

Robotic Arm Allowing a Diabetic Quadriplegic Patient to Self-Administer Insulin

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Abstract—A method which allows a diabetic quadriplegic patient that has had four limb amputations (above the knee and elbow) to self-administer injections of insulin has been designed. The aim of this research project is to improve a quadriplegic patient's self-management, affected by diabetes, by designing a suitable device for self-administering insulin.

The quadriplegic patient affected by diabetes has to be able to self-administer insulin safely and independently to guarantee stable healthy conditions. The device also should be designed to adapt to a number of different varying personal characteristics such as height and body weight.

Keywords—Robotics, diabetes, quadriplegia, self-management.

I. INTRODUCTION

QUADRIPEGIA, also known as tetraplegia, can be defined as paralysis of all four limbs and torso/total loss. Quad comes from the Latin for 'four' and plegia comes from the Greek for 'inability to move'. People affected by quadriplegia are referred to as "quadriplegic".

Tetraplegia, "paralysis of four limbs" is more commonly used in Europe than in the United States. In 1991, when the American Spinal Cord Injury Classification system was being revised, it was recommended that the term tetraplegia be used to improve consistency. Pentaplegia is a less common term referring to paralysis it is similar but includes paralysis to the neck as well as all four limbs. Paraplegia is the paralysis to just the two lower limbs.

The cervical vertebrae are conventionally numbered, with the first one (C1) located adjacent to the skull. Quadriplegia is caused by damage to the brain or the spinal cord at a high level, particularly from C1 to C7, spinal cord injuries secondary to an injury to the cervical spine. The injury, known as a lesion, causes victims to lose partial or total function of all four limbs, the arms and the legs. Quadriplegia is defined in many ways: a C1-C4 injury usually affects arm movement more than a C5-C7 one.

However, all quadriplegics have or have had some kind of finger dysfunction, so it is common to have a quadriplegic with fully functional arms, only having their fingers not working.

The main cause of Quadriplegia is injury of the spinal cord and the functionality of a person's body following a spinal cord injury will depend on the level of injury.

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Injuries above the C4 level may require a ventilator or electrical implant for the person to breathe, as the diaphragm is controlled by spinal nerves exiting at the upper level of the neck. This kind of injury may be referred as "paralysis from approximately the shoulders down".

Most spinal cord injuries result in loss of sensation and function below the level of injury, including inhibition of the functional control of both bladder and bowel.

Nonetheless, cervical injuries usually result in four limb paralysis.

Instead, "paraplegia" is an impairment, that affects either sensory or motor function of the lower extremities.

The inhibition is usually both sensory and motor, thus both sensation and functional control can be regarded as physiologically lost.

Below are some forms of administering medication either by the patient or a competent person appointed either by the patient himself/herself or by a person whom he/she trusts, i.e. carer:

- Oral - frequently used kind of route and most effective if the patient can swallow;
- Sublingual;
- Rectal Administration;
- Topical Administration [1].

Quadriplegics who have total loss of limbs and being paralyzed can also self-medicate by having phrenic nerve pacemakers fitted, these in-turn work as they shrug their shoulders and neck motion will generate information that can be translated by recorders or computers to interpret what one needs [2].

II. OBJECTIVES

- Researching a wide range of both diabetic and quadriplegic patients to start designing a reliable device which can be used for the functions mentioned above;
- Differentiating the types of diabetes;
- Making appropriate changes to the design of the device which has to take into account the discrepancy of mobility among patients due to difference in diabetes, age and lifestyle;
- Stabilizing and improving the medical conditions of the patient, such as his/her lifestyle, range of independency, effective use of the designed device for self-care/assistance;
- Designing a method, that allows a quadriplegic to self-administer their own medication of their own accord, providing them with independence and some control over the life, even with the paralysis.

- Identifying the most appropriate materials and fabrication processes for the device.

III. CLASSIFICATION OF SPINAL CORD INJURIES CAUSING QUADRIPLEGIA NEEDED TO BE TAKEN INTO ACCOUNT FOR DESIGNING THE DEVICE

Classification of spinal cord injuries is based on the ASIA (impairment scale). Levels of paralysis are graded from A-E, A Complete, B Incomplete, C Incomplete, D Incomplete, and E Normal. Complete spinal-cord lesions means the person is completely paralyzed below their lesion. Patients affected by complete spinal cord lesion may have sensation below their lesion but no movement or vice versa. Such injuries are known as Brown-Sequard syndrome, central cord syndrome, anterior cord syndrome and posterior cord syndrome.

Although the injury involves the impairment of the limbs, impairment of the torso is also a product of spinal lesions. Thus, there is loss of control of some bodily functions and, consequently, the bowel, bladder, sexual function, digestion, breathing and autonomic processes can be compromised. Feeling of numbness and neuropathic pain is very common, severity of pain and discomfort depends on both the level of injury. The misconception with tetraplegia is that their arms and legs are not able to move.

For those people suffering from both diabetes and quadriplegia an example of a treatment that could be used is an implantable infusion pump to deliver anti-spasmodic drugs. Similarly, external infusion pumps can also be used, e.g. insulin infusion pumps for diabetes.

Before a method can be designed, research is needed on any products available in the market, to get an idea of what products are available and how they are perceived by those using them. As well as using ideas, which may not have had self-administrating medicine as the priority, could be used for a quadriplegic.

The insulin pump, an already existing medical device, which is surgically implanted under the abdominal skin, is used to deliver insulin to the bloodstream at a controlled rate.

Insulin infusion is scheduled by remote control and can be modified depending on dietary intake, blood sugar level and activity level. Implantable insulin pumps are not widely used and some models are currently in clinical trials, e.g. a case involving an adult quadriplegic man with sensitive insulin-dependent diabetes mellitus (IDDM). He was resistant to high doses of oral medication and unable to self-administer insulin through injection. To resolve this issue, he underwent a pump implantation for continuous infusion [3].

Another example of this technology is in a 40-year-old patient with insulin-dependent (type I) diabetes mellitus since childhood who suffered a C6 spinal transection. Recurrent episodes of hypoglycemia were resolved after the patient was placed on an insulin pump.

The patient is able to set the insulin delivery rate and maintain the pump without assistance [4].

It has been found that the implanted insulin pump has many advantages when compared with multi daily insulin injections including significant advantages in reducing glycemic

variability, clinical hypoglycemia and weight gain, while improving aspects of quality of life [5].

The insulin pumping device could be expensive if adapted for a quadriplegic patient, as the mechanism of the pump would need to be changed by integrated buttons.

In fact, a quadriplegic person, having his four limbs amputated respectively from above the elbows down and from above the knees down, would not be able to press any buttons as he/she will not have any fingers or possibility to exert pressure on his/her own on the button itself [6].

The patient can set the rate at which insulin has to be delivered and keep the pump without requiring any assistance. Quadriplegic patients, such as those ones with spinal cord injury, are generally affected by diabetes and, consequently, they cannot synthesize glucose by themselves [7].

The conventional method of injection of insulin through needles requires motor skills, which for the reasons stated above a quadriplegic patient does not have. Even with the aid of pre-filled syringes, a quadriplegic person cannot self-administer a subcutaneous injection due to the lack of limbs. The use of a so-called 'open loop' or external insulin pump would definitely provide better glucose control for quadriplegic patients affected by diabetes [8].

The firmware present in the insulin pump regulates the amount of bolus dose and determines the insulin levels in patients in response to events, such as eating, sleeping and exercise.

The insulin is contained in a user-replaceable cartridge held inside the pump. This reservoir is a specialized syringe with a piston, which is slowly pressed by a pump. The cartridge output is connected to flexible tubing going to the patient's subcutaneous injection site, usually located on the abdomen [9].

With an automatic insulin pump, a software systemically and accurately determines the dose of insulin, which should be administered to the user, by reading the blood sugar level instantaneously [10].

The insulin patch-pen is a small, flat device, which is attached to the skin and can be operated through a robotic arm, which acts through neural impulses, allowing a delivery of bolus insulin in just a few seconds [11].

The abovementioned device-based approach is, as such, designed to allow quadriplegic patients to self-administer insulin and to acquire that level of independence, which they might have lost further to pathologies and/or infections, and amputations.

Formerly insulin-dependent diabetes, type I diabetes is a form of diabetes mellitus, which results from autoimmune damage of insulin-producing beta cells of the pancreas. The consequent lack of insulin leads to greater than before blood and urine glucose.

Type 1 diabetes is treated with insulin replacement therapy, either by injection or insulin pump, along with attention to dietary controlling, typically including carbohydrate tracking, and careful monitoring of blood glucose levels using glucose meters.

IV. INSULIN PUMP TREATMENT OF A QUADRIPLEGIC TYPE I DIABETES PATIENT

Insulin is usually administered either via disposable insulin pens or via ampoules designed for multiple-use pens. Insulin pumps are also from time to time employed. The pump works by being attached to the patient at all times and feeds constant insulin to the blood via gas-pressurized jet injections.

However, conventional injections are still the preferred method of administering insulin mostly because of cheap costs associated to the application of this method and to the production of the devices involved in its usage [12]. Insulin pump treatment allows a more controlled approach to the cure of the diabetes, along with the major concern on reducing the pain, checking and monitoring that the dosage is indicated to the patients meant to be treated [13].

For both design constraints and practical reasons, which will be discussed later in this document, several advantages and disadvantages of the insulin pumping system still need to be considered. These parameters will need to be evaluated in light of searching for an efficient method of insulin self-administration, which would, indeed, guarantee more independence to the quadriplegic patients affected by diabetes, thus also respecting their own persona along with their privacy further [14].

V. PRIMARY FUNCTION OF INSULIN

When we eat, our bodies break down foods into organic compounds, one of which is glucose. The cells of our bodies use glucose as a source of energy for movement, growth, repair, and other functions. Nonetheless, before the cells can use glucose, it must move from the bloodstream into the individual cells. This process requires a specific hormone classified as insulin, which is secreted by the so-called pancreatic beta cells found in the islets of Langerhans in the pancreas. When glucose enters our blood, the pancreas should automatically produce the right amount of insulin to help cells to absorb or synthesize glucose.

Without insulin, you would actually be in a state of starvation since many of our cells cannot access glucose. This is why diabetics who do not make or use insulin can become very weak or tired easily. To allow sugar to pass into cells, where it can be used for energy, or turn off excess production of sugar in the liver, or turn off fat breakdown; this results in development of ketones. Fat breakdown or lipolysis is due to not having enough insulin available to help the cells burn the needed sugar.

The body, needing more energy (i.e. stress/illness), releases stress hormones such as steroids, adrenaline, and glucagon, causing fat breakdown. Sugar is not available due to vomiting or not eating, and fat is broken down for the energy needed.

Insulin is necessary for normal carbohydrate, protein and fat metabolism. People with type 1 diabetes mellitus do not produce enough of this hormone to sustain life and, therefore, depend on exogenous insulin for survival. In contrast, individuals with type 2 diabetes are not dependent on exogenous insulin for survival. However, over time, many of

these individuals will show decreased insulin production, therefore requiring supplemental insulin for adequate blood glucose control, especially during times of stress or illness.

VI. TYPES OF INSULIN-USE ERRORS

- Administration of a wrong dose,
- Administration to the wrong patient,
- Use of the wrong insulin type,
- Administration via the wrong route,
- Wrong timing of doses,
- Omission of doses,
- Failure to properly adjust insulin therapy, and
- Improper monitoring, timing, and assessment of blood glucose (BG) results.

System changes related to insulin should be designed and evaluated through structured methods, such as failure modes and effects analysis. All changes to insulin therapy related processes are monitored for success and unintended consequences.

VII. PRIMARY FUNCTIONS OF THE DESIGN MODEL

- The most important function of this product is that it allows a diabetic quadriplegic patient, who has no use of the limbs below their elbow and knee, to administer insulin by themselves.
- The product should be easy for a quadriplegic to operate, and safely use in their own homes.

VIII. SECONDARY FUNCTION OF THE DESIGN MODEL

- Adaptable to different circumstances i.e. can be used for people with different heights, weights, and body mass.
- Reusability - When designing the product, it has to be cost effective for a patient. This included making the product reusable, meaning the patient would only need to buy insulin supplies.
- Weight - Taking into consideration that this product is for a quadriplegic to operate, it cannot be too heavy or too light, as it will make it difficult to operate.
- Size - As with weight, the size could neither be too big or too small, as this could make the operation of the product difficult for the patient.
- Easy Tool Replacement - There are many circumstances in which a tool will break, so to deal with this problem, the tools should be easy to replace making the time the syringe is out of use less.
- Aesthetics - This could be designed based to the patients' needs, such as the colour (e.g. blue for boys and pink for girls).

IX. DESIGN CONSTRAINTS

Design constraints are limitations or boundaries that are enforced to a design by the design brief. They decrease the chances of an error in the product and increase its functionality. Listing all design constraints and their possible solutions first will save a lot of time and avoid any unusable

designs.

The task was to design a method for a quadriplegic to self-administer medication, in this case insulin. It becomes obvious that this task will have strict requirements for it to be successful.

One design constraint is that the person using this product will have no use of their limbs from below the elbows and knees. The design cannot be something small and which is difficult to handle. To overcome this restriction, one possible solution is to have a product, which could be fixed down to a table or worktop so it does not require moving the object. Another solution is to have some sort of IV attached to a wheelchair or walking frame, but this solution would not be ideal for more active quadriplegics. A different solution might be a surgically implanted pump, that automatically administers the correct doses regularly on time, this idea might be outside of the design brief, and would also require constantly refilled.

Another problem is that the person will not be able to use a conventional injection method. The probable solution for this is to have mechanism where the person could place their arm and the product will automatically administer the injection. There are also Jet Auto injectors. A jet injector [1] is a type of medical injecting syringe that uses a high-pressure narrow jet of the injection liquid instead of a hypodermic needle to penetrate the epidermis. It is powered by compressed air or gas, either by a pressure hose from a large cylinder, or from a built-in gas cartridge or small cylinder. These can be easily be refilled, and since they would be for the same patient, there is no risk of infection spread, although it would need to be cleaned and disinfected regularly.

Of course, when designing any product, cost has to be taken into account. The product has to be cost effective so it can be mass-produced but it cannot lack quality and durability, and it also has to be lightweight. Another potential material that could be used is epoxy resin mixed with carbon. Better known as carbon fibre, this material is strong and easily shaped and is lightweight. Although it is getting cheaper all the time, it is still quite expensive.

The device might need a way to communicate with a person if it is complicated enough to break due to moving parts or user error. The device could communicate with an owner / technician via sounds or symbols that light up.

If the device is complicated enough it could have a small screen or computer to help communicate via complex error message describing the problem in full, although this will drive up development and production costs.

There would be an additional cost to hire technicians, if the device is complicated enough to require it.

The device does not have to be small and mobile, but it would certainly be advantageous for it to be so. This could be solved by previously mentioned lightweight and cheap materials, and have a focus on a simple, manageable design.

The syringe will need energy to operate. Typically, this would be the mechanical strength of the applicators hand, but, in this case, a different method will be required. The device could also be powered by a simple foot pump, but this would also impact portability and manoeuvrability.

X. FUNCTION TREE

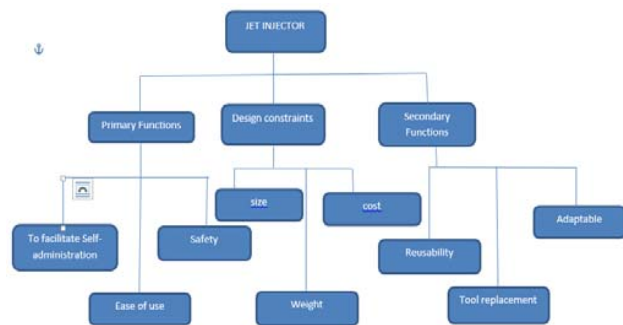


Fig. 1 A function tree of the jet injector implemented within the robotic arm, describing synthetically primary and secondary functions as well as design constraints to be taken into consideration

XI. DETAILED BACKGROUND REMARKED WITH RESPECT TO THE DESIGN PROJECT AND FURTHER OBJECTIVES

A. Quadriplegia

Quadriplegia also known as tetraplegia can be defined as paralysis of all four limbs and torso/total loss. Quadriplegia is caused by damage to the brain or the spinal cord at a high level, C1-C7, in particular, spinal cord injuries secondary to an injury to the cervical spine. In this case, the quadriplegic has use of movement above the elbow and knee.

B. Diabetes

Diabetes is a group of metabolic diseases in which a person has high blood sugar, either because the pancreas does not produce enough insulin, or because cells do not respond to the insulin that is produced. There are three main types of diabetes:

- Type 1 DM results from the body's failure to produce insulin, and currently requires the person to inject insulin or wear an insulin pump. This form was previously referred to as "insulin-dependent diabetes mellitus" (IDDM) or "juvenile diabetes".
- Type 2 DM results from insulin resistance, a condition in which cells fail to use insulin properly, sometimes combined with an absolute insulin deficiency. This form was previously referred to as non-insulin-dependent diabetes mellitus (NIDDM) or "adult-onset diabetes".

C. Insulin

Insulin is a hormone secreted by groups of cells within the pancreas, however in diabetics this is not the case. The cells of our bodies use glucose as a source of energy for movement, growth, repair, and other functions. However, before the cells can use glucose, it must move from the bloodstream into the individual cells.

This process requires hormone insulin, which is why diabetics have to administer insulin to themselves since their pancreas does not secrete enough.

D. Main Objectives

- Selecting a wide range of diabetic quadriplegic patients to start the research on designing a reliable device which can

be used for the functions listed above;

- Differentiating the types of diabetes the patient could have;
- Stabilizing and improving the medical conditions of the patient, such as his/her lifestyle, range of independency, effective use of the designed device for self-care/assistance;
- Ensure that the design complies with the standards and regulations from the Medical Device Directive;
- Analyzing the degree of efficiency of the residual nerves, this can be linked to external neural devices.

XII. ROBOTIC / PROSTHETIC ARM DESIGN

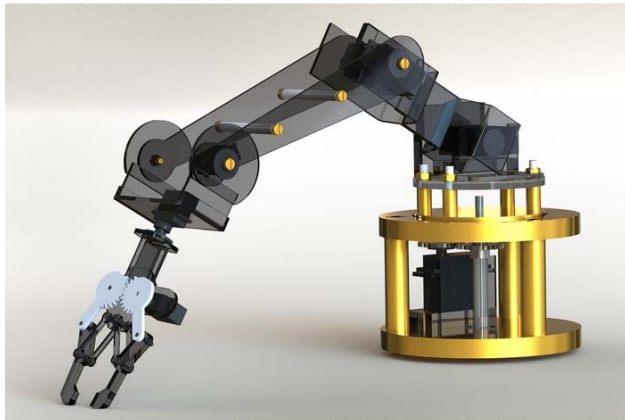


Fig. 2 A sketch with the robotic arm and the frame for the prosthetic arm to be adjusted to the anatomical characteristics of the patient [15]

A. Functions

The robotic arm would be able to help with injecting medication, when needed to the quadriplegic patient. However, it would also be able to carry out simple tasks, such as typing, clicking the mouse when using the computer and, more importantly, writing.

Since the hand is controlled by the patient's own muscle impulses, it would work almost as a natural hand would do. Connected to neural terminations through wires placed on the top of the patient's helmet, the patient would be able to twist the wrist and to raise/lower the robotic arm. Using this brain-controlled machine interface, a paralyzed patient would be able to manipulate objects of different shapes and sizes in a 3D environment. The patient would be able to reach in and out, left and right, and up and down with the arm. The robotic arm would provide the patient with a 3-dimensional control, indeed. The patient would be able to flex the wrist back and forth, move it from side to side and rotate it clockwise and counter-clockwise, grip objects, thus producing a 7D control.

The patient would be able to perform tasks, such as grasping, transporting and positioning objects with high precision.

B. Design Idea

The hand has to have sensors integrated into the thumb and would robotically perceive when a gripped object is slipping. The grip system would automatically start to increase the grip

strength, until the object is securely kept into position.

Before the object starts to slip from the patient's robotic hands, the sensors implanted in the hand would sense a change in the center of gravity, thus enabling it to re-adjust its grip automatically and accordingly. One electrode grid has to be placed with contact points for each side of the brain, which would normally control just one arm and hand movements. The contact points have sensors that pick up information from neurons and computer-processed mathematical algorithms identify the patterns associated with the movements, which translate these instructions into movements of the robotic arm.

Two silicon-substrate grids of electrodes have to be surgically implanted in the upper right motor cortex to record the overall neuronal activity, which eventually is translated into actual movements of the robotic arm.

These neural signals are transferred to sensors, thus having a robotic position feedback.

C. Design Considerations

This method would be really effective if only the sensors integrated helmet were able to communicate ideally with both robotic arms and provide them with the sensorial perception, which would allow the patient to use both arms and to sense the objects he/she grasps.

D. Acknowledgements

The design idea described above shares the same fundamental principle of the project presented in the article entitled "Quadriplegic Woman Moves Robot Arm With Her Mind [16]", which involves the usage of an integrated robotic arm to help the quadriplegic patient restore her motor functions and grasp objects, such as chocolate bars, as well as handle them and perform several translational and rotational movements.

Of course, this mind-controlled prosthetic mechanism is costly and it involves technical testing and clinical trials, which augment the difficulty of producing the robotic arm destined to be used for medical applications, such as self-administration of insulin.

The abovementioned study was conducted by researchers from the University of Pittsburgh, School of Medicine, and UPMC, who helped Ms. Jan Scheuermann, a quadriplegic patient affected by a full paralysis of her body from the neck down; perform tasks which any quadriplegic person would have never thought to be able to do.

The researchers managed to design a mind-controlled humanoid robotic arm suitable for her to perform everyday tasks in a lab environment, which simulated a room of a common house, with everyday tasks needed to be performed and obstacles of different nature taken for granted every day.

However, these may cause relevant issues to the well-being of a quadriplegic patient, thus limiting her independence in her life.

Employing the robotic arm as she would use a normal one, she succeeded in grasping and moving objects in the lab, and also feeding herself some pieces of chocolate.

Ms. Scheuermann lost the use of her limbs further to a

degenerative pathology that first struck her in 1996. The disease progressively damaged her spinal cord further, which forced her to be on a wheelchair. The permanent damage to her nervous system was assessed and proved equivalent to the one that may be caused by a broken neck, generally due to car accidents.

The usage of a robotic arm also requires time for the doctors who assist the quadriplegic patient to teach her how to use it efficiently and to guide her at the very beginning in performing everyday tasks.

After a short period of adapting herself to the robotic device, eventually she learnt how to perform fluid movements in everyday life by the aid of the mind-controlled humanoid robotic arm described above.

ACKNOWLEDGMENT

The author would like to thank Dr C A Holt, Reader in Movement Biomechanics, and Dr G Whatling for giving him the opportunity to carry out a summer research internship at Cardiff University, Arthritis UK Bioengineering Centre, and, therefore, get the chance to develop the present work.

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