Measurement of Torque During Mandibular Distraction

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In a prospective study, 26 patients aged 9 days to 12 years old underwent mandibular distraction. There were 18 bilateral and 8 unilateral distractions performed. Five patients had previous distraction. Torque measurements were performed during the distraction process. A modest linear increase in torque was noted during the distraction process. Older patients required more torque to achieve the same distraction length as younger patients. The results of this study suggest that distraction forces are relatively modest, which may allow for greater freedom of distractor design.

Key Words: Mandibular distraction, torque, force

Resorbable one-stage distractors are finding increasing utilization among craniofacial surgeons.1-4 Mandibular distractors in particular are being used to lengthen the mandible in a variety of conditions. These include Pierre Robin sequence, Treacher Collins syndrome, Nager syndrome, and craniofacial microsomia. The current generations of distractors were designed using strength parameters derived from metallic distractors. Currently, the Food and Drug Administration has approved resorbable mandibular distractors for use in children younger than 2 years. More information is necessary to help guide the design and manufacture of these devices. Very little is known regarding the forces that are applied to the distractors during clinical use. This study was undertaken to clarify 1 parameter of the force vectors that are active during mandibular distraction. Torque, as an indirect measure of force, can be easily measured during the process of distraction using an electronic torque gauge (Imada, Northbrook, IL). We realized that we did not know if the devices were subjected to more force in early, mid, or late distraction phases. The nature of the force necessary during single vector distraction over time has not been well described in mandibular distraction. In addition, we felt that monitoring the amount of force during distraction could yield potentially valuable clinical information. Knowing if the torque is rising rapidly on one side of the mandible but not the other might imply that one side had reached full distraction before the other. Alternatively, a very low unilateral reading could mean that the device has become detached.

MATERIALS AND METHODS

Twenty-six patients undergoing mandibular distraction, using resorbable distraction devices, had torque measurements taken during distraction. An Imada DSD-4 digital torque wrench (Imada) was used for all measurements. There were 14 males and 12 females, ages 9 days to 12 years, with a mean of 2.6 years. All underwent mandibular distraction from 20 to 30 mm (mean, 25 mm). Three models of resorbable distractors were used, mandibular infant, mandibular pediatric, and L shape (see proceeding article in this issue). The choice of which device to use was based largely on the shape and size of the mandible. The approximate linear force required to distract the mandible can be calculated by correlating the material and mechanical characteristics of the distraction device and the recorded clinical torsion data. Laboratory testing was conducted to establish the correlation between torque applied to a distraction drive screw and the corresponding linear force of the plates transmitted to the proximal and distal bone segments (Fig 1). This test established that 1 in-oz of torque correlates to 1 lb of linear force. Measurements were taken at the time of device insertion, approximately half way during the distraction and when distraction...
was nearly complete. For purposes of tabulation, we divide these periods into initial one third, middle, and last third of distraction. Distraction procedures were performed as previously described (see preceding article). A 48-hour latency period was followed by 2-mm/d distraction until full length had been achieved. Five weeks was allowed for bone consolidation before removing the distraction drive screw.

RESULTS

All patients successfully completed their course of distraction. There were no complications in this group. Figures 2 and 3 give a graphic representation of our findings. There were modest increases in torque measurements with increasing mandibular length and patient age. Torque measurements ranged from 1.0 to 13.6 in-oz (mean, 5.0 in-oz). There was no spike in torque as distraction neared completion. In the bilateral distraction cases, torque measurements increased symmetrically. All torque measurements were converted to pounds of linear force (lbf) using the data derived from our laboratory testing (Fig 1). These tests demonstrated that every in-oz of force torque applied to the distraction drive screw translated into 1 lb of linear force transmitted through the plates attached to the surrounding bone. This made the data more relevant to common clinical units of measure. The results in Figures 2 and 3 were statistically significant ($P < 0.005$). Although redistraction cases had slightly higher torque measurements when compared with primary distraction cases, the difference did not reach statistical significance.

Fig 1 Drawing of laboratory setup used to correlate torque applied to resorbable distractor drive screw and linear force that the plates exert on the bone segments. The torque wrench records torsional data at the same time that load cell records linear force.

Fig 2 Graphic representation of data. Distraction force versus distraction length. Note the consistent force throughout active distraction process. (*); outliers in data.
DISCUSSION

The principles of distraction elucidated by Ilizarov predict that through gradual distraction, soft tissues including skin, muscle, and nerves will be stretched at a rate that does not exceed their elasticity modulus. The main opposing force to the distraction vector is the resistance of the soft tissues to elongation. It follows that being able to quantitate this opposing force by measuring torque during distraction would be important in designing distraction devices. When testing the mechanical attributes of a new distractor design, the construct's ability to withstand the linear force needed to lengthen bony segments and cantilever bending forces (needed to withstand masticatory forces) are tested in the laboratory.4,5 In the present study, we studied the more clinically relevant measure, the torque necessary to turn the distractor drive screw in resorbable devices in patients undergoing mandibular distraction. In contrast to the mechanical testing measured in the laboratory, our in vivo measurements include the forces applied from the surrounding soft tissues. This type of in vivo clinical study is quite rare. Robinson et al reported on a limited study of 8 patients undergoing mandibular distraction using titanium devices.6 Interestingly, his torque measurements were consistent with our findings. Ours is the first study to measure torque during mandibular distraction using resorbable devices. Torque measurements can be converted to pounds of force using laboratory-derived measurements (Fig 1). Our measurements show that the force on the distractors is relatively constant throughout the distraction process (Figs 2 and 3). There was no spike in the amount of force required to turn the distractors as the maximal length was obtained. These findings imply that the elasticity coefficient of the regenerate, nerves, muscles, and skin is not exceeded during 2-mm/d distraction. As such, the total force that these devices must withstand is relatively constant and does not increase significantly with increasing distraction length. This observation held true even in reoperative cases where soft tissue resistance would be expected to be higher with much less elasticity. The maximal force we measured, 13.6 lbf, was in a patient undergoing his third course of distraction in 6 years. Even in this extreme case, the forces applied to the distractor were far below the design parameters. Older patients required slightly more force than younger patients for an equivalent amount of mandibular lengthening. This can be explained by the greater weight of the bone and soft tissues that are being lengthened (Fig 2). It would seem that making the distraction devices significantly smaller and thinner would be possible with little chance of device failure. If this were possible, the devices could be more easily applied with greater freedom of design. Current design parameters have been derived from laboratory bench testing. Previous benchmark laboratory testing performed on resorbable mandibular distractors resulted in setting a design acceptance criterion of withstanding 30 lbf. Current resorbable devices are all designed to withstand 60 lbf of force, which gives the design a safety factor of 2 at the time of implantation (due to the resorption tissue, the safety factor drops to 1.4 at 8 weeks). In contrast, our study, which had a wide range of clinical conditions and age ranges, demonstrated that none of the distractors were subjected to greater than 13.6 lbf of force in mandibular distraction of up to 30 mm. Our data indicate that current design guidelines provide a safety factor of 4.4 times the force exerted during initial active phase of mandibular distraction (factory of safety drops to 3 at 8 weeks). Use of these devices in patients older than 2 years is considered "off-label." This is due to concerns regarding masticatory forces during the resorption period of the resorbable distractors. In the authors’ experience with resorbable mandibular distraction during the last five years, in patients ranging in age from 5 days to 14 years, structural device failure has not been observed when the devices were properly applied.1-3 We speculate that studies such as ours will show that in vivo the forces exerted on these devices are relatively modest and that current strength guidelines may be excessive. Smaller thinner devices would facilitate application and increase the rate of resorption, since less material needs to be broken down. We found that the torque measurements were clinically useful in monitoring the course of distraction, since we were able to measure initial torque readings at the time of placement. A dramatic increase or decrease in force measurements would indicate device failure or dislodgement from the underlying bone. This study was limited in scope, measuring only the force applied in the direction of the distraction vector. We did not measure the forces generated during mastication, vocalization, or other activities. Despite these limitations, we were able to start to understand the true magnitude of the force exerted on these devices in the clinical setting. We hope that these data will help to advance the design of the next generation of resorbable distractors.

CONCLUSIONS

Measurements of torque during mandibular distraction can be converted to pounds of linear force. The force exerted during distraction of 2 mm/d remains relatively constant throughout
distraction. The linear force of distraction is far below the current design guidelines. Measurement of the torque during distraction can provide valuable clinical information regarding the state of the devices.

REFERENCES