Conceptual Biomechatronic Distractor Design to Minimize Surgical Intervention in Distraction Osteogenesis

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***Abstract*—This study presents a conceptual design for a fully implantable biomechatronic system aimed at minimizing intervention in the treatment of skeletal deformities and deficiencies. Current treatment methods often require a series of operations, prolonged hospital stays, and frequent, burdensome follow-up visits post-discharge. The proposed system aims to reduce the number and duration of surgeries, significantly enhancing the patient's quality of life during the treatment process. Moreover, the necessity for frequent manual adjustments is reduced, which can alleviate the workload for healthcare providers and potentially decrease the likelihood of human error.**

Keywords— Distraction osteogenesis, mandibular distraction osteogenesis, biomechatronic distractor

I. Introduction

Orthopaedic surgeons traditionally manipulate bones for elongation and restoration using the distraction osteogenesis method [1]. Distraction osteogenesis involves the creation of new bone in a gap formed between two bone segments, which are gradually and systematically separated at a specified rate and rhythm following a surgical incision. This process applies tensile forces to the intervening healing tissue, promoting new bone formation [2], [3], [4].

In current techniques, manipulation of the mandible and maxilla is achieved using external distractors mounted on the body or internal distractors placed within the body. Prior to the placement of these distractors, a surgical incision is made on the bone intended for elongation. Subsequently, the distractor is installed. Daily incremental adjustments of the distractor facilitate the gradual separation of the bone segments, allowing for the formation of new bone tissue in the intervening space [5]. External distractors, which are fixed to the skull with screws, significantly complicate the patient's daily life. Patients experience considerable difficulties with sleep and social interactions and are also required to attend daily follow-up appointments.

The treatment of patients with congenital bone deformities typically involves a series of reconstructive surgical procedures. Currently, the devices and designs used in bone deformity treatment are externally placed, which can expose the body to the external environment, leading to complications such as infection, pain, and scarring [6], [7]. After the surgical placement of these traditional devices, they must be manually adjusted from the outside on a daily basis, necessitating daily hospital visits for the patient. This process often results in the need for successive surgeries [8], [9], which can cause further damage to healing tissues, increase the likelihood of complications, lead to psychological distress, and incur significant time and financial costs.

Some studies in the literature examine the difficulties as a means of the proposed automatized distraction devices. A group presents a clinical application of automatic distraction osteogenesis (ADO) for mandibular elongation in humans. The automatic device enabled a steady distraction process, minimizing the necessity for frequent manual adjustments and potentially enhancing the overall effectiveness of the procedure. However, the power unit requires invasive surgery and hardens the use of the device in daily living [10]. Another study [11] implemented an automated continuous distraction osteogenesis on a pig at a rate of 1mm/day. In this system, the actuation unit is connected to the power unit via a cable and needs to be carried by the subject during the treatment. Due to its bulky design and wired communication between the controller and the distraction device, the system fails to achieve its primary objective of providing a streamlined and efficient solution. Different from employing electromechanical systems, some research groups [12], [13] activate the mechanical distractor apparatus via titanium-nickel shape memory alloy. These materials are noted for their flexibility and durability and are also activated by heat energy. In this concept, distraction osteogenesis is conducted by transporting the bone segments through spring made of shape memory alloy [13]. However, the nonlinear characteristics of these materials make it infeasible to control the speed and position of the distractor apparatus in daily use.

To address the aforementioned problems, this study proposes an electromechanical system design leveraging the benefits of the three personalized biomechatronic subsystems. The

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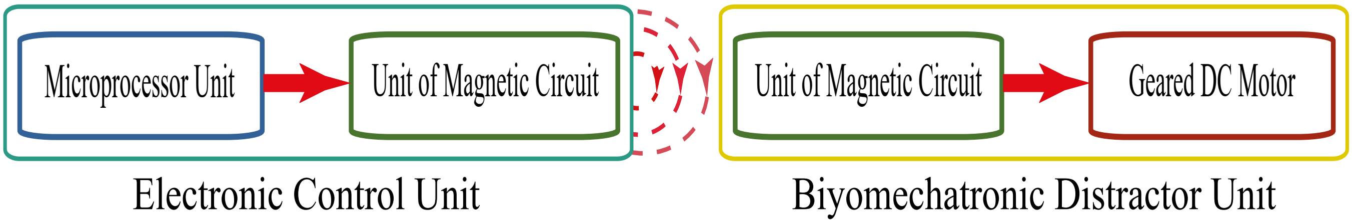

Fig. 1: The communication pathway between the Biomechatronic Distractor Unit and the Electronic Control Unit

nature of the subsystem lies in its fully implantable design, which is expected to reduce the likelihood of complications such as infection, pain, and scarring. Once implanted, the new biomechatronic unit autonomously extends at predetermined intervals and amplitudes upon receiving a vibrational alert from the second subsystem and when the third subsystem, the electronic control unit, is brought near the designated area. This eliminates the need for daily hospital visits after surgery. The user-friendly electronic control unit, combined with the vibrational feedback feature, makes this design accessible to a broad range of users.

II. Biomechatronic Distractor System: Functional Principles

The biomechatronic distractor system aims to replace the currently used apparatus known as the distractor. The device comprises three main components: a biomechatronic distractor unit, an electronic control unit, and a vibrational alert unit.

A. *Biomechatronic Distractor Unit (BDU)*

The BDU relates to a distractor device designed for the application of distraction osteogenesis to a bone that has been segmented into at least two parts, referred to as the first and second segments, through osteotomy. The primary objective of the BDU is to behave like an automatic distractor that gradually separates the two segments of a bone which is divided into at least two parts through a surgical incision as depicted in Fig 2. Such a device takes the role of distractor used for distraction osteogenesis [14] and implements its function in a considerably less invasive and remotely controllable manner. Regulated tension to the site of a surgically induced bone layer is provided by the movable connector actuated by the geared DC motor. In particular, the device includes a worm wheel gear associated with one of the bone segments and a worm gear associated with the other, which, when rotated, induces linear motion in the rack gear. The DC motor is electrically connected to a rectifier antenna circuit, which converts magnetic waves from a magnetic source into direct current to power the motor. This configuration enables the distraction process to be carried out without manual intervention on the distractor. The gearbox connected to the shaft of the DC motor is designed to regulate the necessary torque and speed for the actuation. This configuration ensures that the DC motor operates at the optimal speed and torque for distraction.

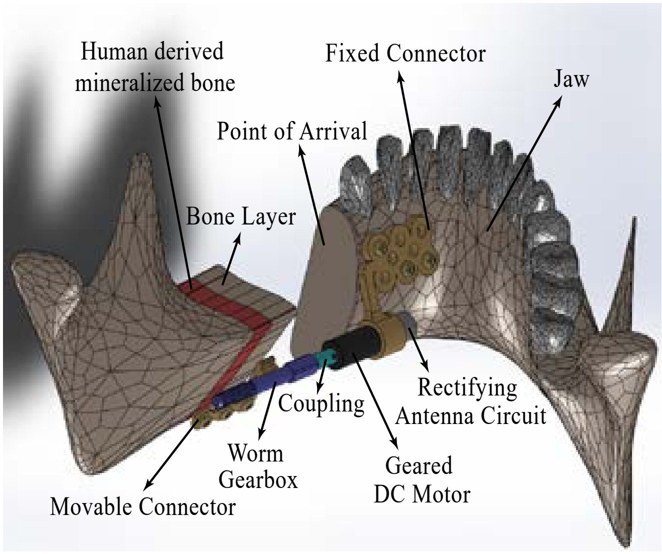

Fig. 2: Conceptual design of the biomechatronic distractor unit placed on mandible

B. *Electronic Control Unit (ECU)*

The Biomechatronic Distractor system includes an ECU designed to wirelessly control and power the BDU described in the first section (see Fig 1). The control unit consists of a housing that contains the electronic components and an ergonomic handle that allows the user to manipulate the BDU manually. This ECU features a magnetic source that generates magnetic waves to be transmitted to the rectifying antenna circuit within the BDU. The described magnetic source is controlled by a microprocessor which includes both a memory unit and an associated processing unit. The memory unit retains information on the number of steps and the duration required for the worm gear to rotate as determined by the physician. Unlike traditional methods, where distractor devices are manually adjusted, this ECU unit collaborates with the BDU to provide guidance for bone elongation. The embedded memory unit in the ECU stores reference data for motor rotation speed and position, ensuring precise control. This approach prevents errors in intervention, eliminates the need for clinical visits for each elongation process, and avoids invasive procedures for each step of the extension.

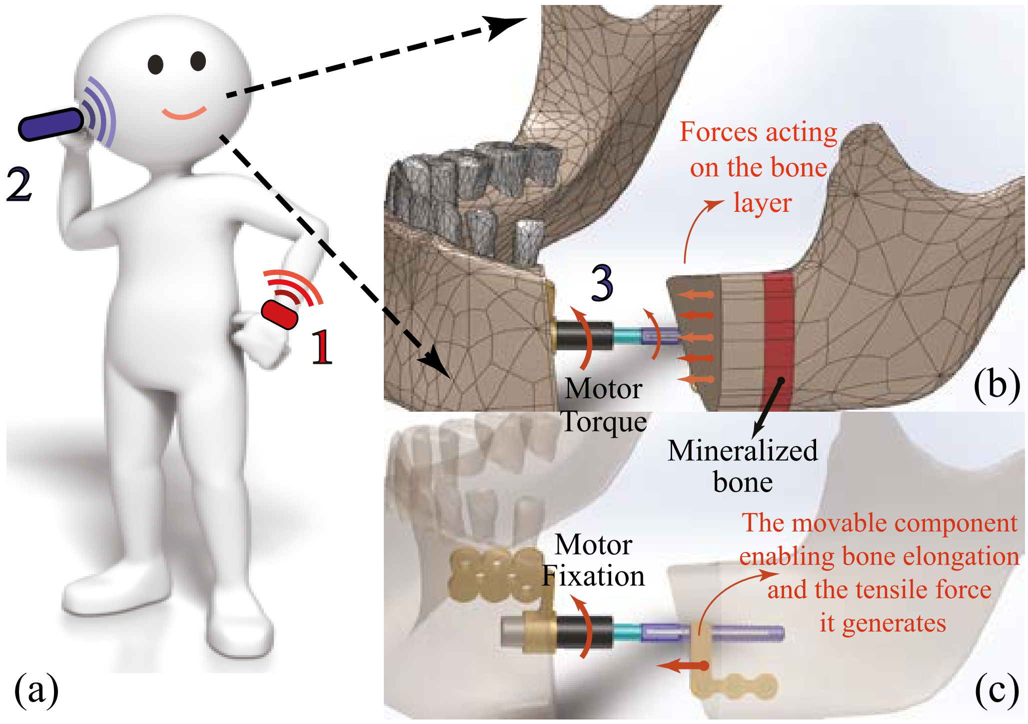

Fig. 3: Working principle of the Biomechatronic Distractor System: (1) Vibrational Stimulation Unit (2) Biomechatronic Distractor Unit (3) Electronic Control Unit

C. Vibrational Alert Unit (VAU)

The VAU, attached to the patient's wrist with a band, sends periodic vibrational alerts throughout the day to remind the patient to activate the device (indicated as number 1 in Fig 3). Upon receiving the alert, the patient positions the ECU, marked as number 2 in Fig 3, near the jawline, thereby activating the implanted BMU (denoted as number 3 in Fig 3). The patient performs this procedure a set number of times per day, as determined by the doctor, and continues the process over the course of several months. The amplitude and period values for control of the BMU can be easily programmed into the system via a user interface. The second key function of the Vibrational Alert Unit (VAU) is to notify the patient about how long they should keep the ECU near the jawline. Since the ECU is responsible for providing power until the Biomechatronic Distractor Unit (BDU) completes its task, the duration set by the ECU is communicated to the VAU. Once the BDU has finished its operation, the VAU delivers tactile feedback to the patient through its wearable component, which contains embedded vibration motors, signaling the end of the process.

III. Conclusion

Unlike current apparatuses that require the patient to visit the doctor for each distractor adjustment throughout the day, this design allows patients to carry out their treatment professionally without altering their daily living conditions. The proposed conceptual design of the biomechatronic distractor system offers effective solutions to the mentioned challenges by enabling individuals to manage their treatment independently without the need for hospital visits, thereby avoiding successive surgeries. This system is designed to simplify the lives of both patients and doctors, reduce surgery-related risks, and provide benefits such as a personalized biomechatronic system implanted within the mandible and an easy-to-use ECU, making it accessible for every individual. The ongoing study concentrates on the dynamic analysis of the BDU, and the design of the magnetic circuit for powering the BDU system through the actuation.

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