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Pull Off Strength of 6 and 10 Pin Halo Fixation in Sawbones Skulls

Eugene Limanovich

Richard Schwend

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Richard Schwend, MD – mentor
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I. INTRODUCTION

Halo skeletal fixator provides the most firm immobilization of all the cervical orthotic devices. (1) Since its introduction in 1959 (2) the halo fixator has been used in a variety of musculoskeletal and neurological conditions. Current uses of the halo fixator include stabilization of many cervical fractures, single column spine injuries, immobilization of cervical instabilities as a result of degenerative, congenital, traumatic, pre and post surgical conditions in adult as well as pediatric patients.(3) The device is comprised of a perforated ring for pin insertion and stabilization onto the patients skull, a halo vest for upper body and torso wear, and connecting rods, which unite and provide stability between the halo ring and the halo vest. The ring is attached to the head using halo pins. Each of the halo pins engages the outer cortical wall of the skull.

Many complications, such as halo pin loosening, halo pin site infection, nerve injury, scarring, and loss of cervical alignment can arise during treatment with a halo orthosis.(4) Studies have shown that halo pin loosening is the most common complication affecting patients.(4,14) Halo pin loosening not only results in the potential loss of fixation but also leads to an increased chance of infection.(4,5) A variety of causes can be attributed to pin loosening. Lack of sufficient fixation strength of the halo to withstand the daily stressors such as walking, twisting, falling, all of which result in micro-motion in the device, as well as the diminution of the compressive force of the halo over time may all contribute to the loosening of the pins.(6,7)

Halo orthosis have been implemented in correcting thoracic and thoraco-lumbar deformities in children. Typically a traction force is applied to the Halo device that equals one half of the child's body weight. This traction force can be applied from several days to weeks.(12,13) Mechanically, this situation raises concern, since it is not yet clear how close to failure is the device after the application of these distraction forces. In a standard application of the halo orthosis, 4 pins are used to secure the device to the patient's skull. Recently it has been suggested that the use of additional pins to secure the halo device may contribute to greater fixation strength by increasing the overall compressive strength of the device.(8) Increased compressive strength of the device may reduce pin loosening and subsequently decrease the rate of infections. The application of the halo orthosis in pediatric patients presents the treating surgeon with several other challenges. Because of the diminished skull thickness in a child, concerns exist about the risk of halo pin penetration through the child's calvarium. As a result, current protocols require that a maximum of 4 inches of torque is applied to pins during fixation of the halo to the child's skull. Given this amount of torque that is used in tightening each pin of the halo orthosis, the maximum distraction force that can be used to induce device failure remains unknown.

The motivation for this research is to determine the minimum distraction force required to induce failure in the six pin and ten pin halo construct secured at 2inch, 4inch, and 6in-lb respectively, mounted to Sawbones Human Model Skulls.

II. MATERIALS AND METHODS

A biomechanical test was conducted using twenty #1344 55 shore D Sawbones Human Skulls (Pacific Research Laboratories, Inc. Vashon, Washington USA), a custom PMT carbon fiber halo fixture and pins (PMT/Permark Corporation, Chanhassen, MI USA), and Instron Model 4400 series test system tensile testing machine (Instron Worldwide Headquarters, Norwood, MA USA) to determine the relationship between vertical disengagement force and the initial halo pin force. All tests were conducted at the Mechanical Engineering Department at the University of New Mexico.

The objective was to determine the fixation strength (load to failure) of the six-pin and ten-pin halo construct tightened at 2, 4, and 6 in-lb respectively through a series of force-deflection tests conducted on biomechanical models of the human skull using tensile testing machine (Fig. 1).

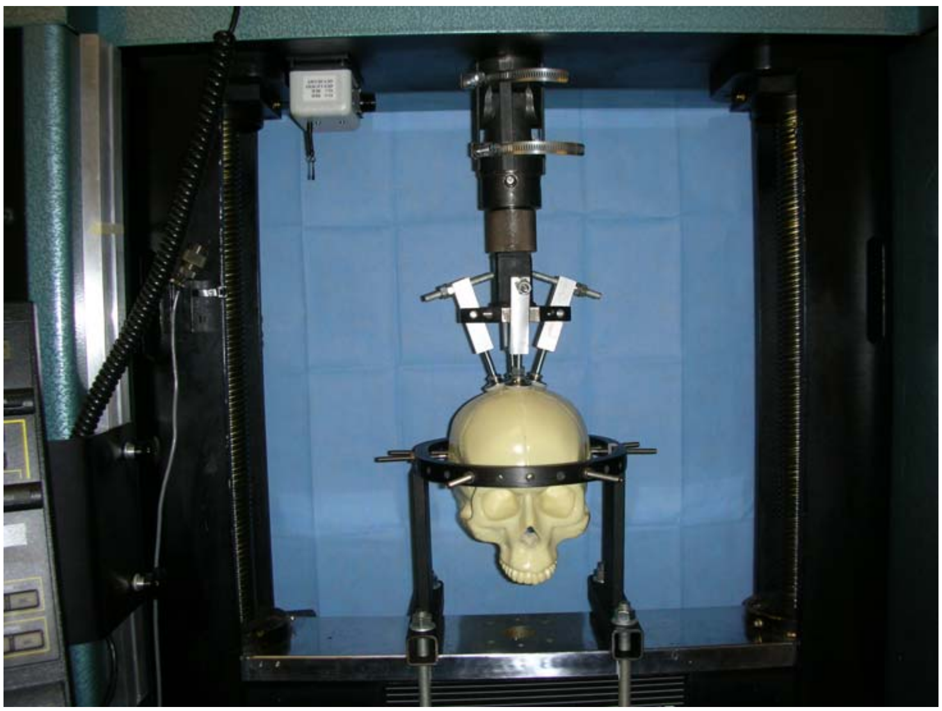

Figure 1: Experimental setup of a biomechanical human skull model in the hydraulic test machine.

Each skull model was fitted with an PMT titanium closed-back halo ring, attached with either six or ten 2-in (5-cm) PMT titanium pins at the model-substrate interface. The PMT halo ring allows for accurate pin placement as a result of perforated pin holes in the ring. Each halo was applied to the skull model according to an established protocol with perpendicular pin insertion tightened to a measurement of 2, 4, and 6 in-lb of torque, respectively. The pins were tightened with use of a calibrated torque wrenches (Stryker Instruments Kalamazoo, MI) in order to ensure the accuracy of application. In the six and ten-pin halo constructs, the anterior pins were placed in similar positions within the safe zone for pin placement. This safe zone is defined as “the anterolateral aspect of the skull, approximately 1 cm superior to the orbital rim, cephalad to the lateral two thirds of the orbit, and below the greatest circumference of the skull.” (3, 9-11) In this position, the pins do not interfere with the temporalis muscle or with the zygomaticotemporal nerve and are not in danger of penetrating the sinuses. There are not the same neuromuscular restrictions with regard to the placement of the posterior pins, and a site 1 cm posterior to each model auricular canal was selected for pin insertion bilaterally (Fig. 2).

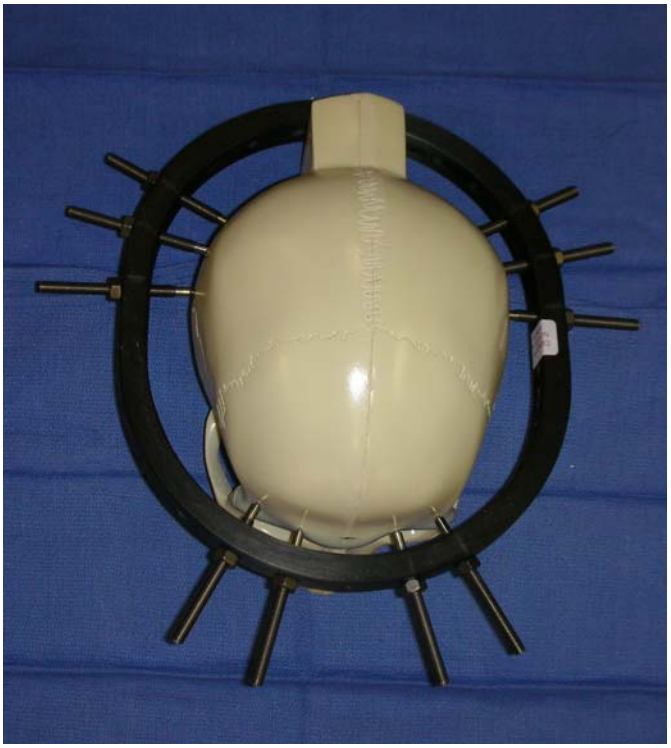

Figure 2: Halo ring with ten pin configuration

Three trials were conducted on each of the six-pin halo constructs tightened at 2 in-lb, 4 in-lb, and 6 in-lb, for a total of nine trials. Three trials were conducted on each of the ten-pin halo constructs tightened at 2 in-lb, 4 in-lb, and 6 in-lb, for a total of nine trials. A combined total of eighteen trials were performed.

Each skull model was mounted in the test frame (Fig. 1), and an axial distraction force simulating traction of the halo was applied at a constant ramp rate of 0.1 mm/sec with use of a servo controlled hydraulic test machine until failure occurred at the pin-skull interface. Failure was defined as a decrease in load, confirmed by visible movement at the pin-skull interface and as detected by the load-cell program.

III. RESULTS AND DISCUSSION

The primary focus of this study was to determine at which point the skull and screw system failed (i.e. the screws moved). More specifically, the interest of this study was to determine at which load and corresponding displacement the screws began to move. To establish the point of screw movement, it was necessary to find the first point within the raw data where the slope changed. A variation in slope indicates a change in the stiffness of the system and implies movement of the screws. The raw data for the 6 pin 2 inch-lb configurations over the entire range of loading for the 3 skulls tested is shown in Figure 3. From the data in Figure 3, one can begin to see change in curvature at a displacement depth of around 0.05 inches. With knowledge of the general region of displacement to look closely at, future plots will only look at displacement values from 0 to 0.1 inches. Further progression past depth of 0.1 inches is difficult to analyze given that integrity of the original setup configuration has changed with movement of the screws.

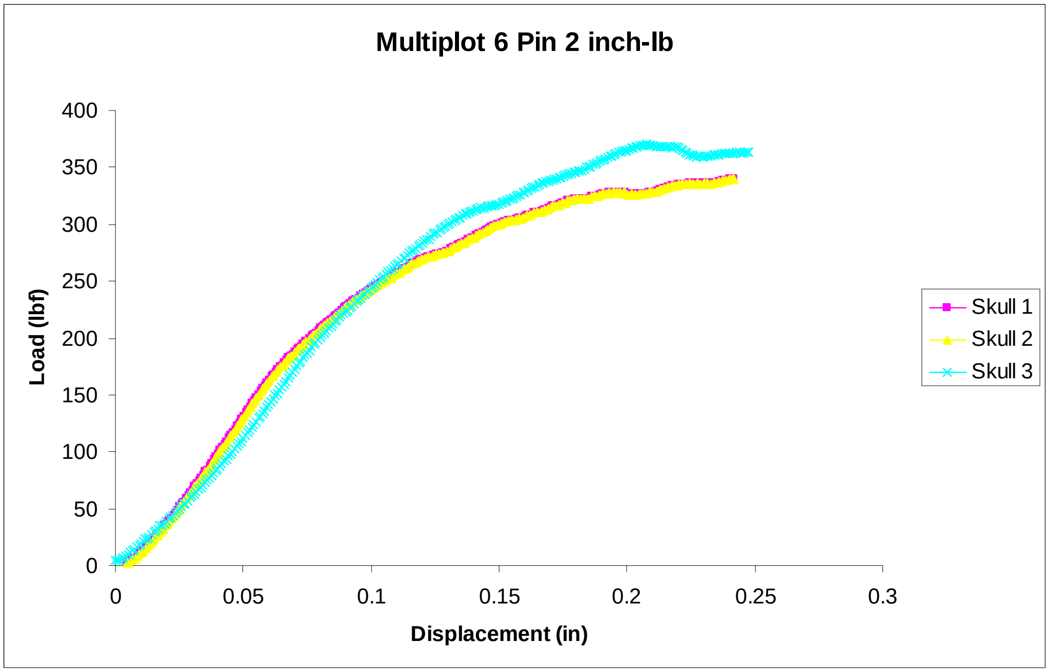

Figure 3: Raw data for 6 Pin 2 inch-lb

During testing, movement of the halo structure was recorded as well as the corresponding load and displacement. This was initially done with the "naked eye", but provided a general region in which to anticipate change in slope. Table 1 displays the recorded naked eye data for the 6 pin 2 inch-lb set of 3 skulls.

Table 1: Recorded movement naked eye for 6 Pin 2 inch-lb

6 Pin 2 inch-lb Naked Eye Data		
	Load at first movement (lbf)	Displacement at first movement (in)
Skull 1	170	0.0628
Skull 2	170	0.0692
Skull 3	170	0.0618

To mathematically determine the values from Table 1 directly from the Instron data, least squares curve fitting was used. Given the variation in the data curvature, multiple degrees of polynomial fits were investigated. Specifically, for each skull raw data set 3rd through 6th order polynomial curve fits were plotted. Figure 4 displays 3rd through 6th order least squares fitting curve data superimposed over the raw data. The blue circles represent the raw data taken directly from the Instron machine. Red, green, cyan and yellow lines correlate to 3rd, 4th, 5th and 6th order polynomial curve fits respectively.

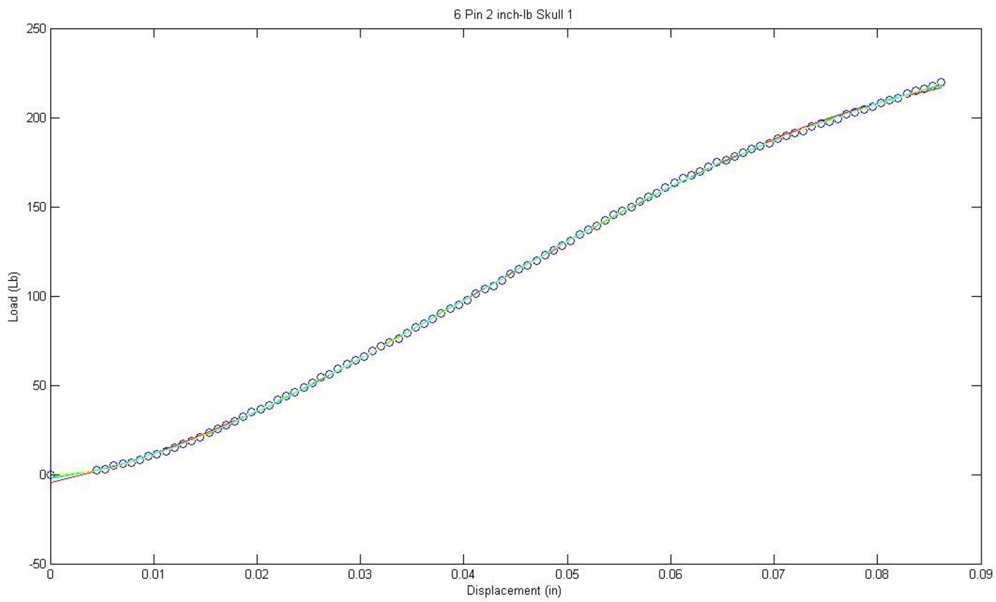

Figure 4: 6 Pin 2 inch-lb Least Squares Fitting

A correlation coefficient R was determined for each ordered curve fit. The correlation coefficient determines the strength of curve fit with respect to the raw data with a value of R closer to 1 indicative of a better curve fit. In the above data set, the correlation coefficient for 3rd through 6th order fits was 0.9979. The value for R varied within each skull set screw and torque combination. The same procedure was conducted for each skull set and the least squares fit with the most consistent correlation coefficient chosen for further investigation. By the value of R, a 3rd order curve fit was chosen for each test case.

With the curve fit was chosen for each skull set, the equation of the curve fit line was established. Then the derivative of the curve fit equation was taken to characterize the behavior of the screws under loading and to mathematically identify when the screws begin to move. The change in slope, which is the derivative, signifies points at which the pins moved from their original placement. It is expected that the derivative will increase in slope until the first point of movement from the pins. At the curve maximum the original fixation of the screws is no longer intact. The pin movement will create a larger hole at the pin skull interface allowing for further movement of the pin.

As stated above, where the derivative reaches a maximum value, the corresponding load and displacement indicates the change in slope. For example, for the 6 pin 2 inch-lb the data in Table 2 indicates that for skull 1 the load at which the pins first shifted was at 139 lbs calculated by taking the maximum derivative value multiplied by its corresponding displacement. Note that this value is significantly less that that observed by the naked eye.

Table 2: Derivative and load

6 Pin 2 inch-lb			
	Derivative max	Displacement at derivative max	Corresponding load
Skull 1	3299.30	0.042	138.57
Skull 2	2890.40	0.064	184.99
Skull 3	3180.80	0.044	139.96

Figure 5 below displays the derivative of the curve fit equations within the 6 pin 2 inch-lb configuration. Note that the maximum values for the red and blue (skulls 1 and 3) have maximum loads around a displacement value of 0.04 inches and 3000 lb/in. Compare these values with those found in Table 2. The green line (skull 2) pictorially shows what is numerically described in Table 2--specifically, a higher displacement value and lower maximum value of the derivative.

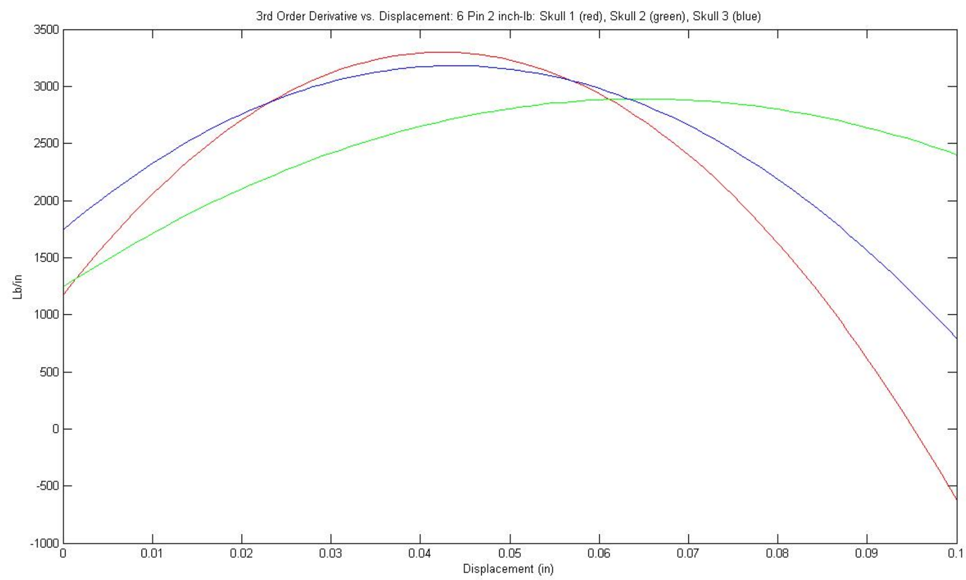

Figure 5: 3rd order derivative plots to show max

For completeness, the maximum derivative values with their corresponding displacement and load data are shown in Table 3. Note that cells containing an N/A were skulls that did not yield a maximum value for the derivative implying that the screws never moved, which is unlikely.

Table 3: All derivative/max load data

6 Pin 2 inch-lb					10 Pin 2 inch-lb			
	Derivative max	Displacement at derivative max	Corresponding max load			Derivative max	Displacement at derivative max	Corresponding max load
Skull 1	3299.30	0.042	138.57		Skull1	3099.50	0.048	148.78
Skull 2	2890.40	0.064	184.99		Skull 2	2665.00	0.069	183.89
Skull 3	3180.80	0.044	139.96		Skull 3	2134.20	0.052	110.98
Average		0.05	154.51		Average		0.056	147.88
6 Pin 4 inch-lb					10 Pin 4 inch-lb			
	Derivative max	Displacement at derivative max	Corresponding max load			Derivative max	Displacement at derivative max	Corresponding max load
Skull1	3381.80	0.068	229.96		Skull1	2049.30	0.038	77.87
Skull 2	2503.80	0.050	125.19		Skull 2	2520.90	0.051	128.57
Skull 3	1810.40	0.093	168.37		Skull 3	2790.60	0.053	147.90
Average		0.062	174.51		Skull 4	N/A	N/A	N/A
					Average		0.047	118.11
6 Pin 6 inch-lb					10 Pin 6 inch-lb			
	Derivative max	Displacement at derivative max	Corresponding max load			Derivative max	Displacement at derivative max	Corresponding max load
Skull1	2664.50	0.209	556.88		Skull1	2327.60	0.056	130.35
Skull 2	2016.50	N/A	N/A		Skull 2	2100.40	0.045	94.52
Skull 3	N/A	N/A	N/A		Skull 3	N/A	N/A	N/A
Average		0.209	556.88		Average		0.051	112.435

General Trends

The data proved to be problematic for the entire 6 pin 6 inch-lb set. All 3 skulls yielded data that did not peak. This implies that a load changing slope was never reached and screws never moved. This also proved to the be case for one skull in the 10 pin 2 inch-lb, 10 pin 4 inch-lb and 10 pin 6 inch-lb sets respectively. Given the small amount of skulls tested within each data set, it is difficult to draw any conclusions as to why the data behaved sporadically within the data sets. Using the data points, which seem to correlate with each other within each data set, some general conclusions may be drawn. Averages were taken for the three data points within each set to also be used for comparison. For example between the 6 pin 2 and 4 inch-lb configurations, one would expect the load at which the pins start to move would increase. For the 2 inch-lb configuration the average value of the three skulls was 154.51 pounds and the 4 inch-lb saw an average value of 174.51 pounds. As discussed earlier, the 6 inch-pound data did not yield credible results and cannot be used in this comparison. It would also be expected that the 6 pin 4 inch-lb configuration would yield a higher value of load at slope change than that of the 10 pin 2 inch-lb set. These values were 174.51 and 147.88 pounds respectively. Per the recorded data, the remaining 10 pin configurations yielded the smallest load at slope change values over all data sets. These values were averaged to be 117.91 and 113.695 pounds for the 4 and 6 inch-lb skull sets respectively. It is also misleading to use the average values within each data set when looking closely at the readings for the 3 data points for the 10 pin 4 inch-lb set. The 3 skulls with useable results yielded pin movement at 77.89, 127.96 and 147.90 pounds.

The data collected are limited in several ways. The force-deflection tests were a laboratory-controlled demonstration of only one type of force acting on the pins; that of axial distraction. The study did not evaluate other types of forces such as shear stress, which are present in in-vivo application of the halo device. It is possible that the variation in the load to failure among the halos was due to the placement of the halo pins in slightly different location within the designated pin-skull interface. The skull model used in this study does not account for the various physiological changes that take place during clinical use of the halo. Processes such as bone remodeling, fracture, and anatomical variation from patient to patient cannot be accounted for by the model.

As discussed earlier, the force-deflection study shows that halo fixation strength may be increased through the use of six pins at increasing torques. However, the results of the ten pin configuration are less clear. In the future, in order to resolve this problem, it is essential to conduct tests with a much larger sample size.

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