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Smart Growing Rod for Early-Onset Scoliosis

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***Abstract*:** *Early Onset Scoliosis (EOS) is a spinal deformity which tends to increase during growth. The current treatment involves the use of growing rods, fitted to the spine which can be extended manually by the surgeon semiannually, requiring invasive surgeries. This paper presents a new smart medical device namely, Smart Growing Rod (SGR), that proposes treating EOS with less invasive procedures to minimize the complications associated with the current techniques as well as reducing cost and improving treatment control. This innovative device will have an internal control system, allowing the growing rod to be adjusted based on neural network estimated monthly growth value and a pressure sensor, which determines when the optimum length has been reached. This study investigates the proposed SGR for the treatment of EOS via testing our prototype SGR with scoliosis model and also with a spine finite element model. The results of those models are very promising and demonstrate system function and effectiveness for treatment of EOS.*

Keywords: *Early onset scoliosis, remote-controlled growing rod, finite element method, neural networks.*

1. Introduction

Early Onset Scoliosis (EOS) occurs in children under 10 years of age and many cases have a higher probability of progression during growth. The magnitude of deformation is often described by the Cobb angle measurement. The Cobb angle is the universal standard of measurement used to quantify scoliosis for the purpose of measuring curve progression over time. The EOS has been treated with “growing rod” procedure to avoid interference with spinal growth Fig. 1. Patients have to undergo a series of operations to have the rod lengthened for maintaining the correction without affecting the growth of the spine. Adjusting the rods requiring major surgery, costly, and is associated with negative psychosocial outcomes [1, 2]. In an attempt to solve these problems, we have developed a new smart medical device namely, Smart Growing Rod (SGR), that proposes treating EOS with less invasive procedures to minimize the complications associated with the current techniques as well as improving quality of life, and is more cost-effective than is the traditional growing rod procedure.

Fig.1: Pre-surgical (left) and post-surgical (right) radiographs.

2. Material and Method

In this research, the most challenge issue of designing the SGR was to study the change of the force and moments components on growing rod during the spine growth period. Since there was no data available documented by clinical or neither academic site about how much force changes as result of the spine growth accepting force required to distract the growing rod [3, 4].

Hence, initially started was by investigating biomechanical behaviour of the human scoliotic spine and its mechanisms [5, 6]. Next goal is to design a control algorithm that makes the growing rod would grow with the spine, correct the deformity as growth occurred, leave no residual deformity at development, and be compatible with a minimally invasive surgical technique. Reaching this goal, a control algorithm that can be implemented in embedded system is described to serve as the brains for the growing rod. Hardware design of a prototype that operates on the same principle of SGR will be also explained in next section.

2.1. Hardware design of the SGR

The SGR was designed to be compatible with currently existing pedicle screws and hooks, and can easily be used in place of existing growing rods on the market. The process of the mechanical design for the SGR prototype begins with building the beta unit prototype (as proof of concept test plan). The mechanical design of the SGR is shown as an exploded version of the set- up in fig. 2. This prototype is made of stainless steel. A “casing” (6) houses the internal part of the device and its outer diameter is only 13 mm which is the smallest outer electronic rod up to now. The closest in size is a device 16 mm in diameter presented by Takaso, et al. in 1998 [7]. A collar (3) consists of a threaded insert threaded rod (1) and a shaft at opposite ends of the device. The rod (1) sized to fit standard pedicle screw (5 mm) and it is acme-threaded and used for the lengthening mechanism which is driven by a shaft micro servo motor (5). The rod that is the same casing part remains fixed on one end of the spine. A thrust bearing (4) and a biocompatible plastic sealed cap (2) are also included.

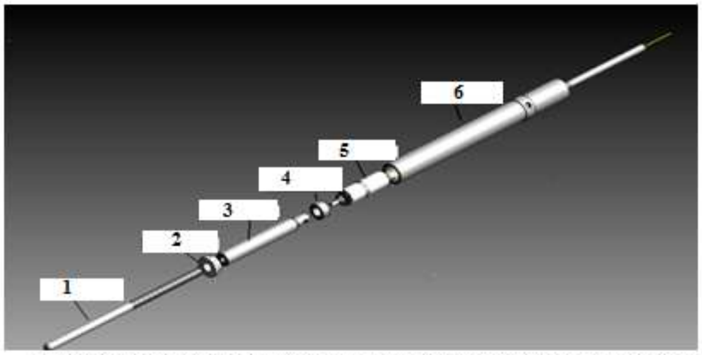

Fig.2: Exposed view of prototype version of the SGRD: (1) threaded rod (2) cap (3) collar (4) thrust bearing (5) motor (6) casing.

The SGR of the fig. 3 has both internal and external electrical components, which control and power the distraction performed by the DC motor. The DC motor attached with the gear was carefully chosen to provide high torque and low speed with less power consumption. The external control unit consists of an embedded system unit, in this SGR prototype; the FPGA DE-2 board is used as embedded control system. The internal control unit is made up of the DC motor, H Bridge, and encoder. Via the real time PID closed loop feedback system (built-in encoder), the motor is able to track the displacement of the rod accurately (0.1mm).

This SGR prototype was implemented with the spine scoliosis model and the holder platform fig. 3, which assisted us to develop the SGR in several ways. First, we investigated the amount of distraction force to the spine in a similar manner that an attending physician would apply to the patient’s spine extension of growing rod to correct the scoliosis, it incorporates an addition two springs attached to resist more of the scoliosis model correction fig. 3. However, the SGR is still able to distract the growing rod. To give an idea, the amount of Distraction Force (DF) that needs to stretch the springs as well as the scoliosis model is similar to the DF necessary to distract the growing rod implanted in patient spine around 300 N. Finally, using the embedded system (DE-2 board) with SGR prototype, we able to implement the real time closed-loop PID control position in order to control the displacement of the rod (mm) to any desired position. PID control law drives the DC motor through Pulse Width Modulation (PWM) and the position encoder.

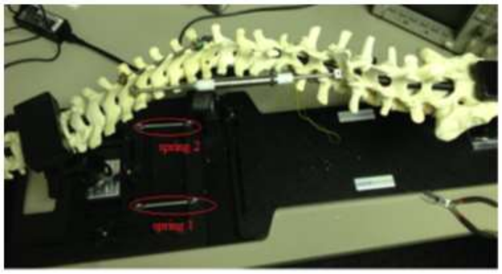

Fig. 3: Smart growing rod prototype installed along the scoliosis model.

2.2. Software design of the smart growing rod

The software design method used neural network to develop spine growth approximation called Trajectory Generation (TG) that would be able to estimate the actual spine growth characteristics and then informs the implant SGR to new growing as closely as possible to actual spine growth in a safe manner. Fig. 4 shows the overall design principle of the SGR control algorithm, which will be explained through the block diagram description.

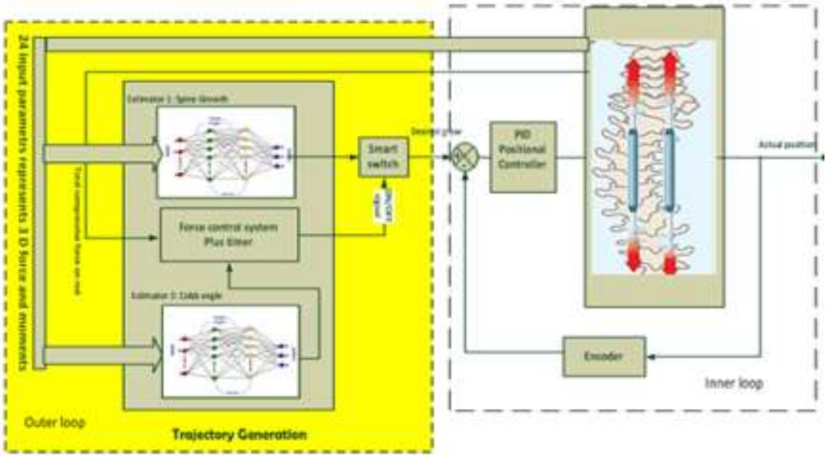

Fig. 4: The block diagram shows control algorithm design of the SGR.

The control algorithm design consists of two closed loop subsystems interacting together for the purpose of distracting the rod (lengthened) as the spine grows. First, an inner loop includes real-time PID control algorithm, which determines position based upon the encoder pulses (feedback). When position for the desired distraction or compression is reached, the PID control stops the motion and reports to the user interface that the motion is complete. Second, outer loop for TG is the smarter part of the program [9]: it was built using neural network algorithm to find a function approximation between the mechanical behaviour of spine growth given by 3D force/moments as input and estimated outputs, which are spine growth (mm) and Cobb angle (degree). The TG contains spine growth estimator (1, 2), which have been previously published and a Force Control System (FCS) block that are shown in fig. 4.

Overall, the TG block expands the implanted rod to track spine growth trajectory using motorized distractor mechanism. The FCS block performs two main functions in the TG: it safely does rod distraction and it serves as a master control for the distraction force. Hence, the FCS allows to expansion of the growing rod only if the force is within pre-specified range. This is necessary to limit the force developed in the vertebra. An additional sensor measures the compressive force on the growing rod to provide the safety limit. Unlike 3D forces and moment's sensor, this sensor (i.e., pressure sensor or strain gage) senses the compressive force on the rod as result of the rod displacement, similar to force measured of Harrington-Rod procedure [8]. The FCS divides the estimated rod growth into four increments. After the rod is extended by the amount indicated in the first increment, the force on the rod is checked to assure that is within safe limits. This process continuous for each increment until the rod distraction is completed or the force reaches the safety limit. The FCS will then terminate the distraction process. An additional feature may be included to allow the surgeon to select the desired Cobb angle range and compare the result to either of the distraction the estimated value of Cobb angle or to a measured value (via x-ray).

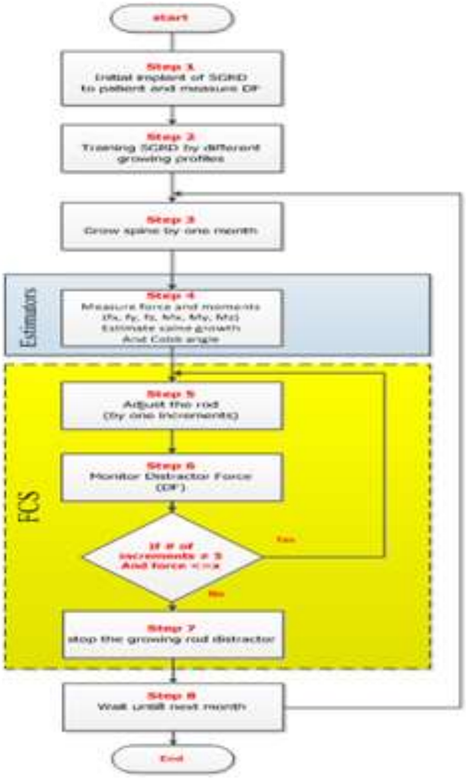

Fig. 5: Flowchart of the algorithm for SGR.

The flowchart of the control algorithm of SGR is shown in Fig. 5. In its normal operation, this SGR has a total of six steps. In step 1, with force sensors the SGR implants to scoliotic spine and records the distraction force required to achieve the desired correction (desired Cobb angle). The step 2 of control algorithm includes training procedure for learning estimators, which will be performed similarly to prvious research work of the author [9]. step 3, the SGR waits until one month has passed which is determined by the timer of the embedded system. The reason of chosen monthly rod distraction over that period is that the same period has been used by current medical device called Magnetically Controlled Growing Rod (MCGR) [10]. Once measured three dimensional forces and moments (for more information about the sensor see) change in step 4 that occurred by spine growth, the SGE would estimate the T1-S1 growth and react to it through calling FCS procedure (given in steps 5, 6 and 7). As the rod distraction process is over, the SGR will be put in sleep mode in step 8 that makes it use less power from the battery. When another month passes, repeat.

3. Simulations results of SGR

SGR approaches for the treatment of EOS were simulated utilizing a Scoliotic Finite Element Model (SFEM) of the spine with integrated growth dynamics, taking in consideration all aspects of the current medical procedure, as well as proposed control algorithm approach. Abaqus and the MATLAB software's are interconnected together for data interchange in order to simulate the entire proposed SGR procedure. To evaluate the SGR for treating the early onset scoliosis procedure, demo software was programed according to the designed control algorithm stepwise shown in flow chart fig. 5 in purpose of simulation use.

(a)
Before lengthing growing rod

(b)
After lengthing growing rod by 10mm

Fig. 6: Step 1 simulation results for spine FEM.

Step 1 is the simulation of the major surgery to implant the smart growing rod device into a scoliotic spine model by the Finite Element Analysis (FEA), which represents the initial adjustment of the growing rod to achieve the desired Cobb angle. The length of the rod was adjusted until the Cobb angle was reduced to from 53.9° to 31.41° as shown in Fig. 6. This requires the rod to be lengthened by 10 mm, resulting in DF of 192.87 N.

In step 2, the training procedure was conducted for the SGE using three different cases data set within the same age group (Juvenile age) [12]. In steps 3, the second part of the analysis is to simulate the growth for the juvenile spine models [5, 6]. The third step has been implemented using the python script code (software). This code finds the amount of the growth (thermal expansion for our case) for each element applying the growth modulation criteria. Table 1 below shows step 4 simulation results of SGE compared with actual value of the spine growth (T1-S1) as well as rod and force distractors sampled every month.

The procedure in step 4, 5, 6, 7 is that every time the spine model grows per one month, 3 D force and moments will be captured to estimate the amount of spine growth segment (T1-S1) to be used as values of rod distractor (Table 1). When the SGE estimate certain values of the rod distractor (mm), we divide this value to four increments (RD1, RD2, RD3, and RD4) and we capture DF that occurs in each increment. This process is controlled by the FCS, as DF is measured continually and automatically (during rod distractor) and used to control the amount of rod distraction. Our FCS is design in such that holds and thresholds the previous DF value and allows 10% more because of the patient growth, which results by i.e., gaining weight and the bone, becomes stiffer in time, which agrees with Noordeen, et al conclusion gradual stiffening or spontaneous fusion of the spine can increased forces required to lengthen [3]. At the same time, the FCS monitors the estimated Cobb and if the Cobb angle is within the desired window. The 10% was selected just for the purpose of Step 4, 5, 6, 7 simulation uses. This upper limit (10%) can be modified to satisfy the medical requirements of patient's safety where process of rod distractor will be terminated if measured distraction force reached. From Table I we can see clearly the ability of SGR to follow a desired trajectory (spinal growing) and keep the Cobb angle within the desired region between 30° and 35° see fig. 7. To visualize more the performance of SGR device, another simulation has been created, this simulation includes the same scoliotic spine finite element model (SSFEM) used in above results attached with growing rod but not a distractor. After the initial implant corrections of the spinal deformity (resulting Cobb angle corrected by 31.41°), we simulate scoliosis progression as a result of one year spine growth (12 months accumulating 1.332 cm growing) that is attached with the growing rod. Therefore, we show how much progression of EOS can be if it is left without the rod distraction. The one year of the spine growth attached with growing rod makes a change in the Cobb angle from 31.41° to 54.22° as shown in fig. 7.

TABLE I: Simulation results of SGR algorithm during spine growth period sampled every month

Time (months)	Actual spine growth (mm)	Estimated spine growth (mm)	Rod distractor (mm)	Force distractor (N)
1	0.77	0.88	0.88	192.87
2	0.89	1.11	1.11	207.46
3	0.94	1.11	1.11	226.07
4	1.61	1.77	1.32	244.69
5	1.52	1.55	1.55	274.36
6	1.61	1.77	1.32	300.35
7	0.72	0.88	0.88	330.42
8	0.49	0.67	0.67	345.57
9	1.78	2.00	2.00	357.21
10	1.60	1.77	1.77	391.56
11	0.55	0.67	0.67	422.03
12	0.84	0.88	0.88	433.67

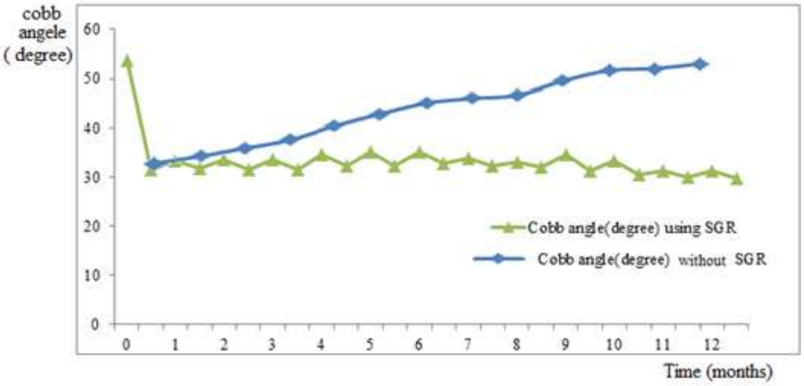

Fig. 7: SGR mimics spine growth (desired growth).

4. Discussion and conclusion

SGR length generally increased with each distraction Table 1. In general, the spine model was distracted between 0.67 and 2 mm per month, with each distraction the mean degree of scoliosis during the 12 month SGR simulation period was 32.35°. Comparing with Cheung et, al. [9] device (MCGRD) finds in the two patients with 24 months follow-up, were distracted 1.5 and 2.0 mm per month where the mean degree of scoliosis, measured by Cobb angle, was 67°(SD 10°) before implantation and 29°.(4°) at 24 months. Although, the SGR distraction had lower values in some months, but both share the same higher distraction value (2 mm). Likewise, Cheung's length mean, SGR (1.18mm) was greater than was the increases in spinal growth predicted by standard growth charts (0.83 mm because we chose juvenile velocity growth case) [11].

The simulation results prove the ability of SGR design method and it is use for change the current treatment practice. We have explained how the TG block makes the growing rod tracking the spine growth (monthly) in a safe manner. The TG includes both the SGE and FCS that both react together based on the force sensing mechanism. SGE and FCS use different types of sensors located in different places within the growing rod's instrumentation. SGE uses 3D force and moments sensor located in each hook, whereas the FCS measures the DF from strain gauge outfitting the growing rod. In fact, the DF that we obtain from the spine finite element model correlated with the real sensor data that was capture during growing rod surgery procedure [5, 6]. The simulation results show effectiveness and safety of a new smart growing rod device for non-invasive automatic distraction.

5. Acknowledgements

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