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Biomechanical Performance of Biodegradable Screw Fixation in Mandibular Distraction Osteogenesis

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Abstract: Internal distraction devices are commonly used in congenital micrognathia. The eventual need for device and screw removal can be challenging, requiring extensive dissection and disturbance of bone regenerate. Bioabsorbable poly-L-lactide (PLLA) screws, compared to traditional titanium screws, simplify device removal. Previous in vivo studies have found that the maximal compressive force generated by mandibular distraction is 69.4N. We hypothesized that PLLA screws could support these compressive/distraction forces. Ten mandibles were obtained from 5 canine cadavers. Paired mandibles from the same cadaver were each xated to a mandibular distractor with eight screws (either titanium or PLLA). Devices were each set to 15 and 30 mm of distraction distance. Compression force of 80 N was then generated parallel to the axis of the distraction device. Distractor displacement was measured to detect any mechanical failure during this pre-set load. Finally, if no failure was observed at 80 N, a load-to-failure compression test was done in the PLLA group to determine the mechanical failure point. All distractors in both the titanium and PLLA screw groups withstood 80 N of compression without failure. When the load-to-failure test was performed in the PLLA group, the average device failure point was 172.8 N (range 148–196 N). Review of high-frame-rate video demonstrated that all failures occurred due to the PLLA screws breaking or falling out. Bioabsorbable PLLA screws can withstand compressive forces more than double that of the maximal *in vivo* forces needed during mandibular distraction. These screws may be an acceptable alternative for the xation of internal mandibular distractors.

Key Words: Biomechanics, mandible, micrognathism, osteogenesis, distraction

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Micrognathia (mandibular hypoplasia) in the neonate is most often benign but can be deleterious should it result in upper airway obstruction. While most cases of micrognathia-related airway obstruction are amenable to conservative treatment (eg, prone positioning), severe cases often necessitate surgical intervention. Of the surgical options to correct mandibular hypoplasia, mandibular distraction osteogenesis is the most common. Mandibular distraction osteogenesis rst involves osteotomy of the mandibles, followed by application of distraction devices for gradual mandibular lengthening.[1,2] In many cases, this obviates the need for tracheostomy.[3–5]

Historically, external distraction devices were primarily used; however, the cutaneous pins of these appliances often resulted in patient discomfort, unacceptable scarring, and carried risks of pin loosening, device dislodgement, and pin tract infection.[6] Internal distraction devices are now generally preferred. In contrast to the external devices, internal distraction is credited for improved patient comfort, less scarring, and more predictable and stable distraction results.[6]

The conventional internal distraction process involves mandibular osteotomy and the placement of a distraction device xated with titanium screws. The main disadvantage of this approach is the need for a second operation to remove the device and screws, which usually requires general anesthesia. In some cases, the removal of titanium screws can be challenging, requiring extensive soft tissue dissection and disturbance of the regenerate.

Bioabsorbable materials such as poly-L-lactic acid (PLLA) have long been used in pediatric population for treating facial trauma, in craniosynostosis surgery, and in orthognathic surgery.[7,8] Yamauchi and colleagues described using PLLA screws for xation of the internal mandibular distractors. Because the screw material was bioabsorbable, this allowed easy removal of the device at the second operation and all the devices

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All the distractors were donated by KLS Martin company (Jacksonville, FL, USA).

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G.B.W. is the principal investigator of this study. The principal investigator made signi cant contributions to the conception and design of this study. J.M.F., Y.X., J.S.W., G.M.S., A.G., T.C.G., B.A., and G.B.W. made substantial contributions to the acquisition, analysis, and interpretation of data. J.M.F. and Y.X. drafted the article. All authors revised the article for intellectual content, gave nal approval of the version to be published, and have suf ciently participated in the work to take public responsibility for appropriate portions of the content.

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were removed under local anesthesia alone in these patients.[9] The patients in this case series were 18 years of age or older.

Although device removal under local anesthesia may not be realistic in young children and infants, the use of PLLA screw material still presents an attractive alternative to traditional titanium screw xation due to its ease of removal. To the best of our knowledge, there are no existing biomechanical studies on the mechanical properties of internal mandibular distractors using PLLA xation material. The present study aims to construct an in vitro model of mandibular distraction using PLLA xation material to perform biomechanical tests to validate the ability of PLLA xation to withstand physiologic distraction forces. We hypothesize that PLLA material provides adequate xation compared to the traditional titanium screw xation method.

MATERIALS AND METHODS

Ten mandibles were obtained from ve fresh frozen canine cadavers (Fig. 1). The dogs were humanely euthanized for reasons unrelated to the study and had owner consent for research or unrestricted use. Canine mandibles were excised and debrided of all muscle, soft tissue attachments, and periosteum. Mandibles were then divided at the symphysis to yield two mandibles per cadaver. Each mandibles from the same cadaver was assigned to either the PLLA group or the titanium screw group. A vertical osteotomy was performed between the rst and second mandibular molars. The distractors were then xated to the lower border of the lateral surface of each mandibles. All the distractors were donated by KLS Martin company (Jacksonville, FL).

In the PLLA group, the specially designed distractors had a small titanium tab within the osteotomy site to provide additional stability (Fig. 2A). Each distractor foot plate was secured to the rostral and caudal segments using four resorbable PLLA pins. The resorbable pins were secured using a proprietary ultrasonic device, the SonicWeld Rx system (KLS Martin). Each hole was drilled rst with a 1.1 mm diameter drill bit, followed by the insertion of the resorbable pins. The SonicWeld device emits an ultrasonic frequency causing the tip of mounted pins to vibrate, generating heat via friction with the contacting bone. The heat energy subsequently melts the pin and allows the insertion into the predrilled hole, securing the metal foot plate to the bone. For the titanium group, the internal distractor was xated using four titanium screws for each foot plate. After drilling with a 1.1 mm diameter drill bit, the foot plates were secured using 4 mm (length) to 1.5 mm (diameter) nonlocking titanium screws.

After the distractor was secured in, the rostral and caudal ends of the mandibles were placed in polymethylmethacrylate (PMMA) blocks (Coe-Tray Plastic, GC America, Chicago, IL). This allowed the mandibles to be mounted in the servohydraulic mechanical testing machine, as shown in Figure 2B (MTS 319.25A/T MTS Systems, Eden Prairie, MN). A laser level was used to ensure that the distractor was placed in the vertical direction along the axis of compression.

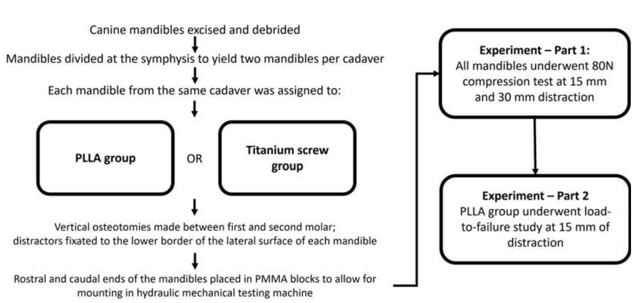

FIGURE 1 Experiment design and sequencing.

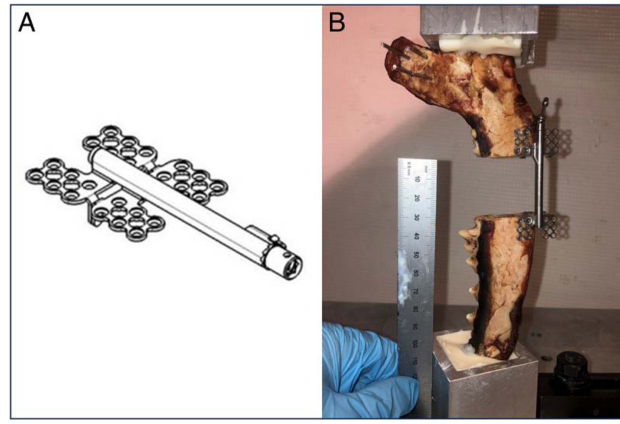

FIGURE 2 A) Internal mandibular distractors KLS Martin) that are used with poly-L lactic acid screw fixation. The distractors have special designs with small medal footplates that extend into the osteotomy site to provide further stability. B) Distractor fixated to a canine mandible with the SonicWeld Rx. In this image, the distraction distance is set at 30 mm.

The rst part of the experiment was to test whether models from both groups could withstand the maximal force of 80N. Each distractor device was placed at 15 mm of distraction. The servohydraulic mechanical testing machine was set to generate an increasing compression force at a rate of 0.5 mm/s with a maximal limit of 80 N. Once this limit was reached, the force returned to zero at the same rate. The machine concurrently measured displacement in millimeters to generate a load–displacement curve. High-speed video (250 fps) (model S-PRI, AOS Technologies, Switzerland) was taken to observe any sign of mechanical failure. This same test was replicated with all the distractors at the maximal distraction distance of 30 mm.

For the second part of the experiment, a load-to-failure study was performed in the PLLA group. In this test, distractors were placed at 15 mm of distraction distance, and the machine applied an increasing load of compression force until mechanical failure was observed. On the load–displacement graph, the point of failure (POF) was de ned as the maximal force achieved on the curve before a drop in load. In all graphs, there was an initial linear region where the load and displacement increased proportionately. When damage began, the load and displacement proportionality ceased. This point was de ned as the "yield point." At this point, the construct has a reduced stiffness, but will unload to close to the original length. This is a material behavior called "elastic-perfect damage."[10] We obtained the yield point by creating a linear t to the proportional part of the curve (region of 20 –50 of maximal load). The slope of this line represented the stiffness of the construct. A 95 secant line was obtained by reducing the slope by 5 ; the intersection of the secant line with the original load–displacement curve determined the yield point.

RESULTS

Five conventional internal distractors were tested in the titanium group, and 5 modi ed internal distractors were tested in the PLLA group. In both groups, all distractors withstood the 80 N compression force at 15 and 30 mm distraction distances without signs of mechanical failure. The load–displacement curve for each test is shown in Figure 3. When a load-to-failure test was performed in the PLLA group, the mean yield point was 101 N (range 78–125 N) and POF was observed at 172.8 N (range 148–196 N) (Fig. 4). Review of high-frame-rate video demonstrated that all failures occurred due to the PLLA screws breaking or falling out.

DISCUSSION

Despite the bene ts of internal mandibular distraction in the treatment of micrognathia, the primary disadvantage of this technique remains the need for device removal following bony consolidation. The use of resorbable xation of neonatal mandibular internal distractors would simplify device removal compared to traditional titanium screw xation techniques. To validate the adequacy of resorbable distraction xation, we created and in vitro model of mandibular distraction, using osteotomized canine mandibles to which distraction devices were af xed using either PLLA or traditional titanium screws. We found that all distractors (at both 15- and 30-mm distraction) could withstand 80 N of compression and that the mean yield point among the PLLA systems was 101 N (range 78–125 N).

To clinically translate these ndings, we may refer to the mandibular distraction biomechanical data reported by Robinson and colleagues.[11] Robinson s group found that during in vivo distraction, the average force needed to distract a mandible was 35.6 N; a maximal distraction force of 69.4 N was encountered in one patient.[11] The average yield point of the distractors in the present study using PLLA xation was 101 N. This is well above the average distraction force of 35.6 N, indicating that the device will function within the elastic zone. While the lowest observed yield point in our study was 78 N, this is still higher than the maximal force of 69.4 N observed clinically during distraction.

The measurement of POF in our study demonstrates that the average ultimate strength when using PLLA xation was 172.8 N. As a result, these devices should be capable of withstanding 4.8 times the strength of average mandibular distraction without failure. Robinson et al reported that the average force of device failure in their distractors (Bone Generator, Inter-Os Technologies Inc., Lone Tree, CO) using titanium screw xation was 235.8 N. In comparison, the devices in our study utilizing PLLA screws demonstrated 73.2 of the comparable ultimate strength. At the time of this writing, there is no widely accepted standard regarding how much of a safety factor must be engineered into the design to ensure device integrity and safety. It is logical to assume that having both the ultimate strength and yield point well above the average distraction force of 35.6 N should ensure device integrity during the distraction process.

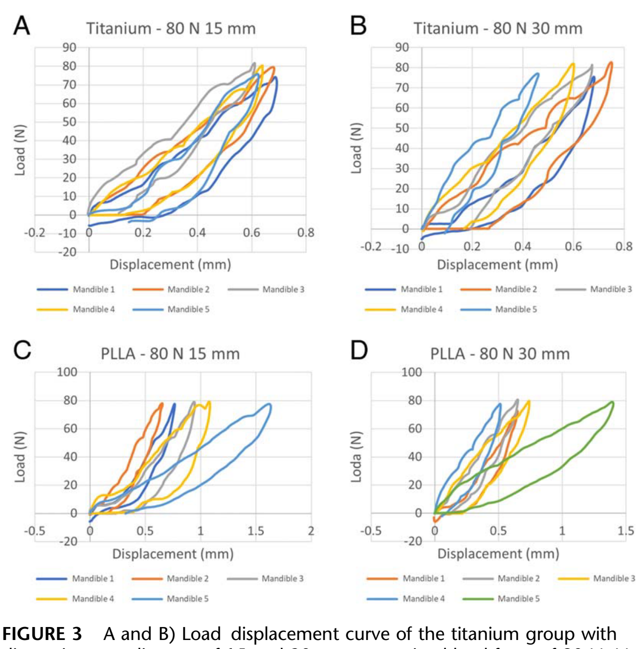

FIGURE 3 A and B) Load displacement curve of the titanium group with distraction gap distance of 15 and 30 mm at maximal load force of 80 N. No devices showed signs of mechanical failure. C and D) Load displacement curve of the PLLA group with gap distance of 15 C) and 30 mm D). No devices showed signs of mechanical failure. PLLA indicates poly-L-lactide.

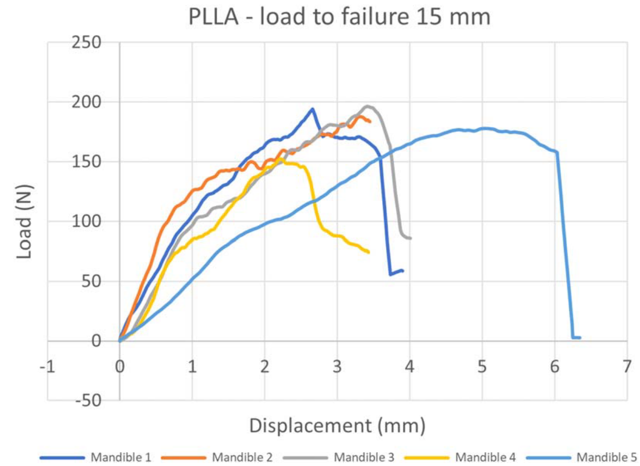

FIGURE 4 Load displacement curve of distractors with PLLA fixation when load is increased to the point of device failure. PLLA indicates poly-L-lactide.

Previously, it has been suggested that current distractor designs may carry too high of a safety margin, with some investigators suggesting device miniaturization to both decrease distractor costs and limit operative dissection.[11,12] Our data indicate that transitioning from titanium screw to PLLA xation of internal distractors may be another mechanism by which the safety margin could be appropriately decreased for overall patient bene t.

The main limitation of this study is that we measured only one of the variable forces encountered during mandibular distraction. Although the axial loading force provides insight into the main force required to distract the callus, it is not the only force encountered by the mandible during distraction. The human mandible has a complex geometrical shape and mechanical properties. Our in vitro model neglects to account for the sagittal biting forces, lateral forces, and rotational forces encountered by the mandible. The exact response and degree to which these forces affect the distraction process is unknown. We do know that device rigidity plays a signi cant role in the success of distraction. In this sense, the comparison between the axial loading forces could allow extrapolation on the overall mechanical stability of the devices. The use of distractors made entirely of biodegradable material such as PLLA has also been reported in the literature, which does not require a second procedure for device removal.[13,14] The clinical success of these devices demonstrate that PLLA material alone may have adequate integrity to facilitate both the distraction and consolidation processes during distraction. Furthermore, there is limited data on in vivo mechanical forces that neonatal mandibles encounter during normal development, and future studies on the subject could help facilitate design of new bioabsorbable devices that are optimized both in size and structural integrity to accomplish mandibular distraction.

Additionally, the adult canine mandible is an imperfect model for the human neonatal mandible. The mandibles used in the present study are assumedly more mineralized than human neonatal bone and may therefore provide a more reliable interface for the PLLA screws, for which xation is partially dependent on pin liquefaction and anchorage into bone cavities.

Finally, it must also be acknowledged that this study could be improved by testing more mandibles, in part to help minimize the impact of outlier values on analyses. As apparent in the load–displacement curves of the PLLA group (Fig. 3), mandible 5 appears to be an outlier.

CONCLUSIONS

The in vitro models of the present study demonstrate that internal mandibular distractor devices utilizing PLLA screw xation can withstand observed distraction forces. The average POF was more than double the maximal distraction forces observed clinically. These screws may potentially be used as acceptable alternative to titanium screws for xation of internal mandibular distractors.

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