Research in Veterinary Science 159 (2023) 81–83

Contents lists available at ScienceDirect

Research in Veterinary Science

journal homepage: www.elsevier.com/locate/rvsc

Short communication: Torsional tests on long-bone cylindrical medullary-canal exo-endoprostheses

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ARTICLE INFO

Keywords:
Torsional test
Exo-endoprosthesis
3D-printing
Ex vivo
Tibia
Canine

ABSTRACT

Torsion tests are performed for cylindrical type of a novel *exo*-endoprosthesis internal part. It is verified that it has values greater than those obtained for elliptical type. The best bonding method between PEEK and threaded rod is the resin adhesive, matching the obtained results for elliptical implant. Results of cylindrical type are discussed versus elliptical type.

1. Short communication

Exo-endoprosthesis is a limb salvage procedure in animals in which the implant is inserted into the medullary canal of a long bone. Now-a-days, thanks to additive manufacturing (AM), polymers, as poly-etheretherketone (PEEK), can be considered for manufacturing small productions of final medical devices with a minimum cost (Mendaza-DeCal et al., 2021). To avoid complications on these 3D-printed medical devices as device failure, ex vivo mechanical assessments should be performed. The quasistatic and dynamic mechanical behavior of the 3D-printed PEEK part of an *exo*-endoprosthesis implant for long bones with cylindrical and elliptical medullary canal have been reported (Mendaza-DeCal et al., 2022b, 2022a). But natural dog motions also exert torsional forces to the anchor inserted into the bone; and only the effects of adhesive applied on the pre-treated threaded rod were evaluated for bones with elliptical medullary canal (Mendaza-DeCal et al., 2022a). The aim of this study was to assess in vitro and ex vivo the torsional behavior of the inner part of a *exo*-endoprosthesis designed for long bones with cylindrical medullary canal, and to compare it with the performance of elliptical-type implants used in previous studies.

An endoprosthesis device was described by Mendaza De Cal et al., 2020. It comprised 2 main parts: 1) the PEEK part in contact with the bone, and 2) the surgical metal threated rod attached to an exoprosthesis. For each PEEK part, stainless steel 316 threaded rod was tightened using a locknut.

The endoprostheses were printed horizontally oriented (18.22*56.00*15.92 mm^3, which are x, y and z of the printing bed, respectively) with a FunMat HT (INTAMSYS, Shanghai, China), and using PEEK filament, and the printing parameters for PEEK such as described in Mendaza-DeCal et al., 2021.

The torque resistance of the 3D-printed PEEK part inside tibiae was assessed by applying the torsional force on the implant's base. The 3D-printed PEEK part–threaded rod interface was assessed by applying the torsional force on the threaded rod. Seven ex vivo fresh tibiae (9.48 $\pm$ 0.29 mm medullary canal) were used to insert endoprosthesis specimens. Their preparation method and sizes were described in detail in a previous work (Mendaza-DeCal et al., 2022b).

The remaining forty-two PEEK parts were impacted with softly hammer blowing inside their respective 3D-printed PETG receptacles. The receptacles for torsional test were printed with a Abax PRi5 printer (Abax Innovation Technologies, Villanueva de la Cañada, Spain) such as described in Mendaza-DeCal et al., 2022a.

In fifteen samples, three biocompatible adhesives were applied to the threaded rod before inserted it for evaluating the torsional strength of each thread locker, such as described in Mendaza-DeCal et al., 2022a. Two types of mechanical locking were made in ten samples for

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https://doi.org/10.1016/j.rvsc.2023.04.007
Received 26 February 2023; Received in revised form 11 April 2023; Accepted 16 April 2023
Available online 17 April 2023
0034-5288/

assessment. In total, forty-nine endoprosthesis were used for torsional assessment.

The two types of mechanical locking were locking nuts (LN) and dowel-pin locking (DP-L). 3D-printed PEEK part design was modified for housing a 10 mm-length coupling nut, then the threaded rod was tightened, finally a locknut was tightened strongly with two wrenches. For the second technique, a 2 mm diameter through hole was perpendicularly drilled into the base of the PEEK part and the threaded rod after inserted the rod. Immediately, a 1.8 mm diameter Kirschner wire was inserted and cut flush to the PEEK part with cutting pliers.

Torsion forces were assessed for each location of the force application (Mendaza De Cal et al., 2020). Two kinds of torsion tests were carried out such as described in Mendaza-DeCal et al., 2022a.

ANOVA test was run for torque force data using the STATGRAPHICS program (XVII Centurion. Ver. 17.2.00, StatPoint, Inc., Herndon, VA, USA). When significant differences were observed ($P \leq 0.05$), Fisher's Least Significant Difference (LSD) was calculated.

Two statistic comparisons were performed (Table 1 and Fig. 1). Firstly, the torsional-locking methods were compared and shown a significant difference between groups (Table 1). A significantly higher mean was obtained for the force application on the PEEK part instead of on the non-pre-treated threaded rod. In addition, statistical differences were observed between non-pre-treated threaded rod and LN methods. Not statistically differences were observed between PEEK part and DP-L methods.

When the torque was applied on the thread rod, only the rod loosened; meanwhile if the torque was applied on the PEEK part, the whole endoprosthesis spun round and broke inside the medullary canal at the same time. On the non-pre-treated threaded rods, butyl-cyanoacrylate adhesive application at the end of the threaded rod had a higher mean—226% higher comparing to specimens without adhesive. All the methods with surface pre-treatment had the higher means and were significantly different than the other torsional lock methods.

Secondly, the type of adhesive applied on pre-treated threaded rods was evaluated (Fig. 1). Statistically significant differences were observed between the three adhesives; zinc oxyphosphate cement was different from resin cement or butyl-cyanoacrylate. Butyl-cyanoacrylate showed the highest torque resistance with the lowest standard deviation of the three adhesives. All values were significantly higher than the torque needed to endoprosthesis failure inside the tibia.

The PEEK part, DP-L and LN methods showed three different breakages of the endoprosthesis—between the umbrella and the beginning of the stem; at the base of the 3D-printed PEEK part, where the hole was drilled; at the housing of the coupling nut—, respectively. On adhesive locking methods, four different failures occurred— threaded rod spun inside the endoprosthesis; loosening torque occurred before the threaded rod would have done; the nuts used to apply the torque force rotated relative to each other; and the threaded rod broke without any damage in the endoprosthesis. Failure modes were detailed on the supplementary material (Supplemental file 1).

Table 1
Torque resistance of each torsional lock method.

Torsional lock method	Maximum Torque (N·m)
PEEK part	5.03 ± 1.86b
No surface pre-treatment of threaded rod	
No Adhesive	1.34 ± 1.00a
B-C Throughout threaded rod	1.67 ± 1.31a
B-C At the end of threaded rod	3.03 ± 1.62a
Surface pre-treatment of threaded rod	
Resin cement	12.38 ± 1.87d
Zinc oxyphosphate cement	8.70 ± 3.38c
Butyl-Cyanoacrylate	14.48 ± 0.94d
Mechanical locking	
Locking nuts	2.74 ± 1.53a
Dowel-pin locking	5.78 ± 0.13b
MSE	2.96

Data are the mean of 5–7 replicates ± standard deviation. Means were significantly different by LSD. B-C means butyl-cyanoacrylate; MSE means square error.

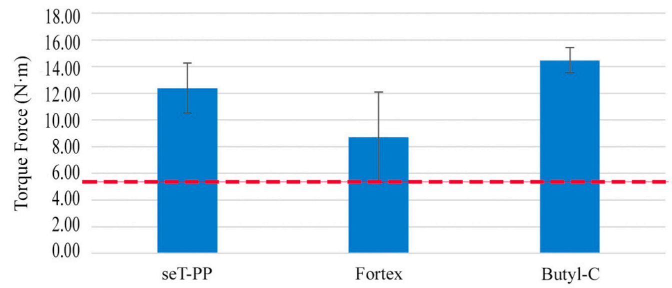

Fig. 1. Data are the means with SD of the torque results for the adhesives applied on pre-treated threaded rods. At least four replicates in each one. The red dashed line indicates the torque needed to spin round the endoprosthesis inside the medullary canal of the tibia. seT-PP is resin cement samples; Fortex is zinc oxyphosphate cement samples, and Butyl-C is butyl-cyanoacrylate samples. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Torque force resistance was assessed to determine mechanical limitation of the studied cylindrical *exo*-endoprosthesis internal part and compare the results with those observed on elliptical type. Different locking methods for the PEEK part-threaded rod interface were performed.

The forces applied to canine limbs during change of direction of the dog at different gaits or torque have been poorly studied, also occurred with this kind of implants. In a previous study of elliptical implants for canine radii (elliptical bones) the results were lower to radii failure at torque (Mendaza-DeCal et al., 2022a), as occurred with these cylindrical implants compared to tibiae failure: 29.27 N·m (Sammarco et al., 1971), regardless of where the torque is applied. Tibia has a larger medullary canal than radius in the same animal, so cylindrical implants were larger than elliptical and could withstand higher torque force. However, the data obtained cannot be compared with unknown canine natural torsional forces. However, based on the torsional resistance obtained for both types of endoprosthesis, it may be necessary to limit the use of these implants to cylindrical medullary canals, given the expected higher torsional loads applied during a dog's gait on the thoracic limbs.

The rod loosening occurred at presumably very low load on the non-pre-treatment methods compared to the pre-treatment one, as discussed in Mendaza-DeCal et al., 2022a. Therefore, it was confirmed that pre-treatment of the threaded rod prior to application of an adhesive should be done if an adhesive method is to be chosen for the PEEK-threaded rod interface (Mendaza-DeCal et al., 2022a; Najeeb et al., 2019). The torque resistance observed with resin cement, zinc oxyphosphate cement or the butyl-cyanoacrylate was around 2.3-fold the obtained if the force were applied on the PEEK part. This result was positive and follows the obtained results for bones with elliptical medullary canal (Mendaza-DeCal et al., 2022a). Statistically significant differences among these three adhesives were observed in cylindrical endoprostheses, with resin cement or butyl cyanoacrylate showing superior results to zinc oxyphosphate cement. The results for zinc oxyphosphate cement differed from those of a previous elliptical endoprostheses study (Mendaza-DeCal et al., 2022a). This difference among studies is likely due to differences in the method of mixing or the difference in size between the implants. Thus, the cylindrical implants, which were larger than the elliptical ones, required more torque to make them fail, but also increased the force per area undergone by the adhesive (Uhrenbacher et al., 2014). This means that the zinc oxyphosphate could exceed its maximum force tolerance. On the other hand, butyl cyanoacrylate exhibits hydrolytic degradation within the organism (Alarcon et al., 2022), which could complicate its use as a permanent solution.

DP-L and LN showed similar results to those when the torsion was applied to the PEEK part or when is applied to the threaded rod without pre-treated surface. DP-L was eventually limited by the PEEK's torque strength, which was preferred to avoid this mechanical effort to the PEEK part as mentioned above. In the same manner, the LN exhibited those results because it depended on the force with which the tightening was performed by the researchers; this condition was similar to a clinical situation. Although these mechanical solutions improved the resistance to rod loosening without pre-treatment, they are limited either by the surgeon's strength or by the torque resistance of the PEEK which would compromise the complete implant.

The failure modes observed can be categorized into those that affected the PEEK part and those that resulted in the loosening of the threaded rod inside the PEEK. It is anticipated that when a force is applied to the PEEK part, it will break at the junction between layers, as this is the weakest area of an object created using 3D printing (Pu et al., 2020). While failure at the threaded rod-PEEK interface is also a potential issue, this type of failure is less critical in the context of an implant in the bone, as require a minor intervention.

Considering the obtained results and other studies, resin cement could be the better option as permanent adhesive above zinc oxyphosphate cement and butyl-cyanoacrylate due to its more lasting and better mechanical properties (Alarcon et al., 2022; Yu et al., 2014).

Ethical approval

Not applicable.

Authorship

Conceptualization R.M-D; design of the study R.M-D and Y.B.; acquisition of data R.M-D, Y.B. and J.C.R-R; analysis and interpretation of data R.M-D, Y.B., J.C.R-R and S·P-F; drafting the article R.M-D; Revision Y.B., J.C.R-R, S·P-F and J.R-Q; Final approval J.C.R-R and J. R-Q; Funding acquisition JRQ, SP.

Funding

This work was supported by the Regional Government of Madrid, Spain [grant IND2017/BMD-7726]. R. Mendaza received a PhD fellowship from this grant.

Declaration of Competing Interest

The authors declare that they have no competing interests. The Regional Government of Madrid has not involved in any decision about the development of this study. RM-D, SP-F and J.R-Q had a patent of the studied implant. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Data availability

The original contributions presented in the study are included in the article/ datasets of supplemental file.

Acknowledgement

R. Mendaza received a PhD fellowship from this grant. The Regional Government of Madrid has not involved in any decision about the development of this study. We thank Abax Innovation Technologies, and Veterinary Anatomy and Embryology Department of Faculty of Veterinary Medicine at Complutense University of Madrid for their technical support and knowledge. In addition, we are sincerely thankful with all people of the Industrial Testing Laboratory at ICAI School of Engineering of Comillas Pontifical University, especially to Susana Guzmán.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.rvsc.2023.04.007.

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