Mandibular Distraction Force: Laboratory Data and Clinical Correlation

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Purpose: In vitro data were collected to measure torque-force values of an internal distraction device. The measurements were correlated with in vivo torque readings in an attempt to better understand the force required to distract the osteogenic bone callus of the human mandible during distraction osteogenesis.

Methods and Materials: Five internal craniofacial distraction devices were mounted on an apparatus to test load limits and torque measurements. The apparatus aligned the devices so that weight provided a force opposite and parallel to the vector of distraction. Weights were added in 5-lb increments, and the devices were activated 0.5 mm for each torque reading. Torque readings were obtained from a calibrated torque wrench. Measurements were plotted on a graph and correlated with clinical torque readings obtained from 8 patients undergoing mandibular lengthening.

Results: The average torque for distracting the human mandible 0.5 mm twice a day was 4.2 ± 1.6 Newton-centimeters (N-cm). The average slope of the in vitro data shows that 4.2 N-cm of torque is equivalent to a force of 35.6 N. The average force of device failure was 235.8 N.

Conclusion: Torque-force diagrams offer an effective means for calibrating safety margins and load capabilities for internal distraction devices. Quantification of axial forces encountered in mandibular lengthening will help contribute to the overall understanding and biomechanics of mandibular distraction osteogenesis.

Distraction osteogenesis is becoming more common for reconstruction of facial bone deficiencies. However, it is difficult to quantify the forces necessary to distract the active reparative bone callus in the human during this process. Therefore, a study of an internal distraction device is needed to determine the torque-force values for the facial bones, failure load limit requirements, and correlation of these in vitro measurements with those found in clinical cases.

Force is the mass times the acceleration (F = ma). In other words, force is the influence to cause a change in velocity of an object. The unit of force in the metric system is the Newton (N). A Newton is that force which, when applied to a 1 kg mass, gives it an acceleration of 1 m/s². Therefore:

\[ 1 \text{ N} = 1 \text{ kg} \times 1 \text{ m/s}^2 = 1 \text{ kg} \cdot \text{m/s}^2 \]

\[ 1 \text{ lb} = 4.45 \text{ N} \]

Torque is the force needed to cause a rotational movement and is measured in Newton-meters or Newton-centimeters (N-cm). Because most distraction devices use a threaded drive shaft to move the ends apart, clinical measurements of torque are the easiest to make. However, although torque is reflective of the load on the device, it is not a direct measure of the distraction force at the osteotomy site. Torque is a factor of the coefficient of friction of the materials, the diameter of the drive shaft, and the pitch angle of the threads in the gears, the surrounding soft tissue, and the bone callus. Therefore, torque measurements are specific to a particular device, and so it is necessary to establish the relationship between the torque and the load for each device design. This relationship is the slope of the line when a load is plotted on the x axis and torque is plotted on the y axis. This linear correlation can be used to indirectly measure the force of distraction at the bone level for a given torque observed during activation. This information can then be used in the clinical setting to
determine the safety margins for device manufacturing and to give immediate clinical feedback regarding what may be happening in the distraction site (eg, premature consolidation, device failure, or incomplete osteotomies). This information can then be used to determine if the rate, rhythm, or distance of distraction should be modified. It can also indicate if additional radiographs should be taken, if an exploration should be made, or if the device should be replaced.

Even though distraction osteogenesis of the mandible is well reported in the literature, no study has been published describing the force necessary to distract the human mandible. The purpose of this article is to report laboratory data on the torque-force measurements of an internal craniofacial distractor, the Bone Generator (Inter-Os Technologies Inc, Lone Tree, CO) and to correlate the data to clinical cases of mandibular distraction with the same device (Figs 1, 2). The study also measured device load limits to failure and related the results to an overall margin of safety for internal distraction.

Methods and Materials

IN VITRO STUDY

Five Bone Generators (Inter-Os Technologies Inc, Lone Tree, CO) were mounted on a custom-designed vice and apparatus to hold them in a vertical orientation. A level was used to confirm the position. Suspension wires from a horizontal steel bar were attached to the movable part of the device so that a vertical load could hang below the device (Fig 3). The vertical load provided a force opposite and parallel to the vector of distraction. The device was lubricated with 1 to 2 drops of mineral oil in a similar manner as in the clinical setting and was opened and closed 2 to 3 times to ensure lubrication of the internal gears. The first torque measurements of each device were made with the suspension wire apparatus only, which weighed 3 lbs. The torque wrench (Seebonk Inc, Seebonk, MA) used a spring scale ranging from 0 to 24 inch-ounces. Mounted on the end of the torque wrench is used to activate device and measure torque. Clamp secures device in the vertical position. Cable hangs free from clamp and vice. Weight is added in five pound increments.
wrench was an activation wrench used to activate the device in the clinical setting. The device was turned 2 full revolutions, or 0.5 mm of distraction, and the average observed torque measurement was made and recorded. The device was closed back down to its original position after the load was removed. Loading and torque measurements proceeded in 5-lb increments up to 28 lbs (including the 3 lb suspension apparatus). The measurements were then plotted, a torque/force line was drawn for each of the 5 devices, and an average slope was established.

After the measurements were made to 28 lbs, each device was progressively loaded in 5- or 10-lb increments until failure. This process was carried out by activating the device for 1 full millimeter or 4 full turns using the activation wrench. Care was given to maintain the vertical orientation because of the lateral load limits. After each test, the weight was removed and the device was closed back to its original position.

**IN VIVO STUDY**

The correlative torque data taken from the clinical trials involved patients who underwent mandibular distraction osteogenesis using the Bone Generator. Fourteen distraction devices were used for both unilateral and bilateral lengthening of the mandible. The study involved 8 patients (1 male, 7 females), whose ages ranged from 6 to 20 years of age at the time of distraction. The clinical indications for distraction osteogenesis were bilateral mandibular hypoplasia (n = 4), mandibular hypoplasia with condylar agenesis (n = 2), oral-facial-digital syndrome (n = 1), and hemifacial microsomia (n = 1). Distraction commenced 6 days postoperatively at a rate of 0.5 mm twice a day until the desired length was achieved. Total distraction distances ranged from 4 to 17 mm, with a mean lengthening distance of 11.2 mm. Torque measurements were taken with the same torque wrench that was used in the in vitro laboratory setting (Fig 4).

**Results**

**IN VITRO DATA**

All devices tolerated the torque measurements up to 28 lbs. The endpoint for torque measurements for the tests was determined by the limits of the torque wrench, which was over 24 inch-ounces. Measurements up to 28 inch-ounces could be made by reasonable continuation of the scale on the torque wrench. The measurements were converted from inch-ounces to Newton-centimeters and recorded on a spreadsheet on a laptop computer (Table 1). A graph was then created using the graphing portion of the spreadsheet program (Fig 5).

The devices all failed at load limits of 48 lbs or above, except for one. This device failed at 38 lbs because of a lateral shift that occurred during loading of additional weight. Two of the devices sustained 58 lbs, and one device sustained 63 lbs. Failure occurred at an average load of 55 ± 10 lbs. The average load at failure, excluding the device that failed because of a loading error, was 56.8 lbs ± 6.3 lbs (SD).

**IN VIVO DATA**

Torque measurements from the clinical trials are shown in Table 2. The average torque for distracting the human mandible 0.5 mm twice a day was 4.2 ±

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**Table 1. WEIGHT AND TORQUE MEASUREMENTS FOR DEVICES 1 TO 5**

<table>
<thead>
<tr>
<th>Trial No.</th>
<th>Weight (lbs)*</th>
<th>Torque Measurements (N-cm) Devices 1-5</th>
<th>Average Torque</th>
<th>SD</th>
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<td>16.95 12.72 15.54 16.95 13.42</td>
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</table>

*Weight increased in 5-lb increments starting with the weight of the apparatus, which was 3 lbs.
1.6 N-cm. The first 3 measurements for both the left and right distraction devices in case number 3 were not used in calculating the average because of skewed data. It was discovered 7 days postoperatively that the device on the right side had jammed secondary to an incomplete osteotomy. The patient was returned to the operating room to complete the osteotomy, and the torque values then returned to expected levels.

Discussion

The torque force diagram shows that for the Bone Generator, 7.06 N-cm of torque is equal to a force of 13 lbs. The in vivo data also show that the average torque value for distraction is 4.24 N-cm (Table 2). This torque value means that the force necessary to move a distraction callus 0.5 mm during a regular rate and rhythm of 0.5 mm twice per day is approximately 35.6 N. Brunner et al\textsuperscript{18} reported that the percentage of muscle and soft tissue in the long bone that contributes to the total force measured is believed to be very low. They also commented on studies by Aronson\textsuperscript{19} and Hollis,\textsuperscript{20} which found that in the sheep tibia 75% of the necessary distraction force was a result of the callus itself and only 25% to the surrounding tissue. It is conceivable that the force to distract is proportional to the cross-sectional area of the callus, modified by the rate, rhythm, and age of the patient.

The average force of 35.6 N needed to distract the mandible means that in designing a device, greater miniaturization is possible as long as a safety factor is incorporated into the design. At times, it is necessary to increase the distraction distance at each activation. This increase approaches 8.48 N-cm for 0.75 mm of lengthening (Table 2), which would place a requirement of 15 lbs on the device.

The current emphasis calls for greater miniaturization of the internal device.\textsuperscript{2,5,9,13,15,17} There is no standard regarding how much of a safety factor should be engineered into the design. However, torque-force measurements will help establish such standards without compromising device integrity or safety. The measurements of the forces at failure demonstrate that the Bone Generator is capable of withstanding 6 times the required force to distract 0.5 mm. It would seem that this margin is adequate to accommodate most clinical problems. Building in a greater margin requires larger designs and possibly greater manufacturing costs and is probably not necessary.

It is important to note that the data obtained from the in vitro portion of this study measures only one of

Table 2. TORQUE MEASUREMENTS FROM CLINICAL TRIALS

<table>
<thead>
<tr>
<th>Case</th>
<th>Measurement No. 1 (N-cm)</th>
<th>Measurement No. 2 (N-cm)</th>
<th>Measurement No. 3 (N-cm)</th>
<th>Measurement No. 4 (N-cm)</th>
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</tbody>
</table>

* Torque increased with each successive turn.

Abbreviations: POD, postoperative day; XX, unilateral case or no data obtained.
the variables related to the force encountered in mandibular lengthening. The axial loads from the laboratory provide a great deal of information about the force required to distract the callus. However, the in vitro testing neglects to account for lateral forces, such as forces from the suprahyoid muscles that are frequently encountered during mandibular lengthening. The exact response and degree to which lateral counteractive forces affect the bone callus will vary with patient age, etiology, device rigidity, device orientation, and the vector of distraction. The effects of device orientation have yet to be established in the clinical setting and have thus far been uneventful. Future studies, similar to the previously mentioned studies by Brunner et al., Aronson, and Hollis et al., will aim to establish the percentage of force for the craniofacial model that is contributed by the callus versus the surrounding muscle and connective tissue.

Device placement and the vector of distraction are of paramount importance when planning craniofacial distraction. This is of particular concern for internal devices, which currently lack the ability for bidirectional control. Even when multiplanar devices are used, the planned distraction vector may differ from the resultant vector because of forces encountered during and after elongation. The multidirectional device allows for a change in the distraction vector. However, changing the vector of the distal segment may induce a change in the position of the proximal segment. Recent studies have demonstrated ways to prevent and augment a faulty distraction vector. Nonaxial forces will vary with different vectors of elongation. Torque-force measurements from the clinical portion of this study dealt primarily with vectors that were parallel and oblique to the mandibular rami. No significant difference was noted between torque readings with the varying vectors.

The ability to anticipate and quantify the force encountered in mandibular distraction enhances the development and design of devices. Torque-force measurements will contribute to manufacturing standards and will help to establish an adequate margin of safety. Calibrating craniofacial distraction devices with torque-force measurements will also allow the surgeon to monitor and exercise more control over the distraction phase. For example, an incomplete osteotomy may be detected and resolved at an earlier stage. Premature consolidation may also be anticipated and possibly avoided. In addition, device failure may be anticipated with excessive or minimal torque measurements, leading to radiologic examination and early detection. Case number 3 in the clinical trial demonstrated 2 of the above situations (Table 2). The progressive nature of the torque values for this case prompted radiologic review and surgical exploration. This patient maintained torque values on the right side of the mandible of 9.89, 9.89, and 14.13 N-cm on the fifth, sixth, and seventh day, postoperatively, respectively. These values were higher than expected and considerably higher in comparison with the left side, which only registered 1.41 N-cm. Surgical exploration confirmed an incomplete osteotomy causing the right distraction device to jam.

Torque measurements are invaluable for monitoring the distraction phase from a perspective of safety and control. Chin and Toth used torque measurements on patients who underwent a Le Fort III advancement to test and monitor the limits of fracture, thus enabling rapid distraction. Chin and Toth used a protocol that deviated from the standard by not observing a latency period and by performing 10 mm of distraction intraoperatively followed by an additional 10 mm of distraction within 2 to 3 days following surgery. Torque measurements of 14 to 18 N-cm were observed without fracture. However, other complications are inherent with this technique. The protocol for the current study maintained the standard rate and rhythm of 0.5 mm twice a day, with a latency period of 6 days. This rate and rhythm have permitted the establishment of an average torque that falls within a range of 1.5 to 7.0 N-cm. Clinical experience has demonstrated that torque-force values that fall within this range appear to be an acceptable measurement during uneventful lengthening of the human mandible.

Measuring the force required to distract the human mandible is difficult and is not currently reported in the literature. The force of distraction has been measured in long bones, and this has helped to advance the field of long bone distraction osteogenesis. Implications for future studies involving the force of mandibular distraction will not only contribute to a better understanding of mandibular distraction, but will also offer the surgeon a valuable tool for monitoring the progression of the distraction phase.

References
19. Aronson J: Mechanical factors generated during distraction osteogenesis. The International Society for Fracture Repair, Ottrot, France, April 1992