Computer Science and Information Systems 18(3):619–640 https://doi.org/ 10.2298/CSIS200224015S

FPGA Implementation of Fuzzy Medical Decision Support System for Disc Hernia Diagnosis

Tijana Šušteršič[1], Miodrag Peulić[2], and Aleksandar Peulić[3,*]

[1] Faculty of Engineering, University of Kragujevac, Sestre Janjić 6,
34000 Kragujevac, Serbia
tijanas@kg.ac.rs
[2] Clinical Centre Kragujevac, Zmaj Jovina 30, 34000 Kragujevac, Serbia
miodrag.peulic@gmail.com
[3] Faculty of Geography, University of Belgrade, Studentski trg 3,
11000 Belgrade, Serbia
aleksandar.peulic@gef.bg.ac.rs

Abstract. The aim of this study was to create a decision support system for disc hernia diagnostics based on real measurements of foot force values from sensors and fuzzy logic, as well as to implement the system on Field Programmable Gate Array (FPGA). The results show that the created fuzzy logic system had the 92.8% accuracy for pre-operational diagnosis and very high match between the Matlab and FPGA output (94.2% match for pre-operational condition, and 100% match for the post-operational and after physical therapy conditions). Interestingly enough, our system is also able to detect improvements in patient condition after the surgery and physical therapy. The main benefit of using FPGAs in this study is to create an inexpensive, portable expert system for real time acquisition, processing and providing the objective recommendation for disc hernia diagnosis and tracking the condition improvement.

Keywords: disc hernia diagnosis, fuzzy inference systems, FPGA, medical decision support system, hardware.

1. Introduction

In diagnosing discus hernia, magnetic resonance imaging (MRI) represents the gold standard. However, MR scans alone are not as accurate as initially believed and should not be used as the only diagnostic tool [1, 2]. While MRI and CT scanning are more or less invasive and not appealing to the examined subject, both of these procedures are time-consuming screening methods, and the queue time is substantial. Therefore, in addition to surgical screening, using one of the appropriate imaging modalities to diagnose lumbar discus hernia, the patient's medical history and physical examination are necessary [3]. Such tests involve a set of measures (neurological evaluation of motor, sensory, deep tendon reflex functions etc.) that will help assess the likely cause of pain and the potential existence of a spinal nerve deficit [4].

[*] Corresponding author

Neurological examination takes into account dermatomes. Dermatomes are described as areas of skin innervated by specific nerves that originate from the spine [5, 6]. The innervation of the muscles and the skin region on toes originate from the nerves between the discs L5 and S1 in the spine, while the innervation of the heels arises from the nerves that arise between the discs L4 and L5 in the spine [7, 8]. This means that when disc herniation is present at either L4-L5 or L5-S1 level, the nerves experience pressure at that level on either left or right side, causing muscle weakness on the corresponding left or right foot. The main medical clausula, used in this paper is that innervation of the muscles and the area of the skin on the forefeet originates from the pressured nerve located between the L5 and S1 vertebrae, while the roots of the nerves innervating the heels are located between the spine disks of L4 and L5 [7, 8]. As a result, if disk herniation is located at the L4-L5 level, the subject would suffer muscle weakness on heels, whilst subjects with disc hernia on level L5-S1, would suffer muscle weakness on forefeet. Therefore, the clinical evaluation of the level of discus hernia includes pushing the patient's forefeet and heels against doctors' hand and attempting to determine whether there is a muscle weakness on the forefoot/heel. Despite the fact that the neurological examination has been identified as a reliable procedure for diagnosing disk herniation [9, 10], the reliability depends on standardization [10] and the tests for muscle weakness are subjective and could be affected by many factors, including disease severity, doctor's experience, etc. It can be concluded that there is a need for an accurate evaluation of the motor function / weakness of the toes, which is non-invasive and can be used as part of the decision support system in the diagnosis of disk hernia. We present the novel methodology for measuring feet forces using the platform with sensors. Such sensors, along with the custom design chip (i.e. programed FPGA chip), would create an independent system for disc hernia diagnostics that can replace the subjective neurological test.

1.1. Related work

Although fuzzy logic is a long-studied topic, and there is a tremendous number of papers that deal with FPGA-based fuzzy logic controllers [11-15], there are not so many studies that deal with implementation of fuzzy systems on FPGAs that are related to medicals diagnostics. Several attempts have been made to resolve fuzzy inference issues using parallel processing and reconfigurable architecture available through Field Programmable Gate Array (FPGA) [16]. Chowdhury et al. have published several papers on the topics of FPGA-based fuzzy architectures for the purposes of medical diagnosis [16-18]. It could be said that their designs focus on defining a processor architecture that would exploit the parallelism fully used in fuzzy inferences and then further use the implemented design in processors like FPGAs, in order to predict possible critical condition of a patient at an early stage [18]. For that purposes, they mainly investigate the coupling between the neuro-fuzzy systems. Their papers theoretically investigate fuzzy neural networks for the purposes of medical diagnosis systems and then apply it on the problem of early detection of the upcoming critical renal condition [17]. In that sense, only rules that have a positive degree of validation are exploited. Developed system is tested with the data from real patients to compare the results from the implemented fuzzy neural network and the "gold standard" which was the actual pathophysiological state of the patient [17, 18]. Accuracy of the predicted critical state was 95.2% using the implemented FPGA based medical diagnostic decision-making system [16]. Similar to their previous work, another research focuses on the development of FPGA based smart processing system that can predict the physiological state of a patient, given the past physiological data of the patient. Developed system can trigger an alarm in advance, before the critical state of a patient and notify the doctor remotely [16]. The main conclusion from their systems is that physiological measures from patients are subjected to noise and uncertainty, and single patient data cannot be enough to derive conclusions due to the sensors' quality and accuracy issues. This is even more true for the cases when decision about the future physiological state of the patient has to be made. Therefore, it is necessary to collect a sequence of patient pathophysiological state data in different time steps [17]. Cintra et al. [19] investigated the method that is capable of detecting cardiopathies in electrocardiograms and implemented that system in FPGA. In order to reduce the amount of data sampling, they adopted the logic of fuzzy clustering. Through a correlation method on the samples, they proved that it is possible to set an initial diagnosis of indication of a cardiopathy and their main contribution is clustering process that improves the hardware implementation without the loss in accuracy (achieved accuracy for correct diagnosis was 91%) [19]. Other authors have also investigated the implementation of VLSI fuzzy classifiers in biomedical applications. For example, Jothi et al. investigated diabetic epilepsy risk level classification and compared it with FPGA output [20]. The results are reported to be a good match between the FPGA and Matlab, however the authors do not specify how the implementation is achieved, nor report any details of implementation. With similar purpose to the previous research, Balamurugan et al. have built a simple and robust SIRM fuzzy processor to classify the epilepsy risk level of diabetic patients and report similar conclusions [21].

Fuzzy logic is often combined with neural networks in order to improve the accuracy. Nilosey et al. employed FPGA based fuzzy interface system cascaded with a feed-forward neural network in order to obtain an optimum decision regarding the future pathology physiological state of a patient. With this methodology, they claim that the chance of predicting the critical diabetic condition of a patient can be achieved accurately, more precisely 30 days ahead of actually attaining the critical condition. The method itself represents an expert system of its kind [22]. Another approach to modelling fuzzy systems is taken by Bariga et al. who adopted a fuzzy logic modeling style using two strategies: behavioral modeling using VHDL and a structural VHDL based on a specific architecture of fuzzy processor. In order to take advantage of the FPGA resources of the devices, they discuss different approaches and employ environment Xfuzzy for the fuzzy system development. This environment is based on the XFL3 specification language, which is a high-level description language, outlining the advantage of focusing on the structure of the system and the behavioral specifications in such way and not on the programming itself, therefore reducing the time for implementing the system [23].

1.2. Advances in FPGA-based processing systems in medical diagnosis

On one side, the main advantage of FPGA-based processing systems is the achieved shorter time span in comparison to the other current processors. High speed simulation of neuron models is becoming the necessity [24]. Intelligent system, which is embedded in one single chip and contains all necessary functionality, gives the FPGAs the advantage over some microcontrollers as it combines high-speed processing and hardware performance with the possibility of software-based changes in the description of the circuits [25]. It has been shown in previous work by Orsila et al. that multiprocessor system-on-chip architecture has the potential to improve the performance of the whole system and reduce the costs [26]. Other researchers like Raychev et al. have outlined the advantages of implementing a processor in hardware [27], such as improved implementation flexibility and design [18]. Chowdhury et al. obtained their results explained in the aforementioned text within an interval of 1.92ms, which guarantees the real-time behavior [18]. Chowdhury et al. also justify the necessity of using FPGAs by explaining that in third world countries like India, doctors are scarcely available in rural areas (only 2% of doctors reside in rural areas). Therefore, these problems necessitate the use of an inexpensive, portable, low power battery operated high-speed equipment that can have the intelligence to predict an imminent health hazard and red alert the patients in rural sectors to contact the doctors for necessary care [17].

On the other side, real time response and controlled accuracy are the biggest outlined issues when it comes to hardware implementation. A delay of a few milliseconds in delivery of results is not something that can be considered a big difference in medical diagnosis. It could be said that software approach could give satisfactory results, especially in more complex systems, as it would be very hard to implement such systems in hardware, without much gain in speed up [16]. The main motivation for a hardware-based implementation in medical diagnostics is the necessity for an inexpensive and non-invasive portable system. Here, it could be said that the main disadvantage one ASIC based hardware are high development costs and low reconfigurability it offers [16]. Contrary, FPGA solution allows new changes in the proposed diagnostic algorithm to be mapped onto the hardware without costly adjustments [16].

It should be also said that medical diagnosis, as a complex and judgmental process, is based not only on the literature data and data obtained from medical tests, but also on the experience of the doctor. However, as already mentioned, subjective decisions made by doctors are affected by many factors including environment and emotional state of a person (being tired or not, influence of private life etc.) [17, 28]. Additionally, there is also inter-physician variability in the decision process [17]. Because of that, the authors of this paper in their previous work [29] have already established the development of a smart system that employs fuzzy logic to predict the level of disc hernia based on objective force values from four sensors placed on two panels designed for feet. This paper aims at implementing that system on FPGA chip to satisfy real time analysis and development of inexpensive portable on-site platform. Main contributions of the proposed system are:

- implementation of the fuzzy logic for the purposes of objective disc hernia diagnostics on FPGA

- fuzzy inference system was realized in the form of look up table (LUT), to meet the demand for effective resource utilization
- the system is able to connect to the portable platform for foot force measurements, achieving the demand for inexpensive portable on-site platform for objective diagnostic, independent of any computer/laptop.
- the fuzzy system was adapted and is using Sugeno method in comparison to the fuzzy system that used Mamdani method described in [29] to be more suitable for hardware implementation
- the portable device is user-friendly with fast analysis in real time, thus reducing the time and queue for patient diagnostics
- the system is able to detect the improvement in muscle strength after the surgery and physical therapy in comparison to the pre-operational condition, which has not been investigated in any other papers before.

2. Materials and Methods

Complex processes that are usually controlled by human experts should be described using uncertainty models [30]. Although an adequate level of precision can be achieved by quantification of uncertainty, for the most of the processes, a better solution is accepting a certain level of imprecision by using fuzzy logic. This logic describes the imprecision and uncertainty using expert knowledge base as the fundament in controlling a complex process control system [30]. Fuzzy inference system (FIS), if organized in the form of addition and subtraction operations, would benefit from implementation on FPGA, in terms of resource utilization and speed-up. To implement division using FPGA is a challenging task and leads to losing some benefits of using hardware, as division occupies a lot of FPGA resources. Therefore, Bhole et al. proposed a novel algorithm that uses fixed to floating point conversion and used it in implementing floating point division in FIS. Their main conclusion was that proposed dignified methodology for fixed to floating point conversion reduces time requirements and improves resource utilization [30].

2.1. FPGA Implementation of Fuzzy Logic for Disc Hernia Diagnostics

As already mentioned, the main challenges in implementation of fuzzy logic are the dimensionality, real time response and accuracy. These objections can be overcome by using reconfigurable architecture, parallel processing and floating-point operations that are available through Field Programmable Gate Array (FPGA). Proposed block diagram for the FPGA implementation of signal processing for Disc Hernia Diagnostics, coupled with the foot force platform measurement system is shown in Fig 1.

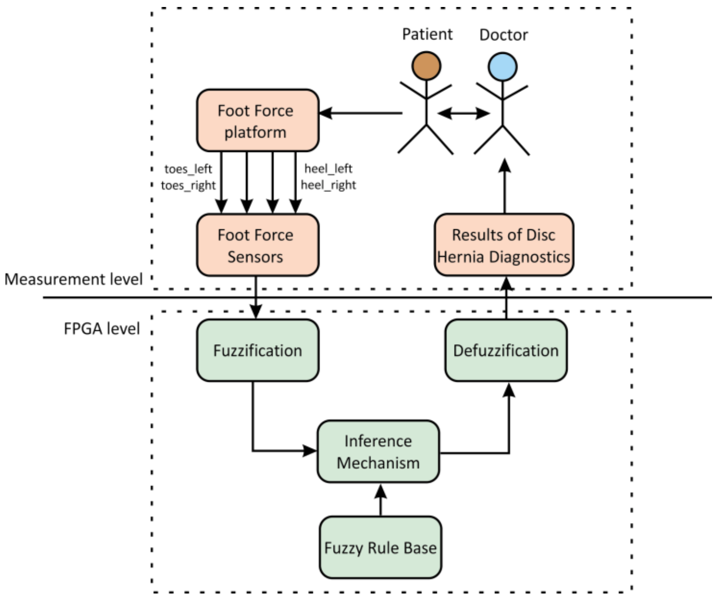

Fig. 1. Block diagram of the proposed coupled FPGA signal processing and foot force platform measurement system

In this figure, on the measurement level, the patient is subjected to the measuring system. The measurement hardware includes two identical platforms with designated surface area for patient's feet. These areas have four sensors per foot placed on specific points of each foot: L1-3 sensors for the left foot placed on the forefeet, L4 sensor placed on the heel of the left foot, R1-3 sensors for the right foot placed on the forefeet, R4 sensor placed on the heel of the right foot. Position of sensors could be adjusted to the patient foot size; therefore, the position is patient specific. Standard Flexi Force A201 [31] sensors are used, with force range from 0 to 440N. The placement choice of four characteristic points of the foot are based on the neurological exam of the doctor. The exam is the standard procedure done by a neurologist and includes pressing each foot of admitted patient against the doctor's hand and examining the pressure that heel and toes are making on the hand. In such a way, the doctor is looking into any differences in pressures between heels and toes of the left and right foot (called muscle weakness in toes/heels). The system is tested with a larger number of sensors (up to 8 sensors per foot - 16 sensors overall), in order to cover greater surface on the platform with sensors. Obtained results were the same, which indicates that at least 4 sensors per foot were enough to capture the phenomena. As a result, the smallest number of sensors that would achieve the highest accuracy was adopted. If another set of sensors (from another producer) would be used, as long as the typical performance of the sensors is not changed (primarily sensor sensitivity and repeatability), the system is able to correctly classify the output diagnosis. Depending on the producer of the sensor, if the operating range is different than the used FlexiForce A201 sensors, the fuzzy system has to be recalibrated to cover the operating range of the sensors. A more detailed explanation of the constructed platform, as well as the place of the sensors L1-L4 and R1-R4 with respect to the platform could be found in [29, 32].

The measurement procedure included three segments which are performed one after another in one continuous recording:

1. patient is standing on both feet normally
2. patient is standing on both feet, but only on the forefeet/toes (term forefoot/toes is used here for standing on the metatarsal heads)
3. patient is standing only on heels

Based on these measurements, average values are calculated directly on the microprocessor:

1. average measurement value from the L1-L3 sensors during the left forefoot standing (further denoted as *toes_left*, also in Fig 1)
2. average measurement value from the R1-R3 sensors during the right forefoot standing (further denoted as *toes_right*, also in Fig 1)
3. average measurement value from the L4 sensor during the left heel standing (further denoted as *heel_left*, also in Fig 1)
4. average measurement value from the R4 sensor during the right heel standing (further denoted as *heel_right*, also in Fig 1)

These values are further sent to FPGA for the fuzzification. The process consists of the usual steps in Fuzzy Logic System (FLS) – fuzzification, inference mechanism that includes knowledge base and defuzzification. Defuzified value is returned to the doctor in the form of indicator whether disc herniation is diagnosed at all, and if it is, at which level it is detected:

1. disc hernia on the left side at the L4/L5 disc level
2. disc hernia on the right side at the L4/L5 disc level
3. disc hernia on the left side at the L5/S1 disc level
4. disc hernia on the right side at the L5/S1 disc level.

2.2. Fuzzy Theory - Fuzzy Inference System Design Steps

Generally, FLS represents a nonlinear mapping of input features into the scalar output based on several steps. The attractiveness of fuzzy logic is the number of possibilities that can be achieved with different mappings [30]. We will further only briefly present the FIS system and describe how it is used to suit the purposes of automatic disc herniation diagnostics. Every FIS should have the following steps:

1. Definition of objectives: Our FIS system should be able to determine the level of disc hernia, based on foot force measurements obtained using the hardware described previously by the same authors [29].
2. Determination of the antecedents, consequents, and fuzzy rules: Fuzzy logic means reasoning using fuzzy sets, and description of linguistic variables, whereas triangular or trapezoidal membership functions are most commonly used. Disc Hernia is a nonlinear process, which can be mapped using trapezoidal membership functions as it was shown in [29]. Normally, since the accuracy of definition is directly dependent on fuzzy patches, it is logical that if the number of fuzzy patches increases, resolution and accuracy increase. However, the complexity of FIS also increases. In order to obtain the balance

between complexity and accuracy, three linguistic variables are selected for each input – very low, low and normal (Fig 2).

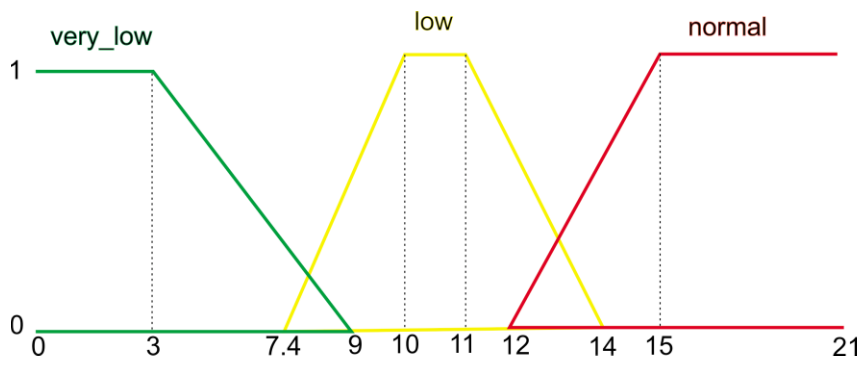

Fig. 2. Linguistic variables used in fuzzification process for disc hernia diagnostics

3. Formulation of the knowledge base: Decision is made based on the expert knowledge, which in our case is defined by the medical doctor. We have defined 42 fuzzy rules implemented as LUT that describe the process of diagnosing the level of disc hernia. Examples of some rules are:
    a. If *toes_left* is VERY_LOW and *toes_righ*t is NORMAL and *heel_left* is NORMAL and *heel_right* is NORMAL, then diagnosis will be L5/S1 ON THE LEFT SIDE
    b. If *toes_left* is NORMAL and *toes_right* is VERY_LOW and *heel_left* is NORMAL and *heel_right* is NORMAL, then diagnosis will be L5/S1 ON THE RIGHT SIDE
    c. If *toes_left* is NORMAL and *toes_right* is NORMAL and *heel_left* is LOW and *heel_right* is NORMAL, then diagnosis will be L4/L5 ON THE LEFT SIDE
    d. If *toes_left* is NORMAL and *toes_right* is NORMAL and *heel_left* is NORMAL and *heel_right* is LOW, then diagnosis will be L4/L5 ON THE RIGHT SIDE
4. Determination of conjunction and disjunction operators: conjunction and disjunction operators are defined in consultation with the medical doctor-expert. For the operators, MAX(x1,x2,x3,x4) was used.
5. Defuzzification: In order to determine the crisp output and final decision from the FIS, several methods can be applied. In Mamdany FIS, crisp conversion is most commonly centre of gravity method where the centroid represents the crisp consequence. However, Mamdani style is not suitable for this project. The reason for this is that Mamdani method requires finding the centroid of a two-dimensional shape by integrating across a continuously varying function [33]. This method is not computationally efficient nor the output in the form of triangle or trapezoidal membership functions is easy to implement. Moreover, defuzzification calculation is very complicated to be achieved in VHDL. Sagaria (2008) proved that with the Mamdani method results are not

necessarily effective or better, and that Sugeno style is much more suitable for hardware implementation [13]. This is due to the fact that the output of this method uses spikes called singletons, meaning there is a unity at single particular point and it is zero elsewhere. This leads to the output of each fuzzy rule being constant [13]. Because of this, Sugeno method has the advantage of being simple as a method, which leads to fast calculations and is relatively easy to implement on hardware. According to [34], fuzzy processor based on the Sugeno method is a good trade-off between the hardware simplicity and efficiency, without the loss in accuracy. Therefore, we have also used Sugeno method to suit the hardware purposes, which is different from the Maamdani method used in [29].

6. Testing and validation: Testing the system and tuning the rules has been achieved through several iterations, until satisfactory results are obtained. The proposed fuzzy inference system has already been proved to be adequate for disc hernia diagnostics in [29].

2.3. FPGA signal analysis

The real time logic (RTL) design of the overall created system is presented in Fig 3. The input to the fuzzy inference system are four values of the foot force measurements as previously mentioned: average measurement value from the L1-L3 sensors during the left forefoot standing (further denoted as *toes_left*), average measurement value from the R1-R3 sensors during the right forefoot standing (further denoted as *toes_right*), average measurement value from the L4 sensor during the left heel standing (further denoted as *heel_left*), and average measurement value from the R4 sensor during the right heel standing (further denoted as *heel_right*). They are all represented as 8 bit *std_logic_vector(7:0).* Of course, inputs to the *top_module* are also clear *(clr*) and master clock (*mclk)* of 50MHz. The reason for using 50MHz is that the master clock on the Nexys 2 board (only available board in our case used for real time implementation) is of that frequency, but the frequency of the *mclk* can be easily changed depending on the available board. Output of the system is the diagnosis in the form of the 4 bit vector (*led(3:0)*), where four 0000 represent the healthy person and each 1 in the four bit vector represents one diagnosis (1000 – L4/L5 on the left side, 0100 – L4/L5 on the right side, 0010 – L5/S1 on the left side; 0001 – L5/S1 on the right side). Another output of the system is the *maximum(7:0),* which represents the certainty value of the calculated diagnosis.

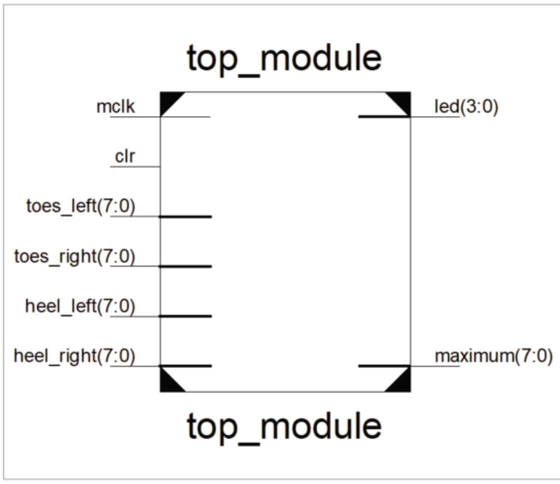

Fig. 3. RTL schematic of the top_module for the fuzzy disc hernia diagnosis system

Inside the *top_module*, the first subsystem is U1 that represents the fuzzification subsystem (Fig 4). The system takes four input values and fuzzifies them according to the defined three linguistic variables - *very low, low and normal*, indicating muscle weakness. After this, based on the LUT table, for each input, an array of three values is created indicating the membership degree to each linguistic variable. This is done in such a way to avoid floating point format, so membership degree is scaled to be in range of 0-100 (instead of 0 - 1). Membership degree is calculated in advance based on the equation for linear function through two points and implemented as LUT table. In the LUT table, the y value with membership degree was calculated for the points on the x axis with the discretization of 0.2. The values are multiplied then with 10, same as for the y axis value, to avoid floating point format and work with integer values. The same logic was applied in [16] and [25]. This means that y value was calculated in advance for 0 (0), 0.2 (20), 0.4 (40) etc. and forwarded to LUT. The input values have to be rounded to the even number, and they are all in the range of 0 – 21 (210), which is covered by 8-bit vector. The system has been tested with both finer and coarser discretization and the adopted described discretization has been shown to have the best tradeoff between the complexity and accuracy. For example, for input *toes_left(7:0)*, an array *fuzzy_t_l* is created, where *fuzzy_t_l(0)(7:0)* indicates the degree of membership to the linguistic variable *very low*, *fuzzy_t_l(1)(7:0)* indicates the degree of membership to the linguistic variable *low* and *fuzzy_t_l(2)(7:0)* indicates the degree of membership to the linguistic variable *normal*. The same output values are further transferred both to U2 and U3.

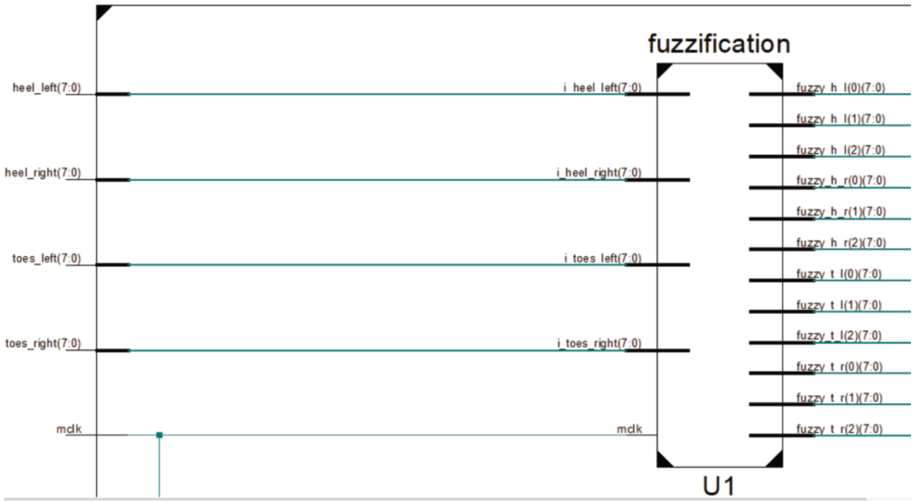

Fig. 4. RTL schematic of U1 subsystem for fuzzification of input data

These variables *fuzzy_t_l*, *fuzzy_t_r*, *fuzzy_h_l*, *fuzzy_h_r* are forwarded to the U2 system (Fig 5) to combine the maximal values for the mentioned variables and determine one overall maximum membership degree and one maximum across three linguistic variables per input. The output of the system is the red colored maximum value (maximal membership value).

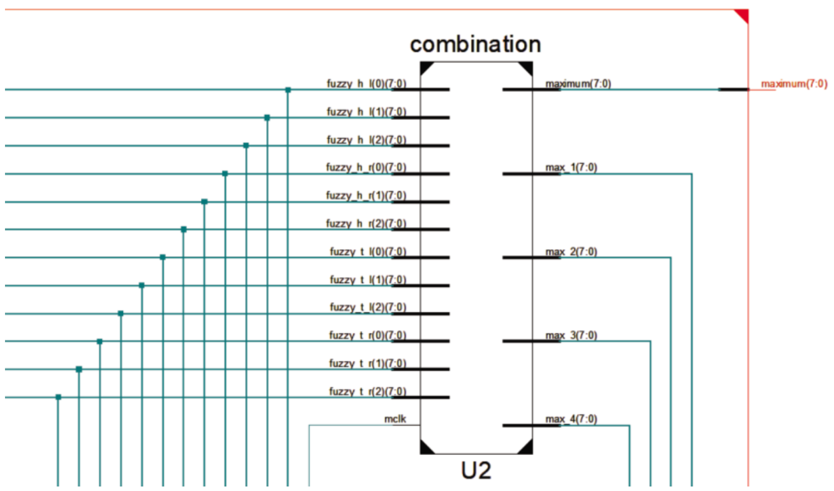

Fig. 5. RTL schematic of U2 subsystem for combination of input fuzzified data

These same variables *fuzzy_t_l*, *fuzzy_t_r*, *fuzzy_h_l*, *fuzzy_h_r* are forwarded to the U3 system (Fig 6), along with the calculated maximum *max_1(7:0)* to *max_4(7:0)* to determine which linguistic variables are active. This is organized in such a way that *max_1(7:0)* to *max_4(7:0)* is compared with the *fuzzy_t_l(7:0)*, *fuzzy_t_r(7:0)*, *fuzzy_h_l(7:0)*, *fuzzy_h_r(7:0)*, and 001 is shifted to the left a number of times that corresponds to the index of the *fuzzy_x_x* that matches the value of *max_x*. This means that only one linguistic variable will be active per fuzzified input bit equals 1 in the place corresponding to the activated linguistic variable. As follows, four outputs r*_toes_left(2:0)*, *r_toes_right(2:0)*, *r_heel_left(2:0)*, *r_heel_right(2:0)* are created, where only one bit will be 1, and the remaining two bits will be 0.

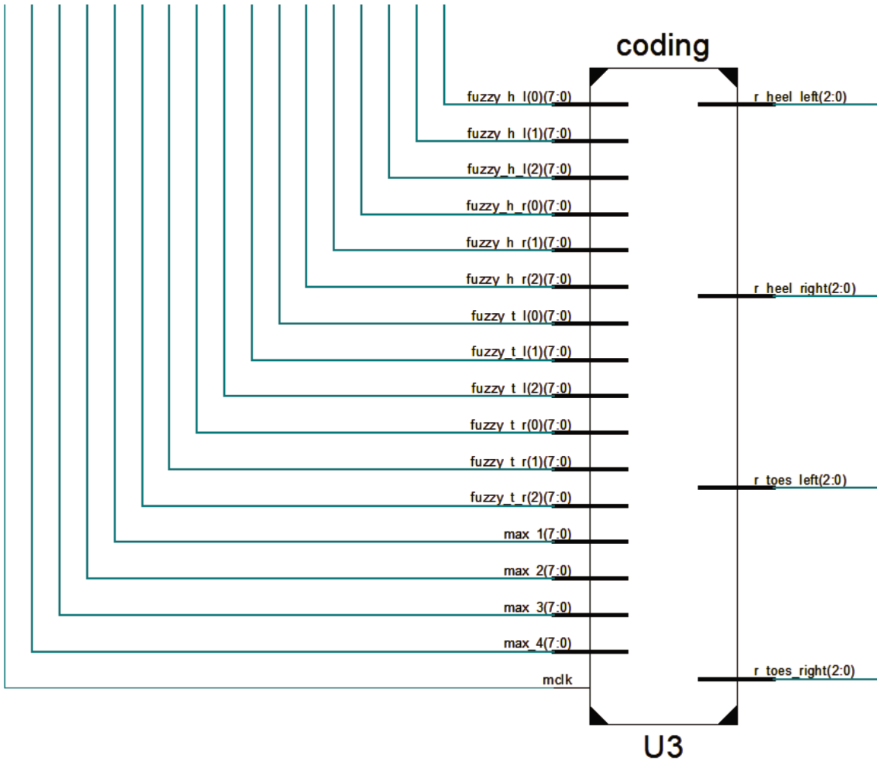

Fig. 6. RTL schematic of U3 subsystem for coding of input data

Calculated variables *r_toes_left(2:0)*, *r_toes_right(2:0)*, *r_heel_left(2:0)*, *r_heel_right(2:0)* serve as the input to the final block U4 shown in Fig 7. This block is responsible for rule activation. Overall, 42 rules were written based on expert knowledge. Final output is a four bit vector output(3:0), where position of the bit with the value 1 indicates the diagnosis (1000 – L4/L5 on the left side, 0100 – L4/L5 on the right side, 0010 – L5/S1 on the left side; 0001 – L5/S1 on the right side). The output diagnosis can be shown as led light on FPGA hardware board, where the position of the led indicates the diagnosis, so no knowledge of the hardware is necessary to understand the final output on the board.

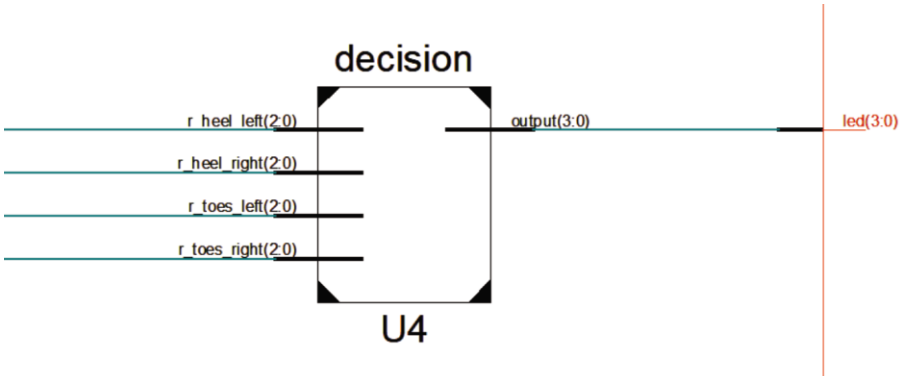

Fig. 7. RTL schematic of U4 subsystem for final decision (defuzzification)

2.4. Dataset

The dataset used in this study included force measurements of 56 adult subjects pre-operationally diagnosed with L4/L5 or L5/S1 discus hernia and 33 adult subjects after surgery and physical therapy. Their medical condition was assessed before operation, after the surgery and after physical therapy using both the designed system and doctor expert. Dataset was collected during the period from 2015 to 2020, in Clinical Centre Kragujevac, Serbia. Demographic details of subjects - gender, age, height and weight were assessed and noted. Information about demographic data is given in Table I in the form of mean ± standard deviation. Inclusion criteria for the study was that patients had only disc herniation at the level of L4/L5 and L5/S1 and were without any other spinal problems. This means that patients with spinal stenosis, spondylolisthesis, cauda equina syndrome, neurogenic claudication or previous spinal surgery, or diseases affecting multiple discs were excluded from the dataset. Patients with pathologies of the lumbar spine, including tumors, infections, inflammatory spondyloarthropathies, fractures, Paget disease, severe osteoporosis, diabetes and pregnancy were excluded from the dataset as well.

Table 1. Demographic details of the tested patients – preoperational, post operational and after physical therapy

Pre-operational	Number	Age (years)	Weight (kg)	Height (cm)
Male with disc hernia	28	43.78±13.41	96.33±14.9	181.33±5.55
Female with disc hernia	28	41.80±9.96	75.5±9.42	172.83±4.96
Post operational and after physical therapy	Number	Age (years)	Weight (kg)	Height (cm)
Male with disc hernia	17	42±13.37	90±13.30	182±5.66
Female with disc hernia	16	42±13	66±9	169±7

Distribution of the patients with disc herniation pre-operationally, belonging to four different categories was as follows:

1. disc hernia on left side at the L4/L5 disc level (12 patients)
2. disc hernia on right side at the L4/L5 disc level (12 patients)
3. disc hernia on left side at the L5/S1 disc level (13 patients)
4. disc hernia on right side at the L5/S1 disc level (19 patients)

Distribution of the patients with disc herniation post-operationally and after physical therapy, belonging to four different categories was as follows:

1. disc hernia on left side at the L4/L5 disc level (9 patients)
2. disc hernia on right side at the L4/L5 disc level (5 patients)
3. disc hernia on left side at the L5/S1 disc level (7 patients)
4. disc hernia on right side at the L5/S1 disc level (12 patients)

Patients with disc hernia L3/L4 were not included in this study as there is no proven relationship between the muscle weakness and this diagnosis. Additionally, it is not so common diagnosis, and only one patient was admitted during dataset collection with this diagnosis. This distribution is logical as previous investigation on distribution of disc hernia diagnosis showed that 75% of herniated discs occur at the lumbosacral junction (L5/S1), 20 % at L4/L5 level and the remaining 5% of the upper lumbar levels (L3/L4 etc.) [35].

3. Results and Discussion

The results showed that the designed system is accurate enough to be used as a transportable system with the measurement platforms. Also, the system is able to detect the improvement in muscle strength after the surgery and physical therapy. As it was previously reported, the results show that smaller forefoot force is recorded on the corresponding foot in the case of the patient diagnosed with L5/S1 disc hernia, whilst weaker heel force was recorded on the corresponding foot in the case of the patient diagnosed with L4/L5 disc hernia. For example, in the case of the patient diagnosed with L4/L5 disc hernia on the left side, weaker heel force was detected on the left foot; if the patient is diagnosed with L5/S1 disc hernia on the right side, weaker forefoot force was detected on the right foot etc. The results are in accordance with previously published results by authors and with diagnostic logic used by the doctor. The medical background that supports this logic lies in the fact that innervation of the muscles and skin area that are present on the toes originate from the nerves between L5 and S1 discs in the spine, while innervation of the heels is done via nerves that originate between L4 and L5 discs in the spine [36, 37].

An example of the diagnosed L5/S1 disc hernia on the right side is given in Fig 8. The most important signals were already explained in the section Materials and Methods. Inputs to the system are four recorded values *toes_left(7:0), toes_right(7:0), heel_left(7:0), heel_right(7:0).* Additional variables *r_toes_left(2:0), r_toes_right(2:0), r_heel_left(2:0), r_heel_right(2:0)* show membership functions activated by each input variable after fuzzification. Variables *max_1(7:0), max_2(7:0), max_3(7:0), max_4(7:0)* show the membership degrees of the previously explained activated membership functions. The output is *led(3:0)* where the position of 1 indicates the diagnosis, in this case, number one in the last position indicates the detected diagnosis L5/S1 on the right side.

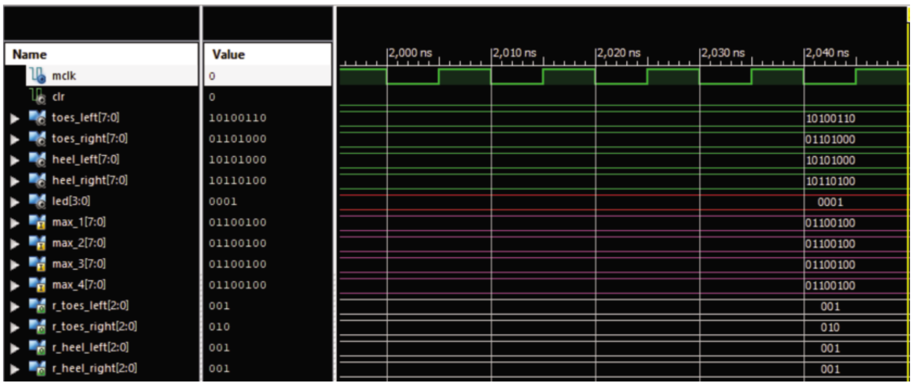

Fig. 8. Simulation results in the case of L5/S1 disc hernia on the right side

The results for the pre-operational state show that out of 56 patients preoperationally, 52 patients were diagnosed with the correct diagnosis by Matlab that matches the gold standard (Table 2). Out of the three wrongly classified diagnosis, two were L4/L5 on the left side and two were L5/S1 on the right side. This means that the overall accuracy was 92.85%.

Table 2. Comparison of the gold standard, Matlab and FPGA results for pre-operational diagnosis

Diagnosis	Gold Standard (medical doctor)	Number of patients correctly diagnosed	
		Matlab	FPGA
L4/L5 left	12	10	9
L4/L5 right	12	12	12
L5/S1 left	13	13	13
L5/S1 right	19	17	15

For the mentioned four patients with wrong diagnosis in comparison to the gold standard, three patients were classified as healthy, meaning the system was not able to detect disc herniation on any level, due to small differences in recorded forces, that were not big enough to diagnose herniated disc. One patient was diagnosed with L4/L5 on the right side (instead of L5/S1 on the right side), because the recorded value of the force on the right heel was close to zero. It is understandable that the system gave such output, both using the Matlab and FPGA, however, the recorded value may not represent the real case, as it could have happened that the sensors were not adjusted well to match the patient's foot size adequately, and the force was not well recorded.

Additionally, we compared the results of the fuzzy system implemented in Matlab, which uses floating point format in order to compare it with the results obtained with the implemented logic in FPGA (Table 2 second and third column). Three patients showed mismatch between the Matlab and FPGA output. The reason for this was the discretization logic that was not detailed enough for these three cases to capture the phenomena. However, if a more detailed discretization is adopted, these cases could have been included. As a result, the patients were misclassified by FPGA, in comparison to the Matlab output (one diagnosis was L4/L5 on the left side and two were diagnoses L5/S1 on the right side). This means that sensitivity, specificity and accuracy respectively, using FPGA in comparison to the Matlab, were:

- L4/L5 on the left side – 0.818, 0.977, 0.945
- L4/L5 on the right side – 1, 0.977, 0.982
- L5/S1 on the left side – 1, 0.976, 0.982
- L5/S1 on the right side – 0.882, 0.975, 0.947

The promising results when comparing the pre-operational diagnosis between the FPGA and Matlab were confirmed also for the post-operational and after physical therapy results. For the case of post-operational state, Matlab and FPGA results matched 100%, where the improvement was detected in 18 cases (54.5% of patients) (Table 3).

Table 3. Comparison of the gold standard, Matlab and FPGA results for improved post-operational condition

Pre-operational diagnosis	Number of patients with improved condition		
	Gold Standard (medical doctor)	Matlab	FPGA
L4/L5 left	4	4	4
L4/L5 right	3	3	3
L5/S1 left	4	4	4
L5/S1 right	7	7	7

Out of these, 4 of the 9 patients with L4/L5 on the left side showed improvement, 3 of the 5 patients with L4/L5 on the right side showed improvement, 4 of the 7 patients with L5/S1 on the left side showed improvement and 7 of 12 patients with L5/S1 on the right side showed improvement. The doctor's diagnosis confirmed these improvements, meaning that gold standard matched the results obtained by either Matlab/FPGA. One patient was wrongly diagnosed with L5/S1 disc hernia on the left side after operation, while before operation the diagnosis was L5/S1 disc hernia on the right side. There was a problem with decision regarding two patients, which had very low values on some sensors – one patient was the same patient as described above, with the force on the right heel that was close to zero. Since the same situation was noticed again after physical therapy, we can conclude that this patient (female) could have had very small feet size that were not placed well on the platform and the sensors were not adjusted well to fit the feet of this patient. Because we had only 33 patients, we did not want to exclude this patient from the dataset, but instead we give this very plausible explanation for the result, which will serve as a reminder for a doctor/physician that will use this decision support system to pay attention when adjusting the placement of sensors. A recommendation for the future upgrades of the system would be to create several fixed positions according to the size of the feet of the tested subjects, which could be changed similarly to the moving rack, so only some positions are available, and not the infinite number of positions.

For the after physical therapy condition, even more patients showed muscle strength improvements (23 patients) - 7 of the 9 patients with L4/L5 on the left side, 5 of 5 patients with L4/L5 on the right side, 5 of the 7 patients with L5/S1 on the left side and 6 of the 12 patients with L5/S1 on the right side (Table 4).

Table 4. Comparison of the gold standard, Matlab and FPGA results for improved after physical therapy condition

Pre-operational diagnosis	Number of patients with improved condition		
	Gold Standard (medical doctor)	Matlab	FPGA
L4/L5 left	7	7	7
L4/L5 right	5	5	5
L5/S1 left	5	5	5
L5/S1 right	6	6	6

As already mentioned, one female patient had a recording of values close to zero for more than one sensor for pre-operational, post-operational and after physical therapy, leading to false alarms as a result of a systematic error in measurement. Other 5 wrongly diagnosed L5/S1 on the right side, 2 wrongly diagnosed L5/S1 on the left side and 2 wrongly diagnosed L4/L5 on the left side matched the logic described by the doctor when diagnosing the level of herniated discs - it was the measurements that mislead to such conclusions. When it comes to the comparison of the Matlab and FPGA results, the match was 100%, meaning that the same outputs were given by Matlab and FPGA in all cases, as well as the same match was achieved when compared with the gold standard.

The simulation time to obtain results was of ns order of magnitudes, while the device utilization summary is given in Table 5. The available used hardware was Nexys 2 circuit board, which is a complete development platform based on a Xilinx Spartan 3E FPGA [38]. Beside the 500K-gate Spartan 3E-500 FG320 chip, the platform has 50MHz oscillator plus socket for second oscillator, 16MB of Micron PSDRAM &16MB of Intel Strata Flash ROM external memory, and several I/O devices and ports that allow user to perform complex implementation of different algorithms.

Table 5. Device utilization summary

	Used	Available	Utilization
Number of Slices	522	4656	11%
Number of Flip Flops	12	9312	0%
Number of 4 input LUTs	933	9312	10%
Number of IOBs	44	232	18%

Some authors used the idea of processing only the active rules (meaning the rules that give a non-null contribution to the final result), instead of all of them [34]. This is done in order to reduce the utilization of the resources on the board. We have achieved this by using the LUT, and as it can be seen from the Table, even with a simple development board, the results are satisfying.

We wanted to prove that discretization logic proposed in this paper, as well as implementation of the fuzzy logic as LUT table does not lead to the loss in the accuracy and in return gives the benefits of using FPGAs in signal processing like parallel processing, speed up etc. Additionally, the main benefit here is that the board platform could be used to be connected to the measurement platform, achieving the real time processing, without the use of different applications, laptops/computers etc. User-friendly interface is achieved in this study via output result that will be in the form of led light, where the position of the led light indicates the diagnosis. However, it could be also easily achieved that the diagnosis is written on the led display or similar, whatever option the doctor (user) finds more appealing. Standard microcontroller provides flexibility in the definition of the knowledge base and choosing the inference algorithms. Nonetheless, the same microcontrollers become inadequate when solving the problems that demand high inference speeds, small size, and low power consumption. For this reason, more specific hardware solutions must be chosen, such as FPGAs, which are more than adequate when the needs for applications related to portable embedded systems or strong real-time requirements have to be met [22,23].

There are couple of papers such as [6], [37] and [38] that examine the neurological relationship between the nerve roots and the dermatomes. However, these studies are conducted mainly from a medical point of view in the form of case studies and describe the justifications for the use of muscle weakness in the treatment of disk herniation and related spine problems. Except some papers from our research group [29, 32, 39], there are no studies that develop the platform for the purposes of disc hernia diagnostics, nor there are papers concerned with the application of any artificial intelligence algorithms on foot force signals to diagnose disk hernia at the levels of L4/L5 and/or L5/S1 levels. Our research group has developed a novel platform with sensor presented in [29], that would be used to record and detect muscle weakness on toes. Another paper by the same research group investigated the statistical significance of the sensor values in comparison to the clinical manual muscle test [39], while an early disk herniation identification system as a supportive tool for physicians is presented in [32], which will serve as a supportive tool to send the tested patients for further examination. No other work has developed such a framework for accurately calculating muscle weakness and implemented any machine learning algorithms to objectively determine disc hernia level (L4/L5 or L5/S1) and side (left or right).

Fuzzy logic may not be the best approach in solving this kind of a problem in comparison to the more advanced artificial intelligence algorithms. This represents the main limitation of this study. However, fuzzy logic is easily implemented in FPGAs in comparison to the neural networks, SVM etc. and the presented results show the accuracy is high enough to be used even without the application of complex algorithms. The logic behind the disc hernia detection is based on IF-THEN-ELSE rules, and therefore the fuzzy logic stands as a logical choice in solving such problems. The main advantage of the system implemented on FPGA is that real time signal acquisition, processing and decision support system in disc hernia diagnosis and post-surgical recovery can be implemented. In that sense, FPGA have the precedence over GPU when it comes to the real time signal acquisition and analysis.

4. Conclusion

Fuzzy Logic provides a different approach to solving a classification problem, which in this study is the level of disc hernia diagnosis. This method is based on the expert knowledge for the formulation of the rule base, which is a powerful tool in solving the problem. It is very convenient to use when there is no mathematical model to describe the phenomena, which was adequate in this study, as the process of disc hernia diagnosis is described with if-then-else rules. We have already used the explained fuzzy logic on the problem of disc hernia diagnostics as presented in [29]. However, system presented in [29] had to be connected to the laptop or desktop computer, with adequate application that the doctor should get familiar with etc. These main drawbacks were addressed in this paper, which lead to the application of the FPGA in processing the obtained signals. The results show that the adapted fuzzy logic system achieves satisfying results both for pre-operational diagnosis, but also detects the improvements after the surgery and physical therapy. Generally, the system showed 92.8% accuracy and very high match between the Matlab and FPGA output (94.2% match for pre-operational condition, and 100% match for the post-operational and after physical therapy conditions). Some mis-classification results were the problem of measurement, possibly due to the bad adjustments of the sensors to the feet of the patient.

Future research would be focused on employing the described system in real conditions as a portable expert system for acquisition, processing and giving the objective recommendation for a final decision of disc hernia diagnosis.

References

1. Jensen, M., Brant-Zawadzki, M., Obuchowski, N., Modic, M., Malkasian D., Ross, J.: Magnetic resonance imaging of the lumbar spine in people without back pain. New England Journal of Medicine, vol. 331, 69–73 (1994)
2. Trafimow, D. and Trafimow, J.: The shocking implications of Bayes' theorem for diagnosing herniated nucleus pulposus based on MRI scans. Cogent Medicine, vol. 3, no. 1, 1133270-1-7 (2016)
3. Al Nezari, N. H., Schneiders, A. G., Hendrick, P. A.: Neurological examination of the peripheral nervous system to diagnose lumbar spinal disc herniation with suspected radiculopathy: a systematic review and meta-analysis. The Spine Journal, vol. 13, no. 6, 657-674 (2013)
4. Shahbandar, L., Press, J.: Diagnosis and nonoperative management of lumbar disk herniation: Operative Techniques in Sports Medicine, vol. 13, no. 2, 114-121, (2005)
5. McGee, S.: Examination of the Sensory System, in Evidence-based physical diagnosis, Elsevier Health Sciences (2012)
6. Hancock, M. J., Koes, B., Ostelo R., Peul, W.: Diagnostic accuracy of the clinical examination in identifying the level of herniation in patients with sciatica. Spine, vol. 36, no. 11, E712-E719 (2011)
7. Winn, H. R.: Youmans Neurological Surgery, Elsevier Health Sciences (2011)
8. Greenberg, M. S., Arredondo, N.: Handbook of neurosurgery (Vol. 1013). New York: Thieme. (2001)
9. McCarthy, C. J., Gittins, M., Roberts C., Oldham, J. A.: The reliability of the clinical tests and questions recommended in international guidelines for low back pain. Spine, vol. 32, no. 8, 921-926 (2007)
10. Vroomen, P. C., de Krom M. C., Knottnerus, J. A.: Consistency of history taking and physical examination in patients with suspected lumbar nerve root involvement. Spine, vol. 25, no. 1, 91 (2000)

11. Sulaiman, N., Obaid, Z. A., Marhaban, M. H., Hamidon, M. N.: FPGA-based fuzzy logic: design and applications-a review. International Journal of Engineering and Technology, vol. 1, no. 5, 491-503 (2009)
12. Sakthivel, G., Anandhi T., Natarajan, S.: Real time implementation of a fuzzy logic controller on FPGA using VHDL for DC motor speed control. International Journal of Engineering Science and Technology, vol. 2, no. 9, 4511-4519 (2010)
13. Sagaria, S. A. M.: Fuzzy logic design using VHDL on FPGA. School of Computer and Communication Engineering, University Maleysia Perlis (2008)
14. Kumbhar, T. R., Nirmale S. S., Mudholkar, R. R.: FPGA implementation of fuzzy logic controller for temperature control. International Journal of Computer Applications, vol. 62, no. 20, 4511-4519 (2013)
15. Akkaya, Ş., Üzgün H. D., Akbati, O.: Fuzzy Logic Controller Implementation with FPGA in the Loop Simulation. In Proceedings of the 2017 International Conference on Mechatronics Systems and Control Engineering, Kayseri, Turkey (February 2017)
16. Chowdhury, S. R., Chakrabarti D., Saha, H.: FPGA realization of a smart processing system for clinical diagnostic applications using pipelined datapath architectures. Microprocessors and Microsystems, vol. 32, no. 2, 107-120 (2008)
17. Chowdhury, S., Saha, H.: Development of a FPGA based fuzzy neural network system for early diagnosis of critical health condition of a patient. Computers in biology and medicine, vol. 40, no. 2, 190-200 (2010)
18. Chowdhury, S. R., Saha, H.: A high-performance FPGA-based fuzzy processor architecture for medical diagnosis. IEEE Micro, vol. 28, no. 5, 38-52 (2008)
19. Cintra, E. R. F., Pimenta T. C., Moreno, R. L.: The use of fuzzy clustering and correlation to implement a heart disease diagnosing system in FPGA. Journal of Software Engineering and Applications, vol. 4, no. 8, 491-496 (2011)
20. Jothi, M., Balamurugan N. B., Harikumar, R.: Design and Implementation of VLSI Fuzzy Classifier for Biomedical Application. International Journal of Innovative Research in Science, Engineering and Technology, 2641-2648 (2014)
21. Balamurugan, N. B., Jothi, M., Harikumar, R.: FPGA Synthesis of SIRM Fuzzy System-Classification of Diabetic Epilepsy Risk Level. Procedia engineering, vol. 38, 391-404 (2012)
22. Nilosey, A.: FPGA Based Diabetic Patient Health Monitoring Using Fuzzy Neural Network. International Journal of Science and Research (IJSR), 394-396 (2014)
23. Barriga, A., Sánchez-Solano, S., Brox, P., Cabrera, A., Baturone, I.: Modelling and implementation of fuzzy systems based on VHDL. International Journal of Approximate Reasoning, vol. 41, no. 2, 164-178 (2006)
24. Graas, E. L., Brown, E. A., Lee, R. H.: An FPGA-based approach to high-speed simulation of conductance-based neuron models. Neuroinformatics, vol. 2, no. 4, 417-435 (2004)
25. Oliveira, D. N., de Souza Braga, A. P., da Mota Almeida, O.: Fuzzy logic controller implementation on a FPGA using VHDL. In Annual Meeting of the North American Fuzzy Information Processing Society, Toronto, ON, Canada (July 2010)
26. Orsila, H., Kangas, T., Salminen, E., Hämäläinen, T. D., Hännikäinen, M.: Automated Memory-Aware Application Distribution for Multi-Processor System-on-Chips. Journal of Systems Architecture, vol. 53, no. 11, 795-815 (2007)
27. Raychev, R., Mtibaa A., Abid, M.: VHDL modeling of a fuzzy coprocessor architecture. In Proceedings of International Conference on Computer Systems and Technologies, Varna, Bulgaria (2005)
28. Lilford, R. J., Pauker, S. G., Braunholtz D. A., Chard, J.: Decision analysis and the implementation of research findings. BMJ, Vol. 317, no. 7155, 405-409 (1998)
29. Peulić, A., Šušteršič T., Peulić, M.: Non-invasive improved technique for lumbar discus hernia classification based on fuzzy logic. Biomedical Engineering/Biomedizinische Technik, vol. 64, no. 4, 421–428 (2018)

30. Bhole, K., Agashe, S., Deshpande, A.: FPGA implementation of type 1 fuzzy inference system for intravenous anesthesia. In IEEE International Conference on Fuzzy Systems (FUZZ-IEEE) (July 2013)
31. Tekscan: Pressure Mapping, Force Measurement & Tactile Sensors (2018) [Online]. Available: http://www.tekscan.com/flexible-force-sensors (current May 2018).
32. Sustersic, T., Rankovic, V., Peulic M., Peulic, A. S.: An Early Disc Herniation Identification System for Advancement in the Standard Medical Screening Procedure based on Bayes Theorem. IEEE Journal of Biomedical and Health Informatics, vol. 24, no. 1, 151-159 (2020)
33. Kusiak, A.: Fuzzy Logic. The University of Iowa, Iowa City (2004)
34. Deliparaschos, K. M., Tzafestas, S. G.: A parameterized TS digital fuzzy logic processor: soft core VLSI design and FPGA implementation. International Journal of Factory Automation, Robotics and Soft Computing, vol. 3, 7-15 (2006)
35. Ahn, U., Ahn, N., Buchowski, J., Garrett, E., Sieber, A., Kostuik, J.: Cauda equina syndrome secondary to lumbar disc herniation: a meta-analysis of surgical outcomes. Spine, vol. 25, no. 12, 1515-1522 (2000)
36. Nexys D.: Reference Manual Nexys2 (2008) [Online]. Available: http://www.ece.umd.edu/class/enee245.F2016/nexys2_reference_manual.pdf (current May 2019)
37. Suri, P., Rainville, J., Katz, J. N., Jouve, C., Hartigan, C. Limke, J.: The accuracy of the physical examination for the diagnosis of midlumbar and low lumbar nerve root impingement. Spine, vol. 36, no. 1, 63 (2011)
38. McCarthy, C., Gittins, M., Roberts C., Oldham, J.: The reliability of the clinical tests and questions recommended in international guidelines for low back pain. Spine, vol. 32, 921-926 (2007)
39. Peulić, M., Joković, M., Šušteršič, T., Peulić, A.: A Noninvasive Assistant System in Diagnosis of Lumbar Disc Herniation: Computational and Mathematical Methods in Medicine. Article ID 6320126 (2020)

Tijana Šušteršič is a Teaching Assistant and Ph.D student at the Faculty of Engineering, University of Kragujevac, Kragujevac, Serbia. She finished M.Sc. and B.Sc. studies at the same Faculty with GPA 10.00/10.00 and as the best student in generation. She participated in the National project by Ministry of Education, Science and Technological Development of the Republic of Serbia [grant number OI174028], three COST projects, several Horizon 2020 projects and was part of bilateral project between Austria-Serbia and Slovenia-Serbia. She is the author and co-author of 14 papers presented at the international conferences and 11 papers published in international journals. She possesses Certificate of Proficiency in English (CPE) level C2 and Goethe Zertifikat in German, level B2 according to the Common European Framework of Reference for Languages. The focus of her current research is on biomedical signal processing using machine learning, as well as implementation of algorithms on Field Programmable Gate Array (FPGA).

Miodrag Peulić is a Teaching Assistant at Faculty of Medical Science - University of Kragujevac and he is a director of Center of Neurosurgery in Clinical Center of Kragujevac. He finished Faculty of Medical Science at University of Kragujevac in 1999. He became specialist of neurosurgery in 2007. at Faculty of Medicine – University of Belgrade. He finished Specialist-academic studies in 2010. and subspecialization of oncology in 2019. at University of Belgrade. He is author and co-

author of 8 published papers in international journals. He deals with the operative treatment of patients from various fields of neurosurgery.

Aleksandar Peulić is a Full Professor at the Faculty of Geography, University of Belgrade, Belgrade, Serbia, and part time professor at Faculty of Science, University of Kragujevac, Kragujevac, Serbia. He received the Diploma degree in electronic engineering and the Master of Science degree in electrical engineering both from the Faculty of Electronic Engineering, University of Nis, Nis, Serbia, in 1994 and 2004, respectively and PD degree at University of Kragujevac in computer science 2007. He was a Postdoctoral Research Fellow at the University of Alabama, Huntsville, in 2008 and University of Applied Science, Augsburg, Germany, in 2010. He is the author and co-author more than 80 papers presented at the international conferences and published in peer review journals. His research interests include embedded systems, digital signal processing and image processing.

Received: February 24, 2020; Accepted: January 15, 2021.