Distraction Osteogenesis in Oral and Maxillofacial Reconstruction Applications: Feasibility Study of Design and Development of an Automatic Continuous Distractor

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ABSTRACT:
Distraction Osteogenesis (DO) is one of the novel techniques widely used in bone Reconstruction Applications (RA). Recently, DO method has got an important role in oral and maxillofacial RA; by using DO bone defects and skeletal deformities in different cranio-maxillofacial areas can be reconstructed, with better results and reduced effects in comparison to conventional methods. In DO by using a tension-stress principle, mechanical stimulations induce bone generation and biological responses of the tissue. A DO procedure starts with bone osteotomy and implementation of the distractor, before proceeding with distraction, there is a latency period which allows the callus to form initially. In the distraction phase, the generated external force goes through the moving bone segment and gradually distracts the callus. After the distraction phase, there is a consolidation phase and then the device is removed. Most of current DO methods are applied by manual devices; low accuracy and reliability, discontinuous force, manually-operated, and associated problems for the patient are major disadvantages of manual devices. Recent studies have revealed using an automatic continuous distractor could significantly improve the DO results while decreasing the existing problems. The purpose of this study is to design and simulate a novel automatic continuous distractor to be used in DO applications. The device contains a mini stepper motor and gearbox, controller, mechatronic system, LCD, and keypad. Design's specification and simulation results revealed the designed device has the capability to generate a continuous distraction force for a successful automatic DO.

KEYWORDS: Automatic Continuous Controller, Distraction Osteogenesis, Medical Devices.

1. INTRODUCTION

Distraction Osteogenesis (DO) is a recent method which has been used in bone Reconstruction Applications (RA) in different areas of the human body. Through unique advantages of this technique, DO receives further clinical and medical attention in Maxillofacial Reconstruction Applications (MRA). By using DO, different bone defects, congenital growth retardation of the bone tissue, and skeletal deformities in the cranio-maxillofacial area can be reconstructed with a better quality, while reducing problems of other bone reconstruction methods [1], figure 1 shows a typical DO procedure for reconstruction of Mandible. DO starts with the bone osteotomy and installation of the distractor. In the next phase, the latency phase, there is a 4 to 7 days delay to allow the callus to form initially. After latency, the distraction phase begins and the external Distraction Force (DF) gradually goes through the bone segment and moves it. After the distraction phase, there is a consolidation period of 7 to 14 days and then the distractor is removed [2-4]. Figure 2 shows a complete process of DO. In the distraction phase, mechanical stimulations induce bone generation and biological responses of the tissue and cause a soft bone lengthening. Different factors affect the distraction procedure, the rate and the rhythm of the distraction are major factors which directly influence a DO procedure [3].

The DO method proposed and developed in 1950 by Gabriel Ilizarov based on many years of experiments and clinical results, Ilizarov used the first manual distractor for human DO in RA. Since that year, different research and experiments have been done to develop the DO method while modifying the design of the distractors [2, 3].

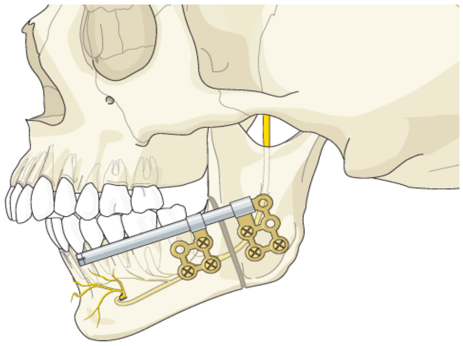

Fig. 1. Distraction Osteogenesis of Mandible [5].

In 1973 Snyder published a report about the first successful DO in MRA; in this study, a manual distractor device was used for reconstruction of a craniofacial skeleton defect in the dog mandible [6]. In 1992 McCarthy and other researchers presented first clinical results of using DO method for MRA; results proved DO is actually an improved solution which offers better results in comparison to other conventional reconstruction methods [7-13]. In a manual DO procedure, the Distraction Rate (DR) is between 0.25 to 1 mm/day which applies a discontinuous force to move the Bone Segment (BS) daily [14]. Further researches demonstrated on a specific DR, increasing DR could improve the bone healing results while reducing the Activation Phase (AP) of the DO [3, 15-19]. From the year 2000, by increasing the application of DO in human RA, researchers started to design and develop continuous distractors using automatic systems. Different studies revealed an automatic continuous distractor can increase the DR up to 3 millimeter/day while decreasing the AP, with a better quality of generated bone, as well as, reducing manual distractors technical problems [20-22]. The key elements of a successful Automatic Continuous Distraction Osteogenesis (ACDO) treatment are; the rate and the rhythm of distraction, the Distraction Vector, and the DF [23-25]. Several investigations have concentrated on advancing the accuracy, the distractor's safety, reducing distraction errors, and the DV of ACDO on unilateral models [26-30].

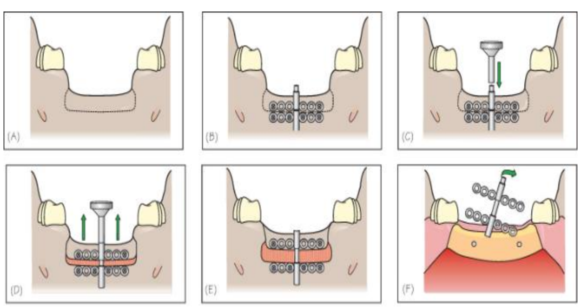

Fig. 2. Distraction Osteogenesis procedure [31].

A few ACDO devices through different movement mechanisms have been designed and developed including; motor based system [14, 32-34], electromechanical system [35-38], hydraulic valve [18, 39-41], spring-mediated system [9, 42-45], shape memory alloy [44], load cell [46], and piezoelectric motor [25]. The first successful application of ACDO devices in human MRA was designed and used in mandibular reconstruction in 2005 [47], in this research a hydraulic valve was used to generate continuous DF. In the year 2009, by using spring-powered hydraulic components, an implant was designed and built with the position error less than 0.09 millimeter to be used in continuous distraction of the mandible [40], in 2015 further experiments and clinical results proofed that this device can be used to successfully distract the bone with the DR up to 3 millimeter/day [20]. In 2010, by using an automatic controller, an implantable battery system was designed and used in animal studies to evaluate the effects of continuous distraction on the DO method, results revealed that such continuous DO can significantly improve the DR and the bone healing results [33]. In 2011 an intraoral piezoelectric motor based micro distractor was developed to be used in continuous jaw bone DO, the results of the experiments proved the advantages of using such ACDO method [25]. Another preliminary study on mini pigs in 2013 proved that ACDO allow faster distraction and it will increase the DR up to 3 millimeter/day with better bone formation [19].

However, there are complications, limitations, and disadvantages still existing both in manual and automatic operated devices. In the manual method, the long period of the treatment, the low accuracy and reliability of the distractor, the need for a manual DF, and the patient compliance in the AP, their discomfort due to the difficult and complicated circumstance of the post-surgery process, physical and psychosocial problems, and the possibility of misapplying of the device are the main disadvantages of the process. These issues become worse when a manual distractor is implemented for children and handicaps [45, 48, 49]. In automatic devices; in the spring-mediated distractors, decreasing of the spring force and the nonlinear DV are major disadvantages of these systems [9, 37, 38, 42, 44], in motor based distractors, technical problems including gear break and program failure, bone fracture, the big size of distractors, and post-operative infections are basic issues [14, 26, 27, 33]. In addition, in hydraulic valve systems, the big size of the distractor and the low accuracy are the main disadvantages of such systems [19, 20, 39, 40]. The purpose of this study is to design a new ACDO device by using a novel automatic linear position controlling method [50, 51], to increase the movement accuracy and reliability, and to decrease the positioning error percentage, the AP, the distractor size, and the complications in the device failure, while reducing side effects on the utilization of the device on the patient.

2. DESIGN AND SIMULATION OF AUTOMATIC CONTINUOUS DISTRACTOR

To design an automatic distractor to be used in DO applications, different subsections has to be designed and simulated. The system needs to have the capability of generating continuous linear force with a high level of movement accuracy. The proposed design for the distractor consists of following sections.

2.1. Linear Movement Translation Mechanism

The designed translation mechanism comprises a mechatronic system to translate stepper motor's rotational motion to linear movement. Figure 3 shows a 3D model of the designed translation system.

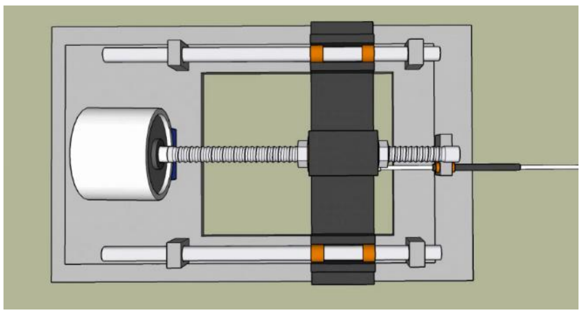

Fig. 3. The 3D model of the designed translation system.

This unit has a Kiatronics 28BYJ-48 mini stepper motor and gearbox, with specifications given in table 1. By using a solid shaft coupling, the motor's shaft gets connected to the leadscrew and transfers the rotation. Consequently, through the designed mechanism, the generated rotational motion is translated to the linear movement.

Table 1. 28BYJ-48 stepper motor specifications.

28BYJ-48 stepper motor	
Rated voltage	5 VDC
Number of Phase	4
Current	40 mA
DC Resistance	54 Ω
Phase inductance	3 mH
Frequency	100 Hz
Speed Variation Ratio	1/64
Stride Angle	5.625 (degree) / 64
In-traction Torque	> 34.3 mN.m
Friction torque	1200 gf.cm
Insulated resistance	> 10 M (500V)

A mini leadscrew of 4-millimeter diameter, right hand external-screw thread with 1-millimeter lead, 1-millimeter pitch, and length of 50-millimeter is used in the design. A miniature carriage with an internal-screw thread is connected to the leadscrew; the carriage will transfer in the linear axis of the system when the leadscrew rotates; for 1 complete rotation of the leadscrew, the carriage moves 1 millimeter. The position accuracy of the designed system can be calculated by considering translation parameters including stepper motor's rotation angle, mechanical gear box ratio, and the TS movement accuracy.

Table 2. The positioning accuracy of the system.

Stepper Motor Driving Mode	Step Angle (degree)	Carriage Movement (nm/step)
Full-Step (1/1)	5.625	244.14
Half-Step (1/2)	2.8125	122.07
Micro-Step (1/32)	0.176	7.63

As shown in table 2, the controller can drive the stepper motor in three modes with different linear and angular step movement. According to these parameters, the movement accuracy of the designed ACDO device is 244 nm/step in full-step drive mode, 122 nm/step in half-step drive mode and 7.6 nm/step in micro-step drive mode. Figure 4 shows the working principles of the designed system.

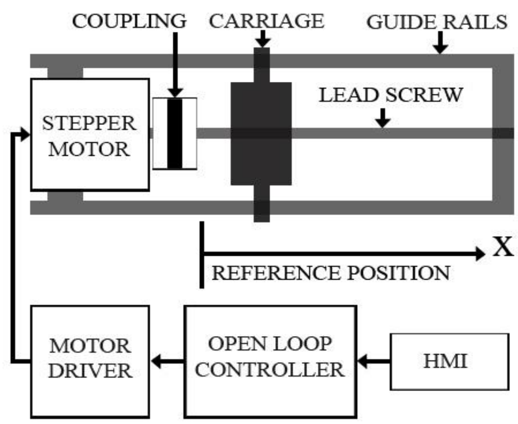

Fig. 4. The schematic model of the mechatronic part.

2.2. Controller Unit

In the designed system, an ATMEL ATmega32A 8-bit micro controller is used, to control the whole process, to set working parameters, and to drive the stepper motor with different sequences. In the proposed system, the controller has the capability to control and drive the selected hybrid stepper motor. Through a keypad, the controller can receive working parameters and calculate the stepping sequences and run the driver unit. In addition, by using a character LCD, working conditions and the moving bone position can be shown. Figure 5 shows the block diagram of the controller.

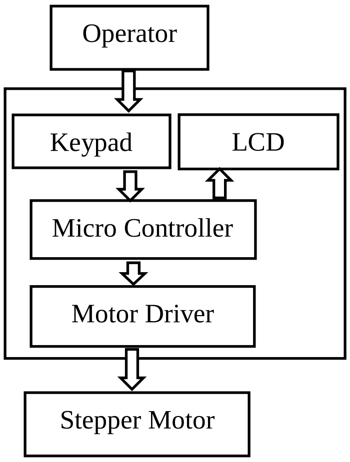

Fig. 5. The block diagram of the controller.

An AT24C02A e[2]prom is used in the design to get connected to the micro controller, to save the distraction data in real time during the DO process. Figure 6 shows the designed circuit of the proposed controller in the PROTEUS software, version 8.5 (build 22252).

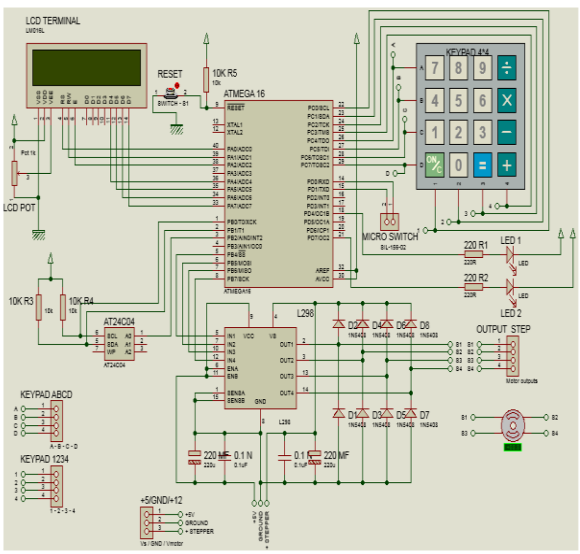

Fig. 6. The designed controller unit.

2.2.1. Simulation of the designed control system

For evaluating the selected stepper motor and the designed system, simulation is implemented in MATLAB-SIMULINK R2017a (9.2.0.538062) with motor's specifications mentioned in table 1. Figure 7 shows the overall design of the simulation, and figure 8 shows the subsystem of the speed and the position.

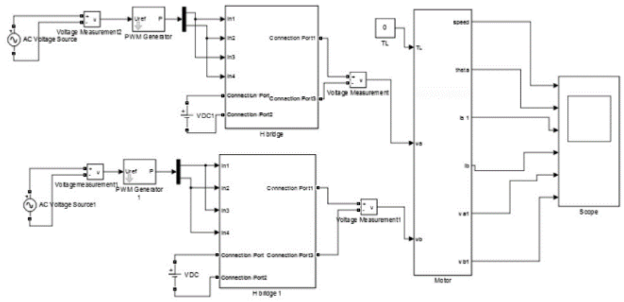

Fig. 7. The overall design of the simulation.

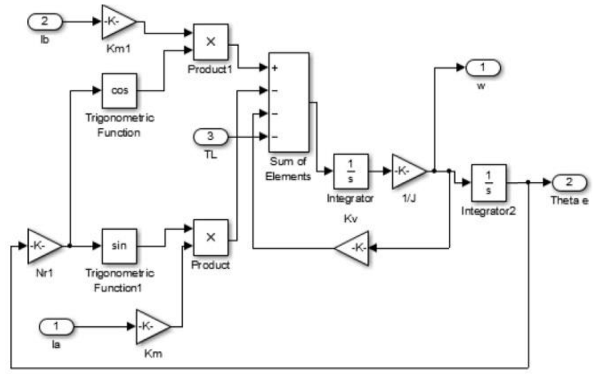

Fig. 8. Speed and Position subsystems.

2.3. Transition Unit

Regarding the external-generated DF, there is a need for a transition system in the design of the distractor, to transfer the DF to the bone segment and moves it. The designed transition unit consists of a flexible wire guide and shield. Figure 9 shows the schematic design of this unit. Each movement command generated by the controller drives the stepper motor for one moving step, by using a mechanical fixture on the carriage which is fixed to the wire guide, the generated DF in each step, transferred to the moving BS which is connected to the other side of the wire guide moves.

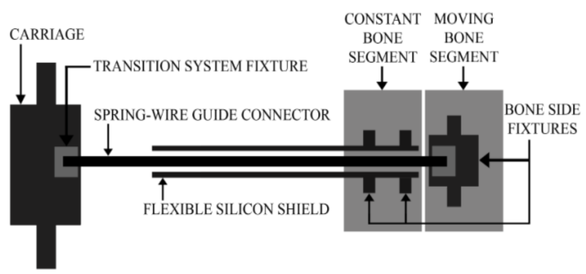

Fig. 9. The schematic model of the TS.

3. RESULTS

The designed controller has the capability to drive the mini stepper motor in micro-step driving mode, with a novel linear controlling system. In the experimental phase, all parameters of the simulation are set based on the designed system, and the simulation is run with execution time of 1 second. As shown in figure 10, the rotational speed of the motor's shaft and the shaft's position are outputs of the simulation.

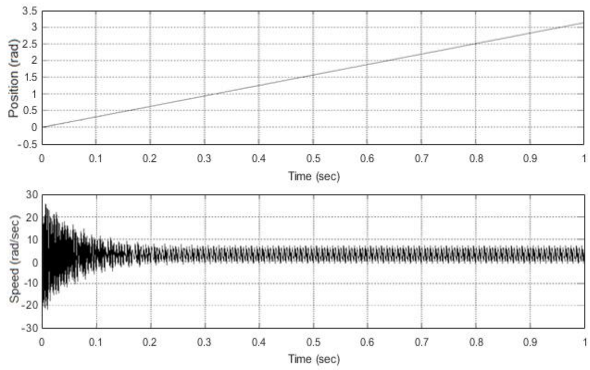

Fig. 10. Simulation outputs of the stepper motor.

4. DISCUSSION

This feasibility study aimed to design and develop a new automatic distractor to generate a continuous DF for RAs with improved accuracy and reliability. The design is equipped with a microcontroller using a novel linear controlling method [50, 51], to generate a stable continuous DF. Results have shown the designed device and the implemented control system work well, and completely agree with the theoretical equations. Compared to the existing distractors and other methods, this device can solve some of the existing problems and limitations, and also, offer a continuous and accurate externally-generated DF. The existing distractors, have position accuracy of about 1 micrometer [25], the designed device can move the bone segment with movement accuracy of 7.6 nanometers, which offers a promising DO procedure. The designed device has a straightforward programming structure based on C language with a simple and user-friendly interface, and there were no failure or error during the device simulations. Advantages of the designed distractor are summarized as follow:

1. Using the stepper motor in the micro stepping drive mode can provide a smooth movement, less vibration and noiseless operation. This is due to the stator flux, which controls the stable rotor stop position, is moved in a more-continuous way, compared to the full and half-step drive modes; therefore it causes a soft continuous distraction for the BS.
2. Using a precise controller with the stepper motor provides a stable and steady movement with high resolution.
3. Through the implementation of a programmed HMI, the related expert could set various DO working factors using the LCD and keypad, or to check or modify the working parameters during the DO process.
4. The connected serial e2prom in the controller, provides a real-time backup system and the controller can read the saved data at any moment. In the case of any unwanted error or system failure, the device is capable of reading and recovering the distraction data, to continue the process without any movement errors.

5. CONCLUSION

A novel automatic continuous controller with using microcontroller, mechatronic system, mini motor and gearbox, and transition mechanism is designed and simulated. Results and design's specifications revealed that the proposed distractor has met all necessary requirements, and medical and mechanical functions. The system can generate a smooth, accurate, and continuous DF for a successful DO. The key conclusions from the proposed device are the following:

1. The design proposed an automatic continuous device with an accurate control system, reliable mechatronic system, and flexible transition mechanism. The design delivers sufficient movement accuracy, with adequate DF, which will provide a successful DO process in RA.
2. With respect that the designed system can generate continuous force, the rate of distraction could increase; consequently the activation phase decreases and the patient will encounter less physical and psychological side effects.
3. The extra-oral design of the system reduces the chance of accruing the tissue injuries, infection, and physical problems.
4. Usage of a simple and ongoing interface makes the device easy to use. In addition, the design of the online backup system makes the system stable, and reliable against unwanted errors. There will be no need for surgery in case of the controller failure as well.
5. Regarding the extra-oral design of the device, it has the capability to be used for different maxillofacial areas including mandible, alveolar bone, mid-face, and cranio-orbit.

6. FUTURE WORKS

The designed system has sufficient accuracy for all conditions of MRA with the capability to drive system and move the BS with a wide range of working parameters; therefore, the next step could be the fabrication of the designed distractor to be used in human MRA.

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