THE DEVELOPMENT OF CRITERIA FOR EVALUATION AND PRESCRIPTION OF REMOTE MEDICAL MANIPULATORS

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Summary

Increases in the availability of number and type of remote manipulation aids for severely constrained patients has necessitated the development of criteria for suitable interfaces of patient and manipulator systems. An evaluation methodology has been developed and implemented that provides an approach to optimization of functional compatibility between the manipulator's capabilities and the patient's needs, abilities, and rehabilitation goals. This evaluation protocol includes comparative assessment of manipulator type, control logic and modality, physiological characteristics, and psychological impact considerations.

This comparative information is directed toward forming a basis for prescriptive decisions.

Introduction

The purpose of this study is to develop and implement an evaluation protocol to provide the comparative information needed to form prescriptive decisions for medical manipulator systems. Through increased research efforts, high technology aids for the severely disabled have become available. A large part of this effort has been the development of medical manipulator systems. The medical manipulator is a robot remote manipulator designed to provide functional rehabilitation to high spinal cord injured and other severely constrained patients through manipulative function and consequent environmental control.

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This evaluation must necessarily be made on a comparative basis as there has been no objective and generally accepted standard of functional rehabilitation for the severely constrained patient. A study by Bruett (1969) indicates that there are twelve "activities of daily living" (ADL) scales concurrently being used as criteria for functional rehabilitation. This evaluation, therefore, provides quantitative and qualitiative data for the comparative assessment of various manipulator and control systems. These data are compiled by consideration of the following:

1. Manipulator performance efficiency and reliability measured in terms of speed, accuracy and range of functional ability

2. Control adequacy judged in terms of number of control moves needed to effect simple and complex motion, number and type of control modalities available to patient and consideration of the physiological appropriateness of control type

3. Training time and technique required to attain a specified level of proficiency on a standardized performance task

4. Safety of operation and control of as primary concerns in dealing with a patient population which is very susceptible to injury from equipment failure

5. Acceptance of and opinion formation toward the manipulator system

6. System reliability and expected down time with regard to availability of appropriate maintenance.

Design considerations for further development can then be made from standardized cross manipulator comparison.

The evaluation protocol for manipulators must be sensitive to the unique and intimate interface between the patient/operator and the machine. The patient lacks control capability in proportion to his need for a wide range of dynamic functional ability by the manipulator. The difficulty of control for the severely constrained patient makes the consideration of control compatibility and patient acceptance of the device an area of concern in the evaluation of these manipulators. There is some evidence to indicate that the patients do not consider the development and use of assistive devices an important part of their rehabilitation (Taylor, 1974). The extent of psychological trauma represented by a debilitating illness (Holmes, 1967) makes concern for the social and personal impact of the manipulator system as much a part of the necessary evaluation data as the description of physical parameters (Kahn, 1969; Leiberman, 1968).

General Method

Because of the nature of the practical situation in dealing with extremely disabled patients, and with consideration for the complexity of manipulator systems, the selectivity of the patient population for which they were designed, and the multiplicity of factors beyond the experimenter's control, the evaluation is conducted in a "semi case study" style (Groth, Lyman and Kaiser, 1963). A wide base of etiologically varied patients was chosen to provide information about the parameters of patient types for which the manipulator systems could be of service.

The evaluation was divided into three stages. Continuation of the evaluation of a manipulator or control system through the stages was contingent upon it meeting performance and safety criteria at the previous stage. This was done to insure patient safety, as the extent of patient participation in and interface with the manipulator system increased at each stage of the evaluation process.

The stages of evaluation are:

1. *System Description and Bench Tests*

At this stage of the evaluation, it is useful to consider the manipulator in terms of subsystems for which criteria of performance have been explored. In later stages, this type of breakdown is not operative and total system function is considered.

The problem which is posed in this study is to combine the previously established subsystem criteria (Peizer, 1963; Lehneis and Wilson, 1972; Lehneis, 1968; Kay and Verdon, 1965; Conroy and Hassard, 1972; Ferrel, 1972) into a whole system analysis sensitive to the unique properties of the manipulator/patient interface.

The protocol to provide evaluative assessment at this level of system function is an extensive bench test. The first area of concentration is the verification of designer's claims about the manipulators' specifications. The next area of interest is a description of the physical components of the system and their dynamic characteristics. Finally, performance limens are established in specific areas of concern, e.g., excursion/recursion time for all degrees of freedom, range of motion, forces and velocities produced, power requirements, control dynamics, etc. These tests serve to familiarize the research staff with each machine's operation, and allow for a rigorous safety check before the presentation of the manipulator to the patient at the next stage of evaluation

2. *Performance Pre-Clinical Tests*

At this stage, the patient uses the manipulator system in the clinical setting under the supervision of the research staff. The patients are demonstrated the function and control of the manipulator and instructed as to the particulars of its use. Then a series of tests are run measuring patient performance.

The first series of tests run with the patients is exploratory. These tests familiarize the patient with the machine and afford the experimenter an indication of the range of the patient's control abilities.

After this introductory phase, a test, practice, retest paradigm is followed for an objective patient cross manipulator measure of learning.

The objective test is to pick up blocks in various forms (cylindrical, square, rectangular, triangular, oval, and hemispheric) and to transfer those blocks from the work table to the lapboard. On the lapboard is a form with areas cut out which correspond in shape with the shape of the blocks. When the blocks are placed in the appropriate holes, 1.27 cm of the block extends above the hole, and there is 1.57 mm tolerance between the block and hole. The test provides an exacting measure of control and manipulator performance.

As practice between tests, the patient performs activities in which the manipulator is used to serve realistic functional goals; an example would be the bringing of a reading stand and reading material into a functional position on the lap board where they can be reached with a mouth stick.

It should be noted here that the type of cooperation just described between high and low technology functional aids should be encouraged at all times. The patient should be urged to make use of all possible rehabilitative aids, and should seek to optimize their interaction.

After these practice sessions, the patients are again tested on the objective performance test.

These data are designed to provide an objective method to judge the progress of learning as well as to provide the patient motivation to learn by practice on functional and beneficial tasks particular to his interest.

3. *Long Term Clinical Evaluation*

At this stage of the evaluation, the patient is provided with the manipulator system, and is asked to use it at his own discretion. This use is monitored through an integrated circuit system which can record frequency of manipulator control use. This information reflects the patient's opinion concerning the usefulness of the manipulator in his daily routine. The long term aspect of this monitoring surmounts the problem of novelty effect produced by the increased attention paid the patient in the previous stage. During this time, the clinical staff is asked to unobtrusively monitor the patient's use of the manipulator, and problems with its use are investigated periodically using a critical incident technique interview (Flanigan, 1954). The same interview is conducted with the patient after an extended time of use (three months), and his subjective opinions about the manipulator as a whole and various subsystems is assessed using a questionnaire. This information can be compiled later and subjected to a statistical treatment, such as Anderson's (1972), and the areas of significance in opinion formation about manipulators can be distilled.

System Description

The manipulators generally fall into two categories of design, either articulated and anthropomorphic or telescoping boom type models. These can be used in either structured or unstructured environments. That is, they can be either designed to be stationary in a desk or bed work area, or they can be designed to be mounted on a mobile platform, usually a wheelchair.

X.1 Telescoping Manipulator Design

Whether used in a stationary environment or wheelchair mounted, the following describes the telescoping systems currently available. The telescoping boom pivots about a central axis worm gear which provides the manipulator with 360° rotational movement. The wrist and prehension equipment is attached to the end of the boom. The extension and retraction mechanism comsists of nested sleeves which are powered using a steel tape connected to a reel located on the opposite side of the central axis from the boom. The location of the reel provides a counter balance for the boom. The functional range of motion for the manipulator is described by a torus around the central axis (Figures 1, 2 and 3).

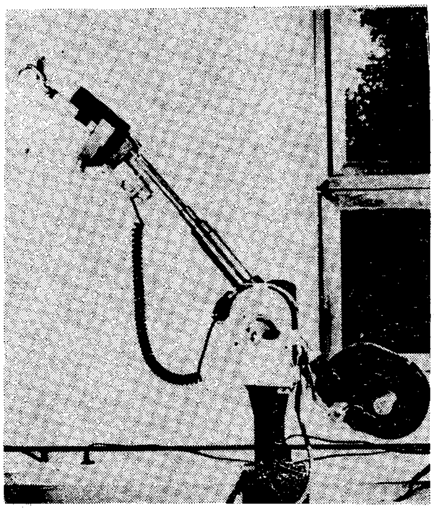

FIGURE 1

Telescoping Manipulator Table Mount

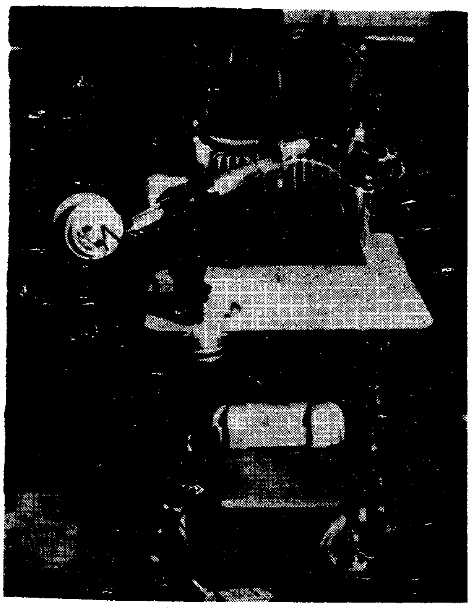

FIGURE 2

Telescoping Manipulator Wheelchair Mount

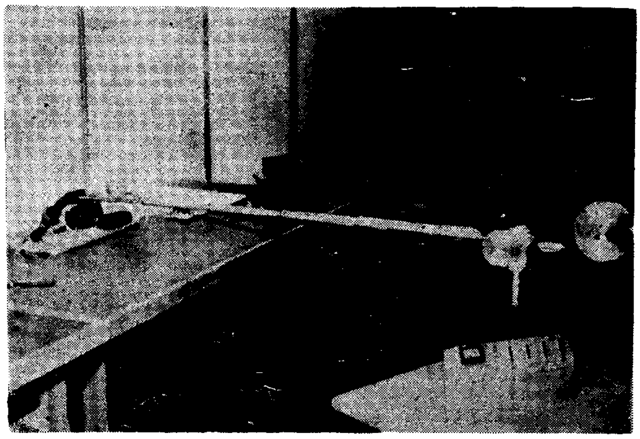

FIGURE 3 Telescoping Manipulator at Full Extension in Grasping Position

General Design Characteristics:

The 360° rotation and telescoping features allow the manipulator to be grossly positioned in its range of motion with only two control commands. The telescoping feature provides for a compact unit while not in use. The motors provide sufficient force to be useful even at full extension of the manipulator (Table I).

TABLE I

JPL MANIPULATOR: FORCES DEVELOPED

Wheelchair	14.0+ kg
Manipulator	
Rotation at Full Extension	0.35 kg
Rotation at Full Retraction	1.50 kg
Extension	8.50 kg
Retraction	5.00 kg
Up at Full Extension	0.50 kg
Down at Full Extension	2.50 kg
Up at Full Retraction	13.25 kg
Down at Full Retraction	4.50 kg
Prehension	2.30 kg

Articulated Manipulator Design

Two types of articulated manipulators were available for evaluation. The first was the Rancho Los Amigos Remote Manipulator #12 (Golden Arm). This manipulator was used both in the stationary mode and mounted on a wheelchair. The second articulated system was the Johns Hopkins Manipulator and Work Environment. This manipulator, as will be described, is designed to function only in the stationary mode.

GOLDEN ARM (RANCHO LOS AMIGOS REMOTE MANIPULATOR #12)

Two types of measurements were conducted on the Golden Arm to determine its range of motion and its motor voltages while in operation. The range of motion results indicate the effective operational volume of the manipulator, or the space within which it can grasp and manipulate objects. The motor voltages indicate the relative efficiencies of the various motors (Table II, Figure 4, and Table III).

TABLE II

GOLDEN ARM PHYSICAL PARAMETERS

Type of Joint	Time for Motion	Force Developed	Torque	Range of Motion
(A) Prehension	0.6 sec closing	3.17 kg "pinch"	--	Limit to Limit
	0.8 sec opening	60 gm	τ_B = 810 dynes	
(B) Wrist				
Extension	5.7 sec			Limit to Limit
Flexion	4.9 sec			Limit to Limit
(C) Wrist Rotation	0.6 sec	2.6 kg	--	Limit to Limit
(D) Elbow Rotation	8.2 sec	1.7 kg*	τ_D = 7.1 X 10^5 dynes	180^o
(E) Humeral Rotation	1.9 sec	15.0 kg	--	Limit to Limit
(F) Shoulder Rotation	9.0 sec	1.1 kg	τ_F = 7,4 X 10^5 dynes	180^o
(G) Horizontal Shoulder				
Rotation		12.3 kg	τ_G = 7.6 X 10^5 dynes	180^o
Clockwise	8.0 sec			
Counterclockwise	8.2 sec			

*Above this load, the device slips

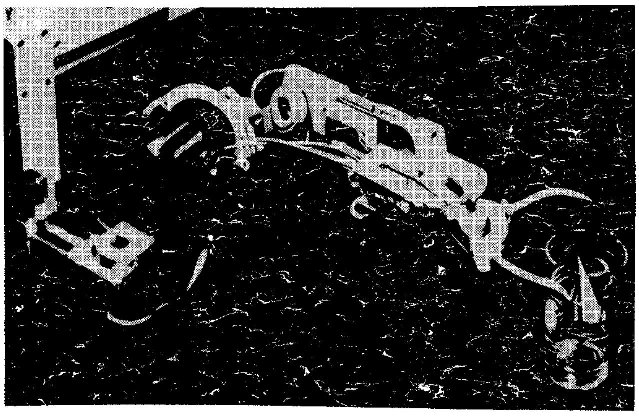

FIGURE 4 Golden Arm: Anthropomorphic Model

TABLE III

MOTOR VOLTAGE MEASUREMENTS

Motion	Voltage Unloaded	Voltage with Load
(B) Wrist		
Flexion	12.16 v	12.17 v
Extension	12.02 v	11.85 v
(C) Wrist Rotation	11.00 v	10.78 v
(D) Elbow		
Flexion	11.57 v	11.78 v
Extension	11.86 v	11.25 v
(E) Humeral Rotation		
Clockwise	11.35 v	11.35 v
Counterclockwise	11.80 v	11.80 v
(F) Shoulder Rotation		
Flexion	11.78 v	11.64 v
Extension	11.30 v	9.60 v
(G) Horizontal Shoulder versus Gravity		
Down	11.90 v	11.90 v
Up	11.30 v	9.60 v

- *Range Motion Test*

  In the Range Motion Test, measurements were made of distances between joints in a static situation. The dynamic characteristics of each joint were then examined. The time needed for complete travel and the force developed were recorded, and torque was calculated for the longitudinal joints. Additional measurements were made to determine the functional wrist rotation, using wrist rotation alone and wrist rotation with humeral rotation.

- *Motor Voltage Measurements*

  For the motor voltage measurements, the manipulator was set up so that each joint could make its motion against gravity loaded and unloaded. For all longitudinal movements, weights were suspended from the center of the prehension device. For rotational movements, weights were suspended from the center of rotation of each joint. Separate readings were taken for both flexion and extension movements.

JOHNS HOPKINS MANIPULATOR SYSTEM

The Johns Hopkins System is designed to be a stationary manipulator which works in conjunction with an immediate surrounding environment that optimizes the manipulator function (Figure 5).

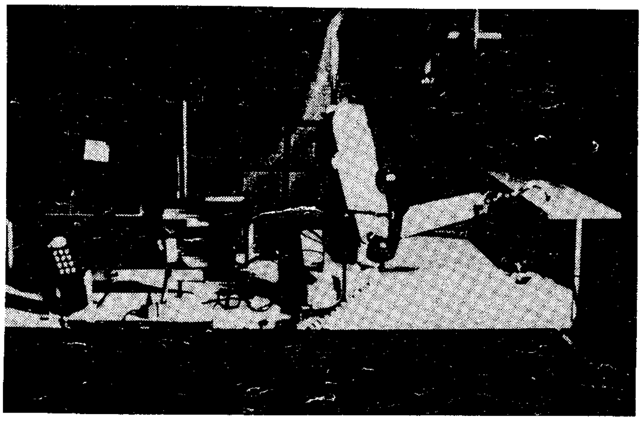

FIGURE 5 Johns Hopkins Manipulator in Programmed Environment

The arm itself has four degrees of freedom, prehension, wrist rotation, elbow flexion/extension, and shoulder flexion/extension. The arm is mounted on a turntable which allows 270 degree rotation. The turntable is mounted on a track which allows the manipulator assembly to be moved 62 cms laterally in the work area. The area of function for the stationary manipulator is represented in Figure 6.

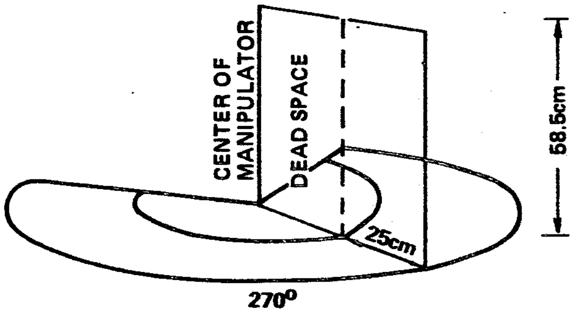

FIGURE 6 Functional Range of Motion of Johns Hopkins Manipulator at Single Track Position

The structured work area with the manipulator includes a bookstand with a reading rack, a typewriter which can be positioned by the manipulator, a loading tray for paper to be inserted into the typewriter (typewriter paper loading is accomplished using a suction system mounted on the arm and also mounted on the reading stand to hold single pieces of paper), a telephone easily answered by the manipulator's turntable motion, and several environmental control switches. Finally, there is a fork arrangement which can be used with a prepositioned plate so the patient can feed himself.

Control of the manipulator system currently is performed using an accelerometer (mounted in eyeglasses) to select the individual degree of freedom to be used. The display feedback to the patient is an LED display. The degree of freedom to be activated can be selected either by stopping a cycling cursor at the appropriate position, or by discretely selecting the individual joint with accumulated teeth clicks switching the accelerometer. After the movement type has been selected, the patient then uses a plunger chin control to regulate the motor speed. This plunger is a proportional control of the velocity of the desired movement, and a directional control of the motor and joint depending on whether the patient is depressing the plunger or releasing its spring mounted lever.

The concept of a controlled and fixed environment around the manipulator allows computer control of motions which are to be performed in the same way each time a particular goal is selected. For instance, a goal is set to read a book; a preprogrammed group of primitive motions is associated with fulfillment of this goal. The preprogrammed motions prepare the reading rack and move it into position to select a book. Many more goals and their attendant primitive completion motions are able to be programmed due to the static physical arrangement of this system. This control methodology is under development at the Johns Hopkins Applied Physics Laboratory.

- *Patient/Subject*

The patients selected to participate in our evaluation were two chronic care males in their mid-fifties, and one semi-independent female in her late forties. In keeping with our evaluative goal of determining parameters of patient populations for which the manipulator systems would be of service, the patients were selected to provide a large etiological range of disabilities.

Patient J. J. is a C4 spinal cord injured patient four years post trauma. His injury involves complete transection. He uses tongue switch control in conjunction with the Golden Arm.

Patient E. B. is Guillian-Barré patient two years post onset. He has some residual arm function with a ball bearing splint assist. He uses joystick control in conjunction with the Golden Arm.

Patient M. B. is a multiple sclerosis patient, sixteen years post onset. She has a complicated pattern of disability involving severe flexor spasticity of the elbow and wrist. She has full proprioceptive faculties, but very little fine motor control. She uses proportional joystick control in conjunction with the Golden Arm.

- *Procedure*

The test arrangement consisted of the patient seated in his wheelchair facing a work table one meter away from and ten centimeters higher than the patient's lapboard. The manipulator is at a 60° angle to the patient and the work table, and .75 meters away from both.

The tests were administered as described in the General Method section. Each patient was allotted 45 minutes to an hour for testing. The pretest was administered as soon as the patient was situated in the work area. After the pretest, the patient was allowed to practice. After practice, the patient was tested again. Timing was performed using a hand held stop watch and a micro circuit timer. A trial was considered complete when the patient released the block in the appropriate position.

- *Results and Discussion*

Figure 6 indicates performance data averaged over sessions and taken over a series of weeks of training and testing.

While there is considerable variation in performance, the subjects showed improvement over the weeks of the experiment. None of the subjects had significant performance within a test, practice, retest cycle. Performance asymptotes at 3.3 to 3.4 minutes/move. This limitation is due to lags in the system, and the complexity of the trajectory of articulated manipulator motion. Such performance time makes complex tasks very large and lengthy efforts, diminishing the utility of the manipulator in functional rehabilitation. The factor which varies between subjects is amount of practice to reach this asymptote. Patients E. B. and M. B., using the proportional control reached asymptote in eight hours practice. Patient J. J., using the tongue switch control, took 11-13 hours to reach the same level of proficiency. There are many factors which vary between the patients and this single study is in no way conclusive, but the preliminary indication is a superiority of a proportional control system.

A study was performed to determine the validity of use of number of control moves as a dimensionless metric. The number of control moves to complete a motion correlated highly (Pearson product moment $r = .91$) with the total task time. This indicates that the most efficient task completion strategy is one which minimizes the number of control moves to complete a motion.

There was also a study performed to discover what type of coordinate reference system the patient used to direct the machine. A tabulation of all movements was kept, differentiating between rotational and horizontal or vertical movements. As there are three degrees of freedom for each movement type, a Chi squared test was run to determine if there was a significant variation from equal use of both movement types. The results ($\chi^2 = 28.59$, $p < .01$ for E. B., and $\chi^2 = 140.1$, $p < .01$ for J. J.) indicate that there are significantly more horizontal and vertical moves attempted than rotational moves. The conclusion drawn, then, is the patients prefer to work in a Cartesian coordinate system.

Given the compatibility of the single polar coordinate system of the telescoping arm to a Cartesian system of orientation, it is likely that patients will find the telescoping system less of a mental burden to position in space.

Rancho Los Amigos Remote Manipulator

- *Patient/Subject*

Patient J. J. was allowed free access to the manipulator for five hours per week in the occupational therapy ward.

- *Equipment*

The use of the manipulator was monitored, as indicated in the General Method Section, through the use of frequency counting integrated circuits. These circuits and read out system were developed in the Rehabilitation Engineering Department, Karolinska Hospital, Stockholm, Sweden (Hägg, 1977). The frequency counters are linked into the circuit at the tongue switch, and record each control move on the switches. The counters accumulate control moves, and are periodically read out.

- *Results*

The results from the switch accumulators indicate that patient J. J. has, for the first month, been monitored as using the machine about one hour per week. These data are confirmed by critical incident interviews conducted with the staff. J. J. is using the machine 20% of the time it is available for him. Monitoring over a period of three months reveals that J. J. uses the manipulator an average of two hours a week when it is available on a twelve hour basis.

Discussion

There can be no doubt that the evaluation procedure represents a considerable novelty effect in the lives of the patients participating. The men are all chronic care patients, either in the Long Beach facility or others, and as such they lead very routine lives. The introduction of the manipulator and tests into that life style will cause an increase in motivation and interest. The long term monitoring has thus far indicated that the patient does not use the manipulator as a functional aid.

A further consideration in the machine's acceptance over the long term is that corresponding to an increase in self sufficiency for the patient will be a decrease in socialization which results from personal care (Taylor, 1974).

Conclusions

The evaluation of medical manipulators in in its preliminary stages. Comparative evaluation over the full range of manipulators will provide information necessary to the engineer for new development and to the health care team for proper prescriptive judgments concerning patient machine interface.

The evaluation protocol described the necessary information concerning the three way interaction of patient, control type, and manipulator to allow informed prescriptive selection.

The overall evaluation of the models supplied to our laboratory indicates that the hardware effector systems are unable to meet the needs of the patient. All but one system was found to be unreliable to the extent that they could not be used by patients. The one system being used by a patient on a long term basis has very limited usefulness, as indicated by the percentage use measures. An excellent measure of the utility of the manipulator in rehabilitation is the extent to which a patient becomes dependent upon the machine function. To that same extent, the manipulator system must be accurate, reliable and well suited to the patient's needs.

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