -based techniques in rehabilitation medicine

[General discussion]

Introduction

Previous studies have indicated that patients with a cervical SCI consider improvement of upper extremity (UE) impairments very important. In addition, various studies show good functional results of augmentative reconstructive surgical procedures and patients who have undergone the procedures are satisfied with the results. However, clinical experiences show that patients with a tetraplegia who are suitable for reconstructive interventions of the UE decide not to undergo these procedures. The rationale for the present thesis was to study this discrepancy with the aim to determine the importance of improvement of UE function for patients with tetraplegia and the importance of treatment characteristics on the choice for reconstructive interventions.

Based on the results of this thesis, described in the previous chapters, this General Discussion comprises three sections that will focus on three important topics.

The first section will address possible consequences of the outcomes of our studies with regard to treatment of the upper limb in tetraplegia, in particular the potential effects of reducing the intensity of treatment.

The second section will discuss practical implications for SCI services. As a result of our studies, from a professional point of view it can be argued that reconstructive therapy should be concentrated in a limited number of specialised centres. However, due to the fact that inpatient rehabilitation time is a dominant negative factor, rehabilitation close to the patient's home environment is preferred. A model service delivery, which combines these two apparently contradictive preferences, is proposed in this section.

Finally, because the preference elicitation methods that were used in our studies have not been used before in rehabilitation research the third section of this chapter will discuss the application of preference-based techniques in the assessment of rehabilitation technology.

1. Potential effect of reducing the intensity of therapy

Both Chapters 5 and 6 demonstrated that potential subjects for reconstructive interventions of the upper limb consider factors related to the intensity or burden of treatment very important in deciding on therapy. It can be argued that factors that reduce the intensity or burden of treatment will have a positive effect on the relative preference for a given treatment scenario. Based on the treatment characteristics (attributes) described in Chapter 5, various different hypothetical treatment scenarios can be formulated. The relative preferences for these scenarios can be calculated with the exponent of the sum of the coefficients of the attribute-levels which were used to establish the various scenarios (see Table 3 in Chapter 5 for the coefficients). The effect of reducing the intensity of therapy on the preference for a treatment scenario will be demonstrated with two examples that reflect clinical controversies; i.e. the inpatient rehabilitation time and the number of operative procedures.

Example 1: reducing inpatient rehabilitation time increases preference for therapy
Currently, in the Netherlands as well as in other European countries patients often stay in the centres that carry out UE interventions for longer periods of time (up to 12 weeks). As demonstrated by the Conjoint Analysis study described in Chapter 5, the inpatient rehabilitation time is the most negative factor with regard to willingness to undergo therapy. As an example two treatment scenarios can be formulated: see example 1
The two scenarios are identical, except for the inpatient and outpatient rehabilitation time. Change in the total rehabilitation time of 12 weeks, from 12 to 4 weeks of inpatient treatment, results in a 26% [(0,63-0,37) x 100] higher relative preference for the scenario with 4 weeks inpatient treatment time. This example illustrates the effect of reducing inpatient rehabilitation time on preferences for augmentative treatment and the potential effect of such a measure on deciding to undergo augmentative treatment.

Example 2: reducing the number of operative procedures is preferred above functional outcome
Technical aspects of the surgical procedures, as well as user-friendliness of the control devices for implanted neural prosthesis, are a challenge in reducing the burden of treatment. With respect to surgical procedures, the possibility of carrying out a Deltoid Posterior to Triceps transfer and using the Brachio-Radialis muscle for wrist or finger activation in one operation instead of two separate operations is still under debate.[1-3]
The potential gain in preference for a treatment scenario with one operative procedure is demonstrated in example 2a.

Scenario A		Scenario B	
tendon transfer	0.28	tendon transfer	0.27
1 operation; 3 weeks cast at home	0.24	1 operation; 3 weeks cast at home	0.24
4 weeks inpatient rehabilitation	0.16	12 weeks inpatient rehabilitation	-0.38
8 weeks outpatient rehabilitation	0.1	none outpatient rehabilitation	0.14
complication risk 5%	-0.01	complication risk 5%	-0.01
no active elbow extension	-0.21	no active elbow extension	-0,21
moderately improved key & palmar grip	0.03	moderately improved key & palmar grip	0.03
Sum	0.59	Sum	0.08
Exponent	1.80	Exponent	1.08
Relative preference	0.63	Relative preference	0,37

Example 1

Scenario A		Scenario B	
tendon transfer	0.28	tendon transfer	0.28
1 operation; 3 weeks cast at home	0.24	2 operations; 2*3 weeks cast at home	-0.25
4 weeks inpatient rehabilitation	0.16	4 weeks inpatient rehabilitation	0.16
8 weeks outpatient rehabilitation	0.1	12 weeks outpatient rehabilitation	-0.21
complication risk 5%	-0.01	complication risk 5%	-0.01
active elbow extension	0.21	active elbow extension	0.21
moderately improved key & palmar grip	0.03	moderately improved key & palmar grip	0.03
Sum	1.01	Sum	0.21
Exponent	2.75	Exponent	1.23
Relative preference	0.69	Relative preference	0.31

Example 2a

In these scenarios the functional results are identical, except that scenario A entails a single operation and post-operative immobilisation period and the outpatient rehabilitation time is 4 weeks shorter. This results in a 38% higher preference for this scenario. In this respect the discussion about the number of operative procedures in relation to the burden of treatment factors and their influence on deciding on therapy is very interesting and worthwhile. Of course, technical aspects determine whether or not changes in treatment protocols are acceptable in relation to functional outcome. Interestingly, the study population described in Chapter 5 still favoured the scenario with 1 procedure and 4 weeks shorter outpatient treatment, even if this resulted in poorer functional outcome. This is demonstrated in example: 2b. A very much improved grasp function in scenario D with two operative procedures and a longer post-operative treatment period, versus a moderately improved grasp function in scenario C scarcely has any influence on the relative preference. Scenarios E versus F shows that even when there is a great difference in functional outcome at hand level there is still a slight preference for the scenario with one procedure and a shorter rehabilitation time.

The calculations in the examples are limited by the fact that only the attributes and levels which were defined and investigated in the Conjoint Analysis study described in Chapter 5 can be used. Other variations in therapeutic approach cannot be assessed. However, the attributes were developed by a local expert team with the help of five international experts and, in our opinion, they cover the spectrum of UE interventions accurately. The calculations give a good impression of what might be the effect of changes in treatment strategy. Conjoint Analysis has been proven to be a valid method with which to investigate the influence of health outcome and non-health outcome factors on health care preferences. However, the external validity has yet to be demonstrated by investigating whether actual changes in treatment scenarios result in increasing interest in and use of the interventions.[4]

Finally, some remarks about another aspect related to the “intensity of treatment”. In the current state of the art in UE-reconstructive interventions in patients with tetraplegia the operation takes place when the patient is in a stable neurological condition and has finished the initial rehabilitation treatment, including intensive UE therapy.

Scenario C		Scenario D	
tendon transfer	0.28	tendon transfer	0.28
1 operation; 3 weeks cast at home	0.24	2 operations; 2*3 weeks cast at home	-0.25
4 weeks inpatient rehabilitation	0.16	4 weeks inpatient rehabilitation	0.16
8 weeks outpatient rehabilitation	0.1	12 weeks outpatient rehabilitation	-0.21
complication risk 5%	-0.01	complication risk 5%	-0.01
active elbow extension	0.21	active elbow extension	0.21
moderately improved key & palmar grip	0.03	very much improved key & palmar grip	0.29
Sum	1.01	Sum	0.47
Exponent	2.75	Exponent	1.56
Relative preference	0.63	Relative preference	0.37

Scenario E		Scenario F	
tendon transfer	0.28	tendon transfer	0.28
1 operation; 3 weeks cast at home	0,24	2 operations; 2*3 weeks cast at home	-0.25
4 weeks inpatient rehabilitation	0.16	4 weeks inpatient rehabilitation	0.16
8 weeks outpatient rehabilitation	0.1	12 weeks outpatient rehabilitation	-0.21
complication risk 5%	-0.01	complication risk 5%	-0.01
active elbow extension	0.21	active elbow extension	0.21
moderately improved key	-0.32	very much improved key & palmar grip	0.29
Sum	0.66	Sum	0.47
Exponent	193	Exponent	1.60
Relative preference	0.55	Relative preference	0.45

Example 2b

The rationale behind this is that no intervention should be carried out when (even minor) neurological recovery is not complete. Furthermore, patients who have lived at home are able to determine which ADL skills they want to improve. In general, the procedures are not carried out until at least one year after the SCI. This means that patients who have (just) finished their initial rehabilitation and are trying to reinstate their lives in society have to interrupt this process for a new period of intensive treatment. Furthermore, all kind of strategies that they have learned in order to compensate for the impaired UE function will no longer be necessary or must be changed after surgery.

Our research on preferences for therapy and the weighting of treatment characteristics described in Chapters 4 and 5 was focussed on a group of subjects in a stable condition who had their SCI for a longer period of time. Research has shown that, in determining life satisfaction in patients with long lasting SCI, psychological and social factors are more important than the severity of the injury.[5] In the initial rehabilitation period, however, self-care goals are frequently considered to be most important by the patients.[6] Improvement of upper extremity function can contribute to achieving these goals. In this respect the Mulcahey et al. case report[7] concerning the application of the Freehand system during initial rehabilitation is very interesting. It would also be interesting to see if preferences for therapy and the weighting of treatment characteristics change over time, and differ in patients with a recent SCI. This needs to be investigated, and the results could be interesting in the discussion about the timing of the intervention.

In this respect it would also be challenging to investigate whether a potential sub-group of patients with tetraplegia could be selected for earlier intervention during the initial rehabilitation period. Such a sub-group could be trained to use the possibilities offered by these interventions during the initial rehabilitation period, and as a result, (surgical) upper extremity rehabilitation procedures after discharge could be avoided. Theoretically, potential candidates, and especially patients with complete injuries, could be selected on the basis of prognosis models.[8,9] This could also be considered for patients who according to the International Classification of the Upper Limb in Tetraplegia [10] show no further improvement, because this is the basis on which decisions for reconstructive interventions are made. In this respect, investigating recovery of UE function according to the International Classification of the Upper Limb in Tetraplegia during the first year after onset of SCI would be worthwhile.

2. Practical implications for SCI services in the Netherlands

In the previous section we showed that small protocol changes could change patient preferences for therapy.

In this respect the results of the studies described in this thesis should be discussed in relation to the current situation of SCI rehabilitation in the Netherlands. The incidence of SCI in the Netherlands is low, compared to other countries.[11] Patients with a new SCI are first admitted to a hospital, and patients with a traumatic SCI preferably to a hospital with special trauma care. After the acute treatment period in the hospital the patients are transferred to a rehabilitation centre for further treatment and rehabilitation.

The Dutch-Flemish Society for Paraplegia (NVDG) has formulated a set of quality requirements for specialised SCI units.[12] Related to the incidence of SCI in the Netherlands the number of specialised SCI units (established in 8 rehabilitation centres) is high compared to other countries [12] and is (more then) sufficient to meet these quality requirements with regard to the minimal number of newly admitted patients per year. With regard to UE reconstructive interventions, clinical experience as well as the results of our studies indicate that, in fact, only a relative small number of patients per year will decide to undergo reconstructive UE interventions. In order to achieve and maintain clinical and technical skills in the complex field of these interventions, not all eight specialised SCI units should aim at offering this therapy to their patients. Concentration, for instance in 2 or 3 units, where specialised SCI-UE rehabilitation teams work closely together with experienced UE surgeons, should be seriously considered and recommended. However, as demonstrated, the inpatient treatment time has great influence on the decision for therapy. This is in contrast to the need to concentrate this therapy in a few centres, because this would force people to travel for longer distances or to accept longer admission times. In this respect, flexible solutions must be found, and these are possible. The NVDG is an excellent forum for the formation of “joint ventures” with regard to UE reconstructive interventions, and probably also for other specialised therapies for small numbers of SCI patients. In this model, as much as possible of the screening procedure for the intervention, as well as the rehabilitation after surgery should be carried out in the unit which refers the patient. This SCI unit is assisted by the UE-specialised SCI unit. This specialised unit carries out the final examination before surgery, formulates the treatment plan in close collaboration with the referring unit and of course the patient, carries out the intervention and also the first phase of the therapy after removal of the cast. The patient will then return to his own unit for further therapy. This unit stays in contact with the specialised unit for advice and help. The actual possibilities of telemedicine [13-15] could be very useful in this process, and it would be very worthwhile and challenging to embark on a project to establish such collaboration in the near future as a practical follow-up of the research described in this thesis.

In this model the patients only have to be admitted to the specialised unit for a few days for the surgical intervention and again for a short period for cast removal, wound control and the initiation of functional training. The rest of the therapy can take place in the patients own centre, preferably on an outpatient basis. As demonstrated above, this will have a positive effect on the relative preference for an UE intervention scenario. In this respect the proposed model could have a positive effect on the decision for reconstructive interventions and as a result more patients might benefit from potentially very beneficial therapy.

Preference-based assessment of rehabilitation technology

The studies described in this thesis used methodology that has not been used in rehabilitation medicine before. Technical innovations in health care are developing rapidly, and also in rehabilitation medicine the technical aspects of treatment technologies are also increasing.[16-19] In decisions concerning the development and application of these techniques the opinion of the public and/or patients is increasingly considered to be a very important criterion.[20] Furthermore, differences in clinician and consumer preferences emphasize the importance of patient-oriented goals.[21] In this respect, the following aspects will be discussed: the multi-factorial evaluation of use of health care utilisation and performance of technology, the use of scientifically valid methods to investigate patient and clinician preferences, the concept of shared-decision making, and finally, the positioning of these techniques in outcome research in rehabilitation medicine.

Multi-factorial evaluation

In our studies we focussed on the evaluation of patient preferences for interventions and the evaluation of treatment-related factors in the decision for therapy. The actual utilisation of health care services is even more complex, and depends not only on treatment characteristics but also on a number of factors such as environmental factors, population characteristics and health behaviour.[22] In our studies the influence of environmental factors is partially demonstrated by the relative importance of inpatient rehabilitation time in the decisions concerning upper extremity interventions. Other non-health outcome or health-process factors were not assessed, and their effect on decision concerning UE interventions in tetraplegia is still unknown and remains a topic for further research.

Evaluation of the performance of new technology should not be based on functional outcome alone. The use of choice-based multi-criteria assessment techniques makes it possible to take all relevant aspects into account in the evaluation. Although to date these methods have not yet been used in rehabilitation medicine research, they have been used successfully in other areas of health care research and were found to be applicable and valid.[4,20,23-25] Our studies show that they are also applicable for research in rehabilitation medicine. The use of the appropriate medical decision techniques can contribute to scientifically based decision-making with regard to the priority, allocation and development of specific rehabilitation technology and should be considered as a standard tool in assessing the potential use and relevance of new techniques. Many examples can be given for research, such as: the application of various techniques to treat the spastic equino-varus foot in stroke patients, the application of various techniques to treat neurogenic bladder and bowel dysfunction in tetraplegia; and the application of various techniques to treat general spasticity in SCI-MS-CP patients.

Just as the clinician and the engineer have to work closely together in the application of rehabilitation technology, in the evaluation of decision-making concerning these technologies the clinician and the medical decision expert must collaborate closely. The future of rehabilitation technology will benefit, and it will probably be determined by the triad “technician-clinician-decision”.

Using appropriate preference elicitation methods

For many years the Hanson and Franklin study [26] has been cited and used to emphasise the importance of improvement in the upper extremity function of subjects with tetraplegia. The survey among a large sample of subjects with tetraplegia, described in Chapter 2, confirms the findings of the Hanson and Franklin study and the clinical experience that UE impairments have a great impact on the quality of life and level of autonomy of individuals with a tetraplegia. This study showed that the impact of UE impairments on the lives of people with tetraplegia is of the same order as the impact of bladder and bowel dysfunction. The latter was a well known fact that was demonstrated by a number of studies which also evaluated a number of other impairments.[27 references 1-10] However, as discussed in Chapter 2, these results cannot be translated into expectations about actual willingness to undergo UE reconstructive interventions. The actual decision for treatment involves a choice between various options, the pros and cons of which should be evaluated. For example, in the process of deciding about a reconstructive UE intervention there are various alternatives: an intensive procedure with maximal benefit at the cost of considerable discomfort and risk, a limited procedure with less discomfort and/or risk, or not doing anything at all and thus avoiding the discomfort and risk at the cost of unchanged severely impaired UE. Choice based methods should be used to study the actual willingness of patients to undergo interventions.[28,29] In the study described in Chapter 4 a preference elicitation method (TTO) was used. The results showed that improvement in bladder and bowel function, improvement in sexual function, improvement in standing and walking and improvement of UE function all significantly improved the health state utility, but no differences were found between the four impairments. In other words, we could not demonstrate a hierarchy in the importance of impairments as judged by the patients. In this respect, discussing “the most important impairment” in patients with (cervical) SCI, or that which should receive the most attention from a general patient’s point of view is useless, because there is no scientific evidence, based on assessment with appropriate research techniques, to support this.

Earlier Studies have shown that the preferences of clinicians and patients can differ.[30-32] Our studies, described in Chapters5 and 6, show that the patients considered treatment characteristics related to the intensity or “burden” of treatment to be very important, and that the clinicians tended to focus more on functional outcome. These differences may play an important role in the opinions of the patients and the clinicians with regard to their preference for reconstructive interventions and in the decision-making. Clarification of these differences is important for an optimal dialogue between the providers and the consumers of clinical services.

Shared decision-making

The research described in this thesis focussed mainly on subjects with tetraplegia at group level. At individual level a subject with tetraplegia and, more in general, a subject who is treated by a multi-disciplinary rehabilitation treatment team, is regularly confronted with various treatment options and a choice has to be made. In this respect the concept of shared decision-making is interesting. Although this is not the focus of the research in this thesis there are some relationships with the outcomes of our studies which can be discussed.

Three broad movements have influenced medical-decision making in the past decade. The concept of evidence based medicine is mainly concerned if the strategies involved are of proven clinical effectiveness. The cost-effectiveness strategy focuses mainly on the aspect of cost in deciding on a treatment option. Preference-driven or patient-centred medicine mainly implies that patient and public preferences steer clinical decisions. Because pure evidence-based medicine neglects the uniqueness of patients and their individual needs, neglecting costs will cause allocation problems due to scarce resources, and taking only patient preferences into consideration is better ideologically than evidence based, the gaps between these concepts should be bridged in order to achieve optimal medical decision-making.[33] Decision analysis-based medical decision-making offers the opportunity to combine the principles of these paradigms into a shared decision-making process between clinician and patient.[34] Haynes et al. describe a new model of an evidence-based medical decision in which patient preferences, clinical state and research evidence are combined, and in which clinical expertise is necessary to weight these factors in order to make a balanced final decision.[35] The importance of this model is illustrated by our findings in the multi-criteria decision studies described in Chapters 5 and 6. Patients and clinicians gave different weights to various treatment characteristics, and the clinicians must be aware of this situation when advising and treating their patients. However, in our Conjoint Analysis study, over 40% of the patients focussed on one treatment aspect only in deciding for therapy. Other studies show that it is very difficult for patients to make balanced complex decisions about therapy fully independently and they tend to follow expert advice even if this advice is clearly wrong.[36] This demonstrates the importance of good clinical guidance in decision-making concerning therapy.

A variety of decision-making programmes, based on medical decision-making techniques such as AHP and CA, have been developed and used, for instance, in rheumatology and cancer treatment. These programmes have not yet been developed for rehabilitation medicine. Although a lot of questions have to be answered in regard to the content and complexity of these decision aids and the patients who will benefit from them, [37-41] it is very interesting and worthwhile to explore the possibilities of shared decision-making in rehabilitation medicine, because many of the decisions involved are elective, multi-factorial and multidisciplinary.

Positioning choice-based health outcome research in models of outcome assessment in rehabilitation

In our TTO study, described in Chapter 4, we investigated the preference for surgical UE interventions in subjects with tetraplegia. These interventions aim at (partially) restoring function in and activities performed with the upper extremities. These are two important domains of outcome in rehabilitation medicine, as defined by the World Health Organisation (WHO) in the International Classification of Functioning and Disability (ICF) which was developed on the basis of the International Classification of Impairments, Disabilities and Handicaps (ICIDH).[42,43] The third domain in this model is participation, which may also be influenced by the interventions. The preference for the interventions in our TTO study was expressed as preference for a health state, i.e. a health state with improved UE function after the intervention. The health state determines the health-related quality of life, [44,45] which is part of the overall concept of quality of life (QOL) defined as a superordinate construct containing both health and well-being,[46] and this is another important outcome model in health-related research.[47] So far, these models have been developed and used separately, although there have been attempts to extend the ICIDH.[46] Post et al. propose and advocate a model in which the QOL model and the ICIDH model are integrated [46,48] to serve as a framework in which different subjective and objective outcomes can be positioned in relation to each other. Other proposals to integrate quality of life assessment in rehabilitation have also been published.[49] In our TTO study a potential choice for interventions which aim at improving function and activity (ICF model) are expressed as preferences for a (potential) health state (QOL model) after the intervention. This demonstrates the applicability and necessity of a combined model for outcome research.

Health-related quality of life assessment instruments, such as the SF-36 and the SIP, which are widely used,[45] evaluate the perception of the present health state which is the result of treatment and other measures which have been undertaken to achieve this state. In contrast, experimental choice-based methods, such as the TTO, provide information about preferences for health outcome or, in other words, preference for a potential health state after future therapeutic intervention. These methods have been reported to be reliable in assessing preferences for health outcome.[50] Although many other factors in addition to health outcome determine actual health care utilisation, as discussed above, choice-based methods also provide, to a certain extent, information about patient behaviour. This information, in addition to the revealed perception of the present health state assessed by instruments such as the SF-36, can be used in the choice for and the development of treatment programmes to improve this health state. In this respect choice-based methods should be integrated in the combined model for outcome research in rehabilitation medicine.

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Summary

A number of studies have reported on the relationship between the level of Spinal Cord Injury (SCI) and the degree of self-care and mobility. Rehabilitation therapy aims at achieving optimal independence within the constraints of neurological deficit. In this respect, adequate therapy of the upper extremities in individuals with tetraplegia is very important.

Therapy of the upper extremities can be sub-divided into 3 phases: the acute phase, the sub-acute phase, and the reconstructive phase. Reconstructive surgery or, more recently, the application of neuroprostheses, can be considered in certain selected cases during the third phase. The aim of these procedures is to improve upper extremity function and, more importantly, upper extremity skills. The results of these procedures have been reported in a number of studies. In general, the results are good and the patients who have undergone these procedures are satisfied with the results. Various studies indicate that approximately 60% of the population with tetraplegia could benefit from reconstructive surgery, and that approximately 10% of this population might be suitable candidates for functional electrical stimulation (FES) implants.

However, clinical practice has shown that suitable patients for reconstructive upper extremity procedures often decide not to undergo these procedures. In this respect it is relevant to know how important improvement of upper extremity function is for individuals with tetraplegia and what factors influence the decision to undergo reconstructive procedures. These questions are the focus of the present thesis.

Chapter 2 describes a study that was carried out to investigate the impact of upper extremity deficit in subjects with tetraplegia, compared to the impact of other impairments.

A survey was sent to all the members of the Dutch and UK Spinal Cord Injury (SCI) Associations. They were asked to indicate on a 5-point scale the improvement in quality of life (QOL) they expected to achieve from improvement in hand function and 7 other SCI-related impairments. The overall response was 42%; 426 of the 700 Dutch questionnaires (61%) and 1122 of the 4800 UK questionnaires (23%) were returned. A total of 565 subjects had a tetraplegia and it is arguable that the tetraplegic sample covers the spectrum of cervical SCI. The results in the Dutch and the UK groups were comparable. Overall, 77% of the subjects with tetraplegia expected an important or very important improvement

in QOL if their hand function improved. This is comparable to their expectations with regard to improvement in bladder and bowel function. All other items were scored lower. This study is the first in which the impact of impairment in hand function has been assessed in a large sample of tetraplegic subjects and relatively compared to other SCI-related impairments. The results indicate a high impact and a high priority for improvement in hand function in tetraplegics, comparable to that for bladder and bowel dysfunction, which is known to have great impact on the lives of SCI patients.

The objective of the study described in Chapter 3 was to explore possible functional effects of the Handmaster-FES system in subjects with tetraplegia. The Handmaster is a non-invasive FES system, and can be regarded as a third-phase treatment option with relatively less intense treatment characteristics than other more invasive treatment options in this phase.

Ten patients with cervical spinal cord injury between C4 and C6, motor group 0-3, were consecutively selected from the inpatient and outpatient department of the Roessingh Rehabilitation Centre. Each patient was fitted with a Handmaster by a qualified therapist, and underwent muscle strength and functional training for at least two months. Functional evaluation was based on the performance of a predefined set of tasks and at least one additional task selected by the patients themselves. The tasks were performed both with and without the Handmaster. Finally, the patients were asked to give their opinion on actual use of the Handmaster as well as their willingness with regard to future use.

Six patients were able to grasp and release with Handmaster stimulation. Four patients could perform the set of tasks with the Handmaster, but were not able to do so without the Handmaster. Upper extremity function improved in three patients after the training period. One patient continued using the Handmaster during ADL at home, and this patient was the only one who succeeded in performing all the tasks he selected with the Handmaster

Based on our clinical experiences, we concluded that the Handmaster could be of functional benefit for a limited group of patients with a C5 level spinal cord injury, motor group 0 and 1. Suitable patients should have sufficient shoulder and biceps function, combined with absent or weak wrist extensors. Furthermore, the Handmaster should improve skills which are important for the patient. This case series showed that the therapeutic use of the Handmaster can also be considered in subjects with tetraplegia.

In the study described in Chapter 2, a non choice-based method was used to estimate the importance of improvement in various impairments. The advantage of such a method is that it is relatively easy to apply. However, there are some theoretical drawbacks. If a method to assess preference involves no actual choice, no trade-off can be observed, and no exact comparison can be made between the preferences assessed in this way. Therefore, further and more precise research was carried out. In the study described in Chapter 4 a choice-based preference elicitation method , the Time Trade Off (TTO) method, was used to determine the quality weight of five tetraplegic health states, and expressed as a single value (the "utility") on a scale between 0 (worst possible situation) and 1 (best possible situation).
A second objective was to evaluate the effect of patient characteristics as well as functional status on the utility of the tetraplegic health state without upper extremity impairments.
A consecutive sample of 47 individuals with tetraplegia in a stable condition, recruited in the outpatient department of two specialised Spinal Cord Injury Centres in the Netherlands, was assessed.
The utility of tetraplegia was 0.57 (SD 0.30). The utilities of tetraplegia without impairment in one of the following functions were: sexuality 0.69 (SD 0.33), standing/walking 0.69 (SD 0.33), bladder and bowel function 0.63 (SD 0.31), and upper extremity function 0.65 (SD 0.32). The differences between these utilities and the utility of tetraplegia were significant ($p< 0.05$). No significant differences were found between the utilities of the impairments. Improvement of a specific impairment contributed between 14% and 28% to the potential overall gain in the utility of the tetraplegic health state. The results of multivariate regression analysis did not indicate a significant set of determinants for the utility of tetraplegia without impaired upper extremity function.
We concluded that, in general, in subjects with long-lasting SCI a combination of impairments is responsible for the low utility of the tetraplegic heath state. Improvement in major impairments results in a significant improvement in the utility of the tetraplegic health state. However, no differences were found between the utility of the tetraplegic health state without impaired upper extremity function and the utility of the tetraplegic health state without three other major impairments respectively.
The TTO method enabled the explanation of the discrepancy between the number of patients who are suitable for surgical treatment, their self reported importance of improved

upper extremity function, and the low number of patients who proceed to surgical treatment in a broad sample of individuals with tetraplegia.

Based on the results of the TTO study, it can be argued that there is no single most important impairment to be treated in tetraplegia, and the decision to treat impairments is based on individual considerations. The decision to undergo treatment is based on a variety of criteria, and multi-criteria decision analysis techniques can be used to study the effect of the various criteria on the decision. The aim of the study described in Chapter 5 was to assess the effect of non-health outcome factors in relation to the effectiveness of the intervention on the decisions of subjects with tetraplegia concerning reconstructive UE interventions. In a sample of 49 individuals with tetraplegia in a stable condition, recruited in the outpatient departments of seven specialised Spinal Cord Centres in the Netherlands, the importance and the relative weight of 7 treatment characteristics on the decision to undergo reconstructive surgery was determined by means of Conjoint Analysis (CA). All 7 characteristics contributed to the decision to undergo surgery ($p< 0.01$). The relative weights were: for type of intervention 0.14 (95% confidence interval [CI] 0.05-0.23), for number of operations 0.15 (95% CI: 0.05-0.25), for inpatient rehabilitation period 0.22 (95% CI: 0.10-0.32), for outpatient rehabilitation period 0.08 (95% CI: 0.02-0.14), for risk of complications 0.16 (95% CI:0.06-0.26), for results of elbow function 0.1 (95% CI:0.02-0.18), and for results of hand function 0.15 (95% CI: 0.05-0.25). In 40.8% of the subjects one characteristic had a relative weight of 0.30 or more.
We concluded that the study demonstrates the applicability of CA in rehabilitation and spinal cord injury research to study the effect of health outcome and non-health outcome factors on the decision to undergo therapy. With regard to reconstructive UE interventions, in subjects with tetraplegia non-health outcome factors indicating the intensity or burden of the treatment are as important or even more important than outcome with regard to hand or elbow function in their decisions concerning therapy. The inpatient rehabilitation period was the most important factor. The fact that over 40% of the subjects focused on only one treatment characteristic in deciding about therapy is important knowledge for clinicians when informing patients about therapy.

With regard to upper extremity interventions, patients are advised and treated by multidisciplinary teams. Although these teams have to work closely together, and are very co-ordinated, the members of the team each have their own experience, knowledge and opinion about the application of therapy. This not only has an implicit effect on the opinions and advice of the team as a whole, but also on the individual advice that team members give to their patients. It is important to be aware of this situation and in complex therapies both team opinions and individual opinions about the application of therapy should be made explicit. In the study described in Chapter 6, another multi-criteria decision method, the Analytic Hierarchy Process (AHP), is used to support the evaluation of the importance of treatment characteristics of reconstructive interventions of the upper extremities (UE) by a rehabilitation team and a group of subjects with a C6 level tetraplegia. Furthermore, the performance of two different treatment approaches (conventional upper extremity reconstructive surgery and reconstructive surgery combined with FES) for the upper extremity in a patient with a C6 motor group 2 tetraplegia were evaluated by the rehabilitation team. The main treatment requirements with their relative importance, as determined by the rehabilitation team and the patients (rehab.team/patients), were: functional improvement (.54/.39), treatment load (.03/.11), risks (.26/.21), user-friendliness (.17/.25) and social outcomes (.05/.04). The differences between the ratings of the rehabilitation team and the patients were significant for improvement of the arm-hand function ($p = 0.005$) and the treatment load ($p = 0.01$). In evaluating both treatment options, functional improvement after FES was considered to be better than conventional surgery. Yet, the overall rating of the rehabilitation team for conventional surgery was slightly higher than for FES (56% versus 44%), based on the better performance of conventional surgery with regard to the other treatment requirements.
We concluded that this study demonstrates that the evaluation of new technology has to be more comprehensive than evaluation of functional improvement alone. Furthermore, it demonstrates that the preferences of patients may differ from the preferences of the rehabilitation team.

In Chapter 7 the most important findings of our research are discussed with regard to the implications for treatment of the UE in tetraplegia, the organisation of SCI services and

future research on treatment of the UE in tetraplegia. Also discussed is the use of choice-based and multi-criteria decision methods to assess rehabilitation technology.

Samenvatting

Bij mensen met een dwarslaesie is er een relatie tussen de hoogte en de ernst van de laesie en het niveau van zelfstandigheid bij activiteiten van het dagelijks leven.
De revalidatiegeneeskundige behandeling van deze mensen is erop gericht om een zo hoog mogelijk niveau van zelfredzaamheid te bereiken. In dit verband is bij mensen met een cervicale dwarslaesie waarbij de arm- handfunctie is aangedaan, de behandeling van de bovenste extremiteiten van groot belang.
Deze behandeling kan worden onderverdeeld in een 3-tal fasen: de acute fase, de subacute fase en de reconstructieve fase. In de laatste fase kan, bij patiënten die aan bepaalde criteria voldoen, de toepassing van reconstructieve chirurgie en/of de toepassing van neuroprothesen worden overwogen. Het doel van deze behandeling is de functie en, belangrijker, de vaardigheden van de bovenste extremiteiten te verbeteren. Over het algemeen zijn de resultaten van deze behandeling, beschreven in een groot aantal artikelen, goed en ook de patiënten welke deze behandeling hebben ondergaan zijn doorgaans tevreden met de behaalde resultaten. Studies geven aan dat ± 60% van de mensen met een hoge dwarslaesie in principe geschikt is voor reconstructieve chirurgie en dat ± 10% van deze populatie een geschikte kandidaat voor de implantatie van neuroprothesen (functionele elektrostimulatie systemen) is. De klinische praktijk wijst echter uit dat het zeer regelmatig voorkomt dat patiënten die een goede kandidaat voor deze behandelingen zijn besluiten om deze behandeling niet te ondergaan. Dit brengt de vraag naar voren hoe belangrijk mensen met een hoge dwarslaesie de verbetering van de arm- handfunctie vinden en welke factoren het besluit om deze behandeling te ondergaan beïnvloeden. Deze vragen worden in dit proefschrift nader onderzocht.

Hoofdstuk 2 beschrijft een studie naar de invloed van arm- handfunctie stoornissen op het leven van mensen met een hoge dwarslaesie, in vergelijking met de invloed van een aantal andere problemen ten gevolge van de dwarslaesie. Hiertoe werd een vragenlijst gestuurd naar de leden van de Nederlandse en Engelse dwarslaesie patiëntenorganisaties. In deze enquête werd aan de deelnemers gevraagd aan te geven in hoeverre men verwachtte dat verbetering van de arm- handfunctie de kwaliteit van leven zou verbeteren. Dit werd aangegeven op een 5-punts schaal. Dezelfde vraag werd gesteld met betrekking tot een 7-tal andere problemen ten gevolge van de dwarslaesie. De totale respons was 42%, 426 van de 700 Nederlandse enquêtes en 1122 van de 4800 Engelse enquêtes werd geretourneerd. Van

deze personen hadden 565 mensen een tetraplegie. Op basis van de demografische gegevens van deze populatie kan worden beargumenteerd dat deze groep het totale spectrum van cervicale dwarslaesie beslaat. De resultaten in de Nederlandse en Engelse groep waren vergelijkbaar. Van de mensen met een tetraplegie gaf 77% aan een belangrijke tot zeer belangrijke verbetering van de kwaliteit van leven te verwachten indien de handfunctie zou verbeteren. Dit was vergelijkbaar met de verwachtingen ten aanzien van toename van de kwaliteit van leven bij verbetering van blaas- en darmfunctie. Alle andere items hadden lagere scores.
Deze studie is de eerste studie waarin de invloed van arm- handfunctie stoornissen werd onderzocht in een grote groep mensen met een tetraplegie en werd vergeleken met andere problemen ten gevolge van de dwarslaesie. De resultaten geven aan dat arm- handfunctie stoornissen een grote invloed hebben op het leven van mensen met een hoge dwarslaesie, vergelijkbaar met de invloed van blaas- en darmfunctie stoornissen waarvan al langer bekend is dat deze een forse invloed hebben op de levenskwaliteit van mensen met een dwarslaesie.

In hoofdstuk 3 wordt een studie beschreven waarin de verbetering van de arm - handfunctie bij mensen met een cervicale dwarslaesie door toepassing van een Handmaster elektrostimulatie systeem werd nagegaan. Hiertoe werden 10 personen met een cervicale dwarslaesie tussen niveau C4 en C6, motor groep 0-3 volgens de Internationale Classificatie van de Bovenste Extremiteit bij Tetraplegie, geselecteerd uit de poliklinische patiëntenpopulatie van het Roessingh. Elke patiënt werd voorzien van een Handmaster welke werd aangemeten door een hiervoor speciaal opgeleide therapeut. Aansluitend kregen de patiënten gedurende minstens 2 maanden gerichte therapie met deze voorziening. De effecten werden geëvalueerd door middel van het uitvoeren van een aantal handvaardigheden door de patiënt. Deze test bestond uit een aantal gestandaardiseerde taken en tenminste één taak welke door de patiënt zelf was bepaald. De taken werden zowel met als zonder Handmaster uitgevoerd. Tevens werden patiënten gevraagd naar hun mening over de voorziening en mogelijk gebruik hiervan in de toekomst. Bij zes patiënten was het mogelijk een gestimuleerde greep met behulp van de Handmaster te verkrijgen. Vier patiënten lukte het de set standaardtaken met de Handmaster uit te voeren terwijl dit niet

mogelijk was zonder de Handmaster. Bij drie patiënten verbeterde de functie van de bovenste extremiteiten na de trainingsperiode met de Handmaster.
Eén patiënt bleef de Handmaster gebruiken bij ADL activiteiten na afronding van het onderzoek. Dit was de enige patiënt welke erin slaagde succesvol de door hem zelf gedefinieerde taken met de Handmaster uit te voeren.
Gebaseerd op de klinische ervaringen met deze beperkte groep patiënten concludeerden wij dat de Handmaster bij een beperkte groep patiënten met een C5 dwarslaesie, met motor groep 0 en 1, functionele meerwaarde heeft. Voorwaarden zijn dat deze patiënten een goede schouder- en bicepsfunctie hebben in combinatie met afwezige of zwakke functie van de pols extensoren. Belangrijk is ook dat met de Handmaster activiteiten kunnen worden uitgevoerd welke voor de patiënt belangrijk zijn. Naast functioneel gebruik kan ook therapeutisch gebruik van de Handmaster worden overwogen.

In de studie die is beschreven in hoofdstuk 2 werd een methode toegepast om het belang van verbetering van diverse dwarslaesieproblemen te onderzoeken waarin de patiënt geen keuze behoefde te maken tussen diverse alternatieven. Het voordeel van een dergelijke methode is de relatief simpele toepasbaarheid. Er zijn echter ook theoretische bezwaren aan dergelijke methoden aangezien zij geen werkelijk keuzemoment bevatten. Hierdoor is exacte vergelijking tussen preferenties voor verbetering van diverse problemen niet mogelijk. Om deze reden vond verder onderzoek hiernaar plaats, waarbij gebruik werd gemaakt van een methode waarbij de patiënten een nadrukkelijke keuze moesten maken. Dit onderzoek is beschreven in hoofdstuk 4. De zogenoemde TimeTrade Off methode werd gebruikt om vijf verschillende tetraplegische gezondheidstoestanden te waarderen. Deze waardering werd uitgedrukt als een getal op een schaal van 0-1 waarbij 0 de slechtst denkbare en 1 de best denkbare gezondheidstoestand aangeeft. Een tweede doel van het onderzoek was om het effect van persoonskarakteristieken na te gaan op de waardering van een hypothetische tetraplegische gezondheidstoestand zonder arm- handfunctie stoornissen. Aan dit onderzoek werkten 47 patiënten met een hoge dwarslaesie mee welke werden gerekruteerd uit de polikliniekbestanden van twee revalidatiecentra met een gespecialiseerde dwarslaesie afdeling. De waardering (de zogenaamde utiliteit) van de tetraplegische gezondheidstoestand was 0.57 (SD 0.30). De utiliteit van de tetraplegische gezondheidstoestand zonder stoornissen van seksuele functies was 0.69 (SD 0.33), zonder

sta- en loopproblemen 0.69 (SD 0.33), zonder blaas- en darmfunctie problemen 0.63 (SD 0.31) en zonder arm -handfunctie stoornissen 0.65 (SD 0.32). De verschillen tussen de tetraplegische gezondheidstoestand en de de tetraplegische gezondheidstoestand zonder de genoemde problemen waren significant ($p<0.05$). Er werden geen significante verschillen gevonden tussen de utiliteiten van de diverse gezondheidstoestanden minus één van de genoemde problemen. De verbetering van één specifiek probleem draagt tussen 14% en 28% bij aan de potentiële totale verbetering in waardering van gezondheidstoestand bij volledige genezing van de dwarslaesie. Multivariate regressie analyse leverde geen significante set van determinanten op voor de utiliteit van de tetraplegische gezondheidstoestand zonder arm- handfunctie stoornissen.
In conclusie kan worden gesteld dat bij patiënten met een langer bestaande cervicale dwarslaesie de combinatie van de dwarslaesie gerelateerde problemen de lage utiliteit van de tetraplegische gezondheidstoestand bepaalt. De verbetering van een separaat ernstig dwarslaesie gerelateerd probleem resulteert in significante verbetering van de utiliteit van de gezondheidstoestand. Er konden echter geen verschillen tussen de diverse onderzochte problemen worden aangetoond. Het gebruik van de Time Trade Off methode maakt het mogelijk om de discrepantie tussen potentieel geschikte patiënten voor chirurgische behandeling, het door patiënten zelf gerapporteerd belang van verbetering van arm-handfunctie en het relatief geringe aantal patiënten dat daadwerkelijk een dergelijke behandeling ondergaat te verklaren.

Op basis van de resultaten van de Time Trade Off studie kan worden gesteld dat er niet “een meest belangrijk” dwarslaesie probleem kan worden gedefinieerd en dat de beslissing om dwarslaesie gerelateerde problematiek te behandelen gebaseerd is op strikt individuele afwegingen.
Het besluit om een behandeling te ondergaan berust op een groot aantal criteria. Zogenaamde multi-criteria besluitvormingsanalyse technieken kunnen worden ingezet om het effect van verschillende criteria op het besluit om een behandeling te ondergaan te onderzoeken. In hoofdstuk 5 wordt een studie beschreven waarin een dergelijke techniek, Conjoint Analyse, wordt gebruikt om het effect van behandelkarakteristieken op het besluit van mensen met een hoge dwarslaesie om reconstructieve interventies van de armen te ondergaan te onderzoeken. Hiervoor werd een groep van 49 patiënten met een tetraplegie in

een stabiele algehele situatie gerekruteerd uit de controlebestanden van de polikliniek van zeven revalidatiecentra met een gespecialiseerde dwarslaesie afdeling. Het belang en het relatieve gewicht van 7 behandelkarakteristieken bij de besluitvorming om reconstructieve chirurgie te ondergaan werd onderzocht. Alle onderzochte behandelkarakteristieken droegen significant bij aan de besluitvorming om de behandeling te ondergaan ($p<0.01$). De relatieve importanties van de behandelkarakteristieken waren respectievelijk: voor interventietype 0.14 (95% betrouwbaarheidsinterval (BI) 0.05-0.23), voor aantal operaties 0.15 (95% BI: 0.05-0.25), voor klinische revalidatieduur 0.22 (95% BI: 0.10-0.32), voor poliklinische revalidatieduur 0.08 (95% BI: 0.02-0.14), voor risico op complicaties 0.16 (95% BI: 0.06-0.26), voor verbetering van elleboogfunctie 0.1 (95% BI: 0.02-0.18) en voor verbetering van handfunctie 0.15 (95% BI: 0.05-0.25). Bij 40.8% van de personen had één behandelkarakteristiek een relatieve importantie van 0.30 of hoger. De conclusie van deze studie was dat Conjoint Analyse goed toepasbaar is in revalidatiegeneeskundig/ dwarslaesie onderzoek om het effect van behandelkarakteristieken op het besluitvormingsproces om therapie te ondergaan te onderzoeken. Met betrekking tot reconstructieve interventies van de bovenste extremiteiten bij mensen met een tetraplegie zijn factoren gerelateerd aan de zwaarte van de behandeling minstens even belangrijk als verbetering van hand- of elleboogfunctie bij de besluitvorming voor therapie. Van deze factoren was de klinische revalidatieduur het meest belangrijk.
Het feit dat meer dan 40% van de mensen de keuze voornamelijk laat afhangen van één behandelkarakteristiek is belangrijke informatie voor behandelaars bij het informeren van hun patiënten.

De behandeling van de bovenste extremiteiten bij mensen met een tetraplegie wordt geadviseerd en uitgevoerd door een multidisciplinair team. Binnen deze teams moet goed afgestemd op elkaar worden behandeld. Elk teamlid heeft echter ook individueel contact met de patiënt waarbij eigen ervaring, kennis en opvattingen over aanwending van therapie een rol spelen. Deze individuele ervaringen van de diverse teamleden hebben een impliciet effect op het advies dat het behandelteam in totaliteit aan de patiënt geeft. Het is belangrijk om bij de dagelijkse behandeling deze situatie goed onder ogen te zien. Bij complexe behandelingen, zoals reconstructieve interventies bij tetraplegische armproblematiek, is het zeer de moeite waard om zowel individuele als teammeningen aangaande de aanwending

van therapie expliciet te maken. In het onderzoek dat wordt beschreven in hoofdstuk 6 is een andere multi-criteria besluitvormingsmethodiek, het zogenaamde Analytisch Hiërarchisch Proces, gebruikt om het belang dat een ervaren revalidatieteam geeft aan behandelkarakteristieken te evalueren. Tevens werd deze techniek toegepast om een groep personen met een C6 dwarslaesie dezelfde behandelkarakteristieken te laten wegen en werd de beoordeling van het revalidatieteam en de groep mensen met een dwarslaesie met elkaar vergeleken. Aan de hand van de beoordeelde criteria werd een tweetal reconstructieve interventies door het revalidatieteam met elkaar vergeleken. De belangrijkste behandelkarakteristieken met hun relatieve importanties zoals aangegeven door het revalidatieteam en de groep patiënten (revalidatieteam/patiënten) waren: functionele verbetering (.54/.39), behandelzwaarte (.03/.11), risico's (.26/.21), gebruiksgemak (.17/.25), sociale acceptatie (.05/.04). Tussen het revalidatieteam en de patiëntengroep werden significante verschillen gevonden voor functionele verbetering ($p = 0.005$) en behandelzwaarte ($p = 0.01$). Bij de beoordeling van beide behandelopties werd functionele elektrostimulatie ten aanzien van functionele verbetering beter beoordeeld dan conventionele reconstructieve chirurgie. De totale beoordeling van het revalidatieteam gaf echter een lichte voorkeur voor conventionele reconstructieve chirurgie te zien (56% versus 44%) gebaseerd op betere beoordeling van conventionele chirurgie met betrekking tot de andere behandelkarakteristieken.
Wij concludeerden dat deze studie aantoont dat evaluatie van nieuwe behandeltechnologie uitgebreider moet zijn dan uitsluitend de beoordeling van te bereiken functionele verbetering door deze behandeling. Daarnaast werd aangetoond dat preferenties van patiënten op een aantal punten afwijken van preferenties van het behandelteam.

Hoofdstuk 7 behandelt de mogelijke praktische implicaties van de resultaten van dit proefschrift voor de behandeling van de arm- handfunctie bij personen met een tetraplegie en de organisatie van dwarslaesiebehandeling. Daarna wordt het gebruik van preferentie en multi-criteria besluitvormingstechnieken bij onderzoek naar toepassing van revalidatietechnologie besproken.

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Drs. Kees Pons. In 1989, voorafgaand aan mijn start op de dwarslaesieafdeling van de Maartenskliniek, mocht ik een aantal weken op jouw afdeling in Hoensbroek meelopen. Hier werd mijn speciale belangstelling voor de problematiek van de bovenste extremiteiten van mensen met een hoge dwarslaesie gewekt en daarmee de kiem voor dit proefschrift gelegd. Je belangstelling voor mijn professionele en wetenschappelijke wel en wee was een belangrijke stimulans om met het promotieavontuur te beginnen, dank je wel!
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Het heeft iets langer geduurd maar het is er dan toch van gekomen.

Curriculum Vitae

Govert Snoek werd op 12 april 1956 geboren te Capelle aan den IJssel. Hij volgde de middelbare school aan het Christelijk Lyceum te Arnhem waar in 1974 het VWO diploma werd behaald. Van 1974 tot 1981 studeerde hij geneeskunde aan de Rijksuniversiteit Groningen wat in oktober 1981 werd afgesloten met het behalen van het artsendiploma. Van oktober 1981 tot oktober 1983 werkte hij als "arts-assistent niet in opleiding" in het Diaconessenhuis in Groningen. De specialisatie tot revalidatiearts volgde hij van oktober 1983 tot oktober 1987 in Enschede in revalidatiecentrum het Roessingh en ziekenhuis de Stadsmaten met als hoofdopleider Prof. dr. G. Zilvold. Aansluitend werkte hij tot begin 1989 in revalidatiecentrum Groot Klimmendaal in Arnhem met consulentschappen in ziekenhuis De Gelderse Vallei (Ede-Wageningen-Bennekom) en verpleeghuis De Halderhof (Bennekom). Van 1989 tot medio 1995 was hij werkzaam in de Sint Maartenskliniek in Nijmegen met als speciaal aandachtsgebied dwarslaesieproblematiek. Tevens werden in deze periode consulentschappen verricht in ziekenhuis Rieverenland en verpleeghuis Nieuw Vrijthof in Tiel en het scholingsinstituut Werkenrode in Groesbeek. Vanaf 1993 was hij plaatsvervangend opleider revalidatiegeneeskunde in de Maartenskliniek. Sinds medio1995 is hij werkzaam in revalidatiecentrum het Roessingh in Enschede met als specifiek aandachtsgebied dwarslaesieproblematiek. In 1998 werd hij erkend als plaatsvervangend opleider revalidatiegeneeskunde in het opleidingsciquit Twente. Sedert 1995 werkt hij tevens bij Roessingh Research and Development waar in 2001 werd gestart met het promotieonderzoek. Vanaf 1993 is hij voor een belangrijk deel van de werkweek gedetacheerd naar ziekenhuis Medisch Spectrum Twente waar ook het stage-opleiderschap revalidatiegeneeskunde wordt ingevuld.
Hij is getrouwd met Angenieta Dekkers en heeft twee zoons: Hans en Niels.