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Engineering by the New Light of Bioethics the Team to Develop Research in the Improving of Life Mechatronic Validation of Tendons of a Finger and its Operation

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Abstract

A true needed team is the one made by bioethics and engineering, in fact all the sciences have to team up with Bioethics, sooner than later. The planet has become the most hostile place; the human race is the biggest danger to its own species. No matter how many new techniques and inventions, the man develops, as long as is not seen with the light of ethics and concretely bioethics, is due to failure. In this paper three professionals teamed up to show the importance of bioethics in every act of human race, including the developments of the engineering in mechatronics. How about human consent? Autonomy and dignity? This paper emphasizes the importance of the principles of bioethics to be considered in every situation, particularly in the development of new inventions as a result of engineering research seeking to improve the life of wounded people, due to war or other accidents including birth defects.

Keywords: Flexor tendon, fingers, bio mechatronics, bioethics.

INTRODUCTION

Bioethics, research and engineering

All research in general and especially those conducted with people or elements that are going to be at the service of individuals must contemplate aspects of Bioethics, which incorporates science and forgetfulness in today's society, such as ethics and morality. As such, Bioethics is a science that we can identify as old, however, it has begun to be discussed since the Nuremberg trial and specifically with the birth of principles that seek to protect the fundamental rights of individuals [10], [11].

Following important scientific advances, the result of recent research, humanity has realized the need to touch the issue of ethics, because it feels that it must by all means, tend to humanize as soon as possible. The development of bioethics and biotechnology have been accompanied by an important debate in most Western countries since the new possibilities, especially those of the new genetics, generate a manifest ambivalence: on the one hand, they are considered the origin of great benefits and, on the other, they are the starting point of new possibilities of abuse. The contrast between hope and concern is easily detected in the media, in the opinion of the most and least informed citizens and that of the scientists themselves [2].

The criteria of ethics and morals are as old as man, Bioethics, however, we can say that it gained importance from the second half of the 20th century, immediately after the Second World War and as a result of scientific experiments, that they were more than horrendous crimes committed against humanity for the "perfection" of a race. As a result, the Nuremberg Code promulgated ten basic principles to be taken into account in human research. Bioethics assumes four fundamental principles that will be presented shortly.

We can say that, since the Hippocratic Oath, legislation has evolved in accordance with the advances of science and the requirements of technology and society. However, in the 21st century, we could affirm that the Law is at least one step behind the new discoveries and that in matters of biotechnology, the problems are just beginning, with the law sometimes remaining short or lagging behind in its need to solve problems and in its objective of imparting justice.

In fact, in biotechnology we can only hope that the law and specifically biopolitics and bio law, serve as an instrument to avoid future controversies, and that we live in a robotic society where the limits of ethics have been transferred and the fundamental rights of the individual not they respect each other. We could even get to the society raised by Donna Haraway in the manifesto Cyborg (1984). In this text, the virtual reality of what societies will be when only the individuals built in the laboratories are walking all over the cities like normal beings. Therefore, in the biopolitical language a cyborg is a technological organism, a cybernetic being, a hybrid that some would say is half machine and half organism, a creature of social or virtual reality and also of fiction that indeed exists [3]

The aspects that have to be taken into account in relation to research in robotics and mainly with the proposal of anatomical prostheses, are the four fundamental principles of Bioethics not only for when the individual is using the instrument, but also in the process of making the machine.

According to the available record, the term bioethics is introduced in the title of the book by Van Rensselaer Potter, researcher in Oncology, "Bioethics, Bridge to the Future" published in 1971. It shows the synthesis of "two cultures" and a key to build the "bridge to the future" proposed by the subtitle: moral biology as quality of life in the face of the planetary ecological challenge.

The second use of the word belongs to an institution, The Joseph and Rose Kennedy Institute of Ethics for the Study of Human Reproduction and Bioethics, founded by André Hellegers with the sponsorship of the Kennedy family in 1972 and which, after his death, became [5].

However, despite both bioethical megaprojects, the word was delayed in imposing itself as the name of the new medical ethic or bioethics, to which the epistemological statute and baptismal font gave the "Encyclopedia of Bioethics" (1978) created by [9], important character of the Bioethics that visited Colombia, in 2012. This event has been considered as the starting shot of bioethics: this would have a quarter of a century.

The term has made a fortune because it is supposedly broad and clearly expresses its content: the ethics of biological life. However, when it comes to engineering research it is of the upmost importance to consider the autonomy and the dignity of the individual benefited by the research mechanism created t improve his or her life. This responded to the need to formulate a concept that incorporates a more encompassing and interdisciplinary ethical dimension than those others, more historical, such as "medical ethics" or "medical deontology", that really came to conclude about the duties of the doctor towards his patients Also for engineers is important to get to know bioethics, and its basic principles.

METHODOLOGY

The research method is empirical analytical. Divided in two steps, the first one is the empirical part, which responds to the engineering research. The second part is the analysis and interpretation of the principles of bioethics in the light of the engineering research of human fingers.

RESEARCH

The traumatic tendinous injuries produced by situations from violence, by activity or as a result of accidents have become common. For the reconstruction of tendons in upper limb (wrist and hand), surgical procedures are used, which must be previously validated in order to ensure the success of a procedure.

For this, it is required the support of automatic systems and devices for generate a higher reliability based in the information obtained throw different electronic devices as sensors, which allow obtaining information about what is being done, or actuators who are in charge of generating movements in a certain mechanism.

In medicine the interphalangeal joints are called "Pulleys", if exists an injury from the pulleys A2 or A4 (the last two joints of the finger), It produces a deformity in the flexor tendon which the performance and the efficiency of this is affected.

Clinically this is presented as loss of strength, reduction in range of motion, local instability and sometimes pain when gripping.

This paper presents a discussion from the ethical point of view of the development of a mechatronics app used for the validation of a surgical technique for the reconstruction of the flexor tendon A4 in hand by using a mechatronic device and its respective analysis from an ethical perspective when an animal (chicken) is used for experimentation and validation of the technique.

The prototype developed allows to observe both the strength and the range of flexion of the interphalangeal joints, in order to better analyze the technique developed. This allows to validate the technique of suture and reinsertion of the tendon object of study, before performing procedures in human patients. [6], [7], [8]

The human finger

Lesions of the flexor tendons of the hand are common in our environment, secondary to trauma due to situations of violence, as well as occupational and accidental injuries. The osteon fibrous sheath and the pulley system are also frequently affected by these injuries. The lesions of the pulley system can be caused by closed trauma in activities such as climbing; however, most of the injuries are produced by injuries of the flexor system or during repair, as it is often necessary section the pulleys to perform an adequate tendon repair. The pulley system of the flexor sheath (Figure 1) is composed by five ring pulleys that maintain the flexor tendon tightly attached to the underlying bones in relation to the axes of the joints, and three intermediate cruciform pulleys that are compressed to allow the flexion digital without deforming the annular pulleys. Besides being a protective cover, it facilitates the sliding of the tendon maximizing the skill and efficiency of moves of the interphalangeal joints. To bigger distance from the tendon to its axis of joint rotation, bigger is the lever arm and smaller the movement that it generates the muscular contraction in the articulation. Contrary, a shorter lever arm will result on bigger joint rotation with the same tendon excursion. The lever arm, flexor tendon excursion and rotation of the articulation produced by it, are controlled by the integrity of the pulley system. The pulleys A2 (located on the proximal phalanx) and A4 (located on the middle phalanx), are the most important biomechanically, fundamental for the flexion of the interphalangeal joints proximal and distal, respectively. If there is an injury of the pulleys the performance and efficiency of the tendon are affected. Clinically this is represented as loss of strength, reduction in range of motion, local instability, and pain in grip and deformity in "bowstring" [4]

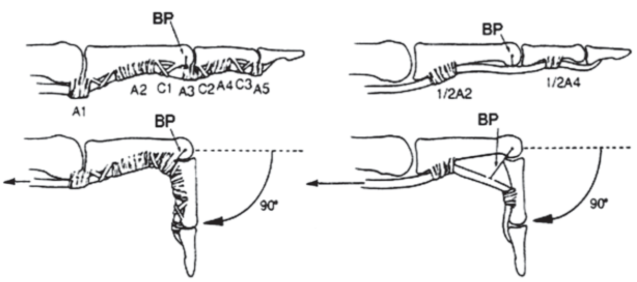

Figure 1. Tendons of a finger and its operation

Due to clinical importance, it has been described in the literature multiple techniques for the reconstruction of the pulleys flexors, most of which recreate their fibers in one direction transverse, as they are originally found. So much the original pulleys as the rebuilt ones generate on the tendon a frictional force that influences statically and dynamics about its slip. The main author has described a technique of reconstruction of the A4 pulley that uses a Flexor Digitorum Superficialis band (FDS), which is transposes and is oriented on the middle phalanx in an oblique way. With this technique, the frictional force exerted by the pulley presents a different vector from the other techniques. They do not exist until the moment reported in the literature studies that evaluate the biomechanics of flexion with different reconstruction techniques of the A4 pulley. The present study has as object evaluate in an animal model the effect of the isolated section of the A4 pulley in the biomechanics of the flexor mechanism, and compare the flexor function after its reconstruction with vector oblique using a shock absorbing technique FDS band vs reconstruction with transversal vector.

THE SURGICAL TECHNIQUE

An experimental biomechanical study was conducted using an animal model with legs of fresh chicken carcasses (Gallus gallus), whose dissections show the similarity of flexor and pulley system with the human fingers. The models were elaborated cutting the chicken legs at the level of the tarsometatarsal diaphysis immediately after his sacrifice, preserving proximally the deep flexor tendon of the third finger. For perform the tests was designed a special device, in together with the DaVinci research group of the Department of Mechatronic Engineering of The Nueva Granada Military University. Likewise, adapted software was designed to said device, for the collection and storage of the data.

Initially they were tested on the legs of 5 chickens (n: 10) to determine the biomechanical effect of the section from the A4 pulley in the function of the flexor mechanism. To each leg was measured the force and angle of maximum flexion of the Distal Interphalangeal Joint (DIJ); It was sectioned longitudinally the pulley located on the third phalanx (equivalent to the A4 pulley in the human) and measurements were made again. Subsequently, comparative measurements were made between the two surgical techniques. The sample of 32 legs (16 hens) using the programmed EPIDAT 3.1 for a p of 0.05 and a power of 80%. The legs were sectioned longitudinally the pulley "A4". To one leg of each chicken reconstruction was performed with oblique vector using a FDS band (n: 16), and the contralateral leg with transverse vector using two handles made with graft of tendon (n: 16). The strength and angle were also measured of maximum flexion of the DIJ. [1].

The legs to which was rebuilt the flexor pulley A4 with oblique vector were operated with to technique described by [1], in which identifies the superficial flexor tendon with its two bands, which insert at the base of the middle phalanx; one of the two bands at the level of their proximal origin, preserving their insertion distal, and rotated 180° to suture it to the remnant of pulley A4 with U- shaped of vascular prolene 5-0; it is verified adequate excursion of the tendon below the A4 pulley reconstructed, and the absence of the bowstring effect at flex the finger. For its part, the legs that were made reconstruction with transverse vector were operated with the loop tendon. Figure 2. show the clinical procedure and functionality of chicken finger.

a) Pulley reconstruction

b) Rebuilt pulley

c) Recovery of movement capacity

Figure 2. Finger pulley reconstruction in a chicken foot

MECHATRONICS VALIDAATION

To carry out the tests a device was designed and built measurement (Figure 9) consisting of a base to which the leg is fixed with Kirschner nails at the level of the first and second phalanges (equivalent to the metacarpal and the phalanx proximal in humans, because the fingers of the birds have 4 phalanges). The deep flexor tendon is fixed with a gag connected to a pinion that pulls it proximally millimeter to millimeter, moved by an engine that is controlled by the software designed for the device. For the measurement of angles are placed red marks on the head of the phalanges (pins), which are captured by the camera and identified by the software, which calculates the angles formed by said marks with precision of 0.1 °. For the measurement of force, the device has a sensor that measures the force of pressure exerted by the distal phalanx at the moment of maximum flexion.

All data is captured and stored instantly for the software. A total of 42 models (legs) were used, from 21 chicken adults, of 8 weeks of life. The first 10 legs with the pulley intact they reached an average angle of flexion maximum of the IFD of 96.5° (standard deviation 1.7°). To the sectioning the pulley longitudinally there was an increase in the angle (decrease in flexion) of 19.8% on average (96.5° to 115.6°; $p<0.001$) (Figure 11). With respect to force of flexion, a decrease of 15.2% was found after the section of the A4 pulley; from an average of 8.16 psi with the intact pulley (standard deviation 0.23 psi), to one of 9.92 psi with the sectioned pulley ($p <0.001$).

For the 32 legs intervened, those whose pulley was rebuilt with transverse vector angle reached a maximum flexion angle of DIJ of 98.13° on average, while those reconstructed with oblique vector reached an angle of 96.9°, with a difference of averages of 1.23° ($p = 0.03$). The force in the first group of legs was on average 8,119 psi and in the second group 8,093 psi, with a mean difference of 0.026 psi ($p = 0.6$)

(a) Resident of plastic surgery, preparing the finger

(b) Final Graphic Interface for the study

Figure 3. Sinergy work in medicine and mechatronics

CONCLUSIONS

The ethical considerations must be always considered when doing research in engineering. In the area of international commitments, in 1964, the 18th Assembly of the World Medical Association adopted the Declaration of Helsinki, whose most recent revision took place in 1989 (at the 41st Assembly, held in Hong Kong) that defines ethical guidelines for the research on human beings. This Declaration, with its subsequent modifications, constituted the basic body of principles that were incorporated since then to the numerous Research Standards that have emerged in the different fields of biomedical research, with particularities defined by the local realities of the countries where they are applied. or of the scientific areas involved in the research, but without neglecting in any of them the basic principles contained in said Declaration and which include the following, in summary:

- The research must respond to a scientific design and have previous experiences in animals.
- It must respond to the principle of proportionality and consider the predictable risks, in relation to the possible benefits.
- The right of the human being subject of investigation must be respected, and his interest must prevail over the interests of science and society.
- Informed consent must be obtained and the freedom of the individual respected at any time during the study.

At present, this Declaration is being revised again, considering the new advances in biotechnology that lead to introduce other criteria for the protection of the rights of people who are in agreement with these advances, and to correct the contradictions contained in it, such as the well-known distinction between investigations clinical and non-clinical, which will surely be eliminated.

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