Ciência Rural, Santa Maria, v.53:12, e20220027, 2023
http://doi.org/10.1590/0103-8478cr20220027
ISSNe 1678-4596
CLINIC AND SURGERY

Development of an intervertebral disc prosthesis prototype for the canine cervical spine

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ABSTRACT: Cervical arthroplasty with disc prosthesis has been proposed as a treatment option for dogs with Cervical Spondylomyelopathy. The present study developed a novel vertebral disc prosthesis for dogs. Sixteen Functional Spinal Units (C5-C6) were collected from dog cadavers with body weights ranging between 25 and 35 kg, and their vertebral measurements were used to design a prosthetic disc. The sizing of the prosthesis was performed based on the averages of the measurements of width, height, and length of the vertebral bodies from C5-C6 of all specimens. The prosthesis was developed using the Rhinoceros 3D® and SolidWorks® programs, and 3D prototyping was carried out to define the best design. The developed prosthesis consisted of two independent parts that are fixed to the cranial and caudal vertebral bodies, in the intervertebral space, and fitted together by metal-to-metal surfaces capable of moving in the lateral, ventral, and dorsal directions. Each part of the prosthesis is angled in two portions: vertically, in the intervertebral space, and horizontally, in contact with the ventral surface of the vertebral bodies, both of which are fixed by means of monocortical locking screws. The design of the developed prototype allowed a good fit in the intervertebral space between C4-C5, C5-C6, and C6-C7.
Key words: spine, arthroplasty, prothesis design, veterinary surgery.

Desenvolvimento de um protótipo de prótese de disco intervertebral para a coluna vertebral cervical de cães

RESUMO: A artroplastia cervical com prótese de disco tem sido proposta como uma opção de tratamento para cães com Espondilomielopatia Cervical. O presente estudo teve como objetivo desenvolver uma nova prótese de disco intervertebral para cães. Dezesseis Unidades Funcionais de Coluna Vertebral (C5-C6) foram coletadas de cadáveres de cães com peso corporal variando entre 25 e 35 kg, e suas medidas vertebrais foram usadas para projetar um disco intervertebral protético. O dimensionamento da prótese foi realizado com base nas médias das mensurações da largura, altura e comprimento dos corpos vertebrais de C5-C6 de todos os espécimes. A prótese foi desenvolvida nos programas Rhinoceros 3D® e SolidWorks® e utilizou-se prototipagem em 3D para a definição do melhor *design*. A prótese desenvolvida é formada por duas partes independentes que se fixam às espífises dos corpos vertebrais cranial e caudalmente ao espaço intervertebral, e se encaixam entre si por superfícies de metal-metal com capacidade de movimentação nas direções lateral, ventral e dorsal. Cada parte da prótese é angulada em duas porções: a vertical, que fica no espaço intervertebral, e a horizontal, que fica em contato com a superfície ventral dos corpos vertebrais, ambas as quais são fixadas por meio de parafusos bloqueados monocorticais. O *design* do protótipo desenvolvido permitiu bom encaixe no espaço intervertebral entre C4-C5, C5-C6 e C6-C7.
Palavras-chave: coluna vertebral, artroplastia, desenho da prótese, cirurgia veterinária.

INTRODUCTION

Cervical spondylomyelopathy (CSM) is a disease that affects large and giant breed dogs and is characterized by abnormalities of the cervical spine that can culminate in neurological deficits, cervical hyperesthesia, or both (ADAMO et al., 2007; DA COSTA, 2010).

The disease is characterized by static and/or dynamic lesions that mainly involve the caudal cervical region (C5-C6 and C6-C7) (BONELLI et al., 2021; FALZONE et al., 2022). This condition may be present in two forms: bone-associated compression, characterized especially by vertebral canal stenosis secondary to bone malformation and/or osteoarthritic alterations, and disc-associated, characterized by

Received 01.17.22 Approved 02.06.23 Returned by the author 03.27.23
CR-2022-0027.R2
Editors: Rudi Weiblen Alexandre Mazzanti

spinal cord compression caused by the protrusion of one or more intervertebral discs in combination or not with vertebral abnormalities (congenital vertebral canal stenosis), ligamentum flavum hypertrophy, and intervertebral foraminal stenosis (DA COSTA, 2010; DE DECKER et al., 2012; BONELLI et al., 2021).

In disc-associated CSM, the distraction-fusion surgical technique is widely described as treatment for the condition and aims to distract and stabilize the vertebrae in an attempt to promote spinal decompression (DA COSTA, 2010; MARINHO et al., 2022). This method provides good results; however, procedures that promote fusion or excessive vertebral stability can generate biomechanical alterations in the segments adjacent to the stabilized site, with consequent accelerated degeneration, culminating in the long-term recurrence of the problem (PINDER & SHARP, 2016).

The cervical arthroplasty technique (ADAMO et al., 2007; ADAMO, 2011; ADAMO et al., 2014a, 2014b) was proposed for dogs with disc-associated CSM. It aims to preserve the vertebral range of motion after surgical decompression while providing distraction and stability in order to achieve complete spinal cord decompression (ADAMO, 2011; ROBERTS et al., 2018; KORECKIJ et al., 2019).

Some authors have reported good to excellent outcomes in most dogs that underwent cervical arthroplasty surgery. The procedure has shown effectiveness in providing vertebral distraction and preserving segmental motion; although, complications such as subsidence with loss of vertebral distraction and vertebral instability have occurred over time (ADAMO et al., 2014a, 2014b; ADAMO & FORTERRE, 2015). Subsidence of the prosthesis into the vertebral bodies is also one of the most commonly reported complications of intervertebral disc arthroplasty in humans (VAN LOON & GOFFIN, 2012; PARISH et al., 2020). One of the most important causal factors is improper device design, in which there is stress misdistribution on the surface of the anchorage structure relative to the vertebral endplates (LIN et al., 2009; VAN LOON & GOFFIN, 2012).

This study designed and developed an intervertebral disc prosthesis prototype as an alternative treatment method for dogs with disorders of the cervical spine, especially cervical spondylomyelopathy. The main characteristic of the proposed prototype is its fixation to the vertebral bodies by means of locked monocortical screws, which differs significantly from the prosthesis currently available for use in dogs (ADAMO et al., 2014a, 2014b). The fixation of the latter in the intervertebral space depends exclusively on compression between the vertebrae and the thinning of the vertebral endplates, which has led to subsidence and loss of vertebral distraction in the medium and long term.

MATERIALS AND METHODS

Specimen collection

Sixteen cervical (C5-C6) specimens were collected from skeletally mature adult mixed-breed canine cadavers with ages ranging from 7 to 12 years, body weights ranging from 25 to 35 kg and dissected into functional spinal units (FSUs). The animals died from conditions unrelated to the present study, and their cervical spines were radiographed in orthogonal views to exclude anatomical abnormalities. Immediately after the radiographs, the spinal units were cleared of superficial soft tissues and individually sealed in plastic bags, which were stored at -20 °C until testing. One day prior to performing the measurements, they were transferred to a refrigerator at 4 °C to defrost. On the day of the measurements, the spines were defrosted at room temperature and kept moist in 0.9% NaCl solution.

The FSUs were randomly allocated into two groups: a median group (Group 1), represented by eight cervical columns that were sectioned in the median plane to measure the length of the vertebral bodies of C5-C6 and the angulation between their ventral surfaces and endplates; and a transverse group (Group 2), comprising the remaining FSUs, which were sectioned in the transverse axis, at the level of the intervertebral space, to assess the width and height of the vertebral bodies of C5-C6 (KNELL et al., 2019).

Vertebral body morphometry

Direct spinal measurements were taken from the collected FSUs using digital calipers and recorded. The vertebral dimensions were obtained in the axial and median sagittal planes, and the mean FSU dimensional shape was determined. The intervertebral discs were measured from their central mid-points to establish the average intervertebral disc dimensional shape.

The width, height, and length of the vertebral bodies of C5-C6, obtained from the collected cervical spines, were measured, as well as the angulation between their ventral surfaces and endplates, to determine the average size of the prosthesis to be developed.

In order to define the width and height of the prosthesis, measurements were taken at the level of the intervertebral disc space of the vertebrae in Group 2 between C5 and C6. As for the length of

the prosthesis on the horizontal axis, measurements of half the length of the vertebral bodies in Group 1 were taken for both C5 and C6. All measurements were carried out through pachymetry of the vertical and horizontal axis, and the final average established for each measurement was used for the sizing of the prosthesis. In order to determine the angle representing the caudal-ventral portion of the vertebral body of C5 and the cranioventral portion of the vertebral body of C6, the median-sectioned vertebral spines were used, in which the angles between the line parallel to the vertical axis of the intervertebral space and the line parallel to the ventral horizontal axis of the vertebral body were measured. The same procedure was performed for the vertebral bodies of C5 and C6. All measurements were carried out using a goniometer, and the final average established for each angle was used in the development of the prosthesis (Figure 1).

Prosthesis design and modeling

Based on the acquired vertebral morphometry (Table 1) and the study by ADAMO (2011), the first-generation prosthesis (FGP) was designed using the softwares Rhinoceros 3D® (Robert McNeel & Associates, Seattle, WA, USA) and SolidWorks® then printed in 3 mm ABS (Acrylonitrile Butadiene Styrene) filament using the Fused Filament Fabrication (FFF) technique by a 3D printer (Rapman 3.2, 3DSystems®, SC, USA), coupled with the Axon2® management software. Once printed, the FGP was applied to the FSUs (sectioned in the transverse axis) to assess proper fit. After each after application to the FSUs, the limitations and difficulties inherent to the implantation of the prosthesis in the FSUs were recorded, and adjustments to the computational project were carried out until the prototype exhibited adequate three-dimensional sizing. This process was repeated until reaching a model that best suited the intervertebral space of the cadavers. Once the model was obtained, it was refined so as to create three generations of the prosthesis.

Regarding final certification, the DICOM (Digital Imaging and Communications in Medicine) international standard was used, in which the cervical spine of three large breed dogs (Rottweiler, Bernese Mountain Dog, and Labrador Retriever) from the VetCraft 3D database (2 mm-thick slices) were exported into a medical free image-processing software (Invesalius®, SP, Brazil) and converted into STL (standard triangulation language) format. After exporting the files to a computer-aided design software (Blender®, Amsterdam, NL), all generations of the prostheses were virtually implanted on cervical spines. After virtual implantation, 3-dimensional biomodels of each spine were printed in ABS, and the prostheses were resin-printed using the SLA (Stereolithography) method. Next, all 3D-printed prosthesis generations were tested for insertion in the C4-C5, C5-C6, and C6-C7 intervertebral spaces of the cervical vertebral biomodels. The vertebral columns were printed three times in order for each generation to be tested. Only the

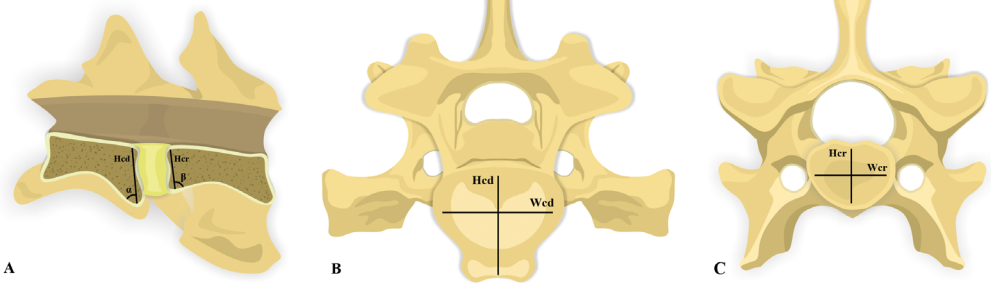

Figure 1 - Schematic of the C5 and C6 vertebrae of a dog cadaver in median and transverse sections. (A) Median sectioning with the respective demarcations that guided the sizing of the prosthesis. "Hcd": height of the vertebral endplate of C5, "Hcr": height of the vertebral endplate of C6, "α": angle formed between the caudal vertebral endplate and the ventral cortical endplate of the vertebral body of C5, "β": angle formed between the cranial vertebral endplate and the ventral cortical endplate of the vertebral body of C6; (B) Transverse section of the C5 vertebra in caudal view. "Hcd": height of the vertebral endplate of C5, "Wcd": width of the vertebral endplate of C6; (C) Image of the transverse section of the C5 vertebra in cranial view. "Hcr": height of the cranial vertebral endplate of C6, and "Wcr": width of the vertebral endplate of C6.

Table 1 - Dimension values (mean ± standard deviation): total length of C5 and C6, height of the endplates of C5 and C6, width of C5 and C6, and angle between the ventral surfaces of the vertebral bodies and the endplates of C5-C6 of the dog cadavers, which guided the sizing of the first generation of the prosthesis.

Vertebral body dimensions	C5	C6
Total Length (mm)	51.2 ± 2.0	48.7 ± 2.8
Height (mm)	17.6 ± 1.8	15.2 ± 1.4
Width (mm)	16.8 ± 1.0	13.8 ± 1.5
Angle (degrees)	70.87 ± 1.2	110.4 ± 1.6

third generation, considered ideal, underwent machining in ASTM F67 pure titanium [Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)], manufactured using the wire EDM (Electrical Discharge Machining) process and a 6 Axis CNC (Computer Numeric Control) router machine (Aldrivet, Campinas/SP, Brazil), for later evaluation of the possibility of inserting and positioning the prosthesis in the intervertebral space and the fixation power of the screws through direct digital manipulation.

RESULTS

For the creation of the prosthesis, the main aspects taken into account were the adequate adjustment in the intervertebral space and the possibility of additional fixation of the prosthesis to the vertebral body with screws, in a way that fixation was not solely dependent on intervertebral compression.

Considering these factors, the prosthesis called PVTM Cervical Disc (patent application BR10201403025) was designed and presents specific characteristics that have evolved during its development. All generations include two parts: P1, the cranial portion of the prosthesis, which is in direct contact with the caudal vertebral endplate of C5, and P2, the caudal portion of the prosthesis, which is in direct contact with the cranial vertebral endplate of C6. Each part of the prosthesis is angled and formed by two plates: a vertical plate located in the intervertebral space and a horizontal plate that is in contact with the ventral surface of the vertebral bodies. The two plates were angled to fit perfectly on each vertebral body. The prosthetic surface that is in contact with the cranial and caudal vertebral bodies is slightly convex, obeying the anatomy of the vertebrae. P1 and P2 interlock via concave-convex metal-to-metal surfaces with multi-directional movement capability. Each horizontal plate is fixed to the respective vertebral body by means of two monocortical locking screws.

The first-generation prosthesis (Figure 2) was designed according to the previously recorded mean vertebral dimensional shape (Table 1). P1 was angled at 71º and P2 at 110º to fit perfectly between each vertebra. The contact surface has a support bracket (rib) and can be fixed to the vertebral bodies with 2.7 mm locking screws. Also, in order to maintain physiological vertebral motion, a 3.7 mm ball-and-socket shape was developed. The prosthesis can move 12º in extension, 25º in lateral bending, and 18º in flexion (Figure 3).

After designing the first-generation prosthesis, it was noticed that dimensional and conformational adjustments were needed in order to allow a better fit of the prosthesis in the intervertebral disc space. Therefore, the second-generation prosthesis was developed (Figure 4),

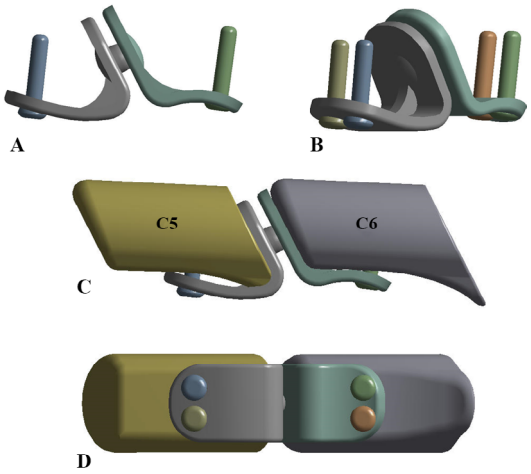

Figure 2 - Computerized schematic image of the Ansys Workbench® program representing the first generation of the PVTM Cervical Disc prosthesis inserted into the C5-C6 intervertebral space. (A) Lateral view of the prosthesis before insertion into the intervertebral space; note the ball-and-socket shape in order to maintain physiological vertebral motion; (B) Craniolateral view of the prosthesis before insertion into the intervertebral space; (C) Lateral view of the prosthesis after insertion into the intervertebral space, and (D) Ventral view of the prosthesis after insertion into the intervertebral space.

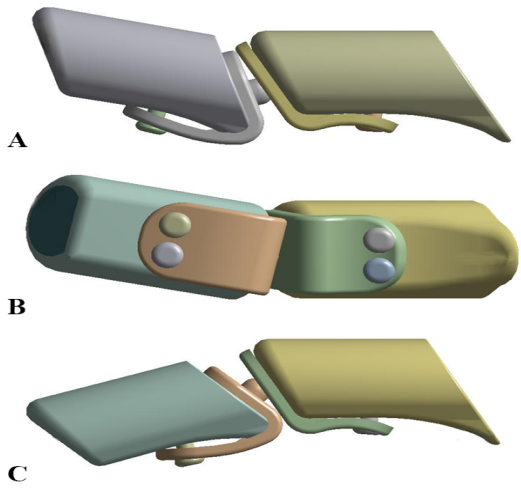

Figure 3 - Picture of the schematic rendered by Ansys Workbench® representing the degree of freedom of the prosthesis after its insertion into the C5-C6 intervertebral space in the different positions: extension (A), lateral (B), and ventral (C) bending.

whose adjustments were focused especially on the surfaces that came into direct contact with the cranial and caudal vertebral endplates, with the addition of a convex grooved surface to facilitate initial fixation and posterior osseointegration. In addition, the horizontal surfaces that receive the screws in both P1 and P2 were also adjusted by creating a narrow central groove between the holes to enable greater adjustment during possible molding to the ventral surfaces of the vertebral bodies. In this generation, the width of the prosthesis was also reduced since, during the implantation of the first-generation prototypes in the intervertebral spaces of the spines printed in PLA, it was noted that there was difficulty in implanting the prosthesis, as its width extended to the lateral limits of the intervertebral disc, the virtual location of the lateral fibrous annulus. As a result, the width of both parts of the prosthesis was reduced, respecting the presence of the lateral portions of the annulus fibrosus (Table 2).

After its 3D printing, the second-generation prosthesis proved effective in terms of fitting into the intervertebral space of C5-C6; although, when it was inserted into consecutive intervertebral spaces (C4-C5, C5-C6, and C6-C7) in the PLA-printed spines, the length of the horizontal plates of both P1 and P2 made it difficult to simultaneously implant the prosthesis. Due to this limitation, adjustments were made for the development of the third-generation prosthesis, with horizontal plates reduced by approximately half the length, which allowed the fitting of the prosthesis into consecutive intervertebral spaces. The convex cranial and concave caudal surfaces were also increased to enable articulation and movement between the independent parts of the prosthesis and a larger area of contact (Figures 5, and 6; Table 2).

Once the design and modifications were computationally finalized, the machined prosthesis (Figure 7) was inserted into the caudal cervical intervertebral spaces (C4-C5, C5-C6, and C6-C7) of the three cervical vertebral columns printed in PLA, fitting considerably well to the caudal cervical intervertebral spaces, with adequate fixation evaluated by means of digital manipulation (Figure 8).

DISCUSSION

Cervical arthroplasty has been performed with great success in humans for years, and several studies have shown that this procedure, when compared to discectomy and spinal fusion, has higher long-term clinical success rates, better functional outcome measurements, and results in less symptomatic adjacent segment degeneration and fewer secondary

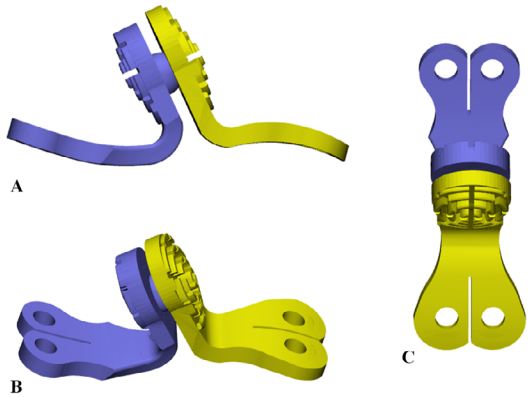

Figure 4 - Picture of the schematic rendered by Ansys Workbench® representing the second generation of the PVTM Cervical Disc prosthesis. (A) Lateral view; (B) Dorsolateral view, and (C) Ventral view. The modifications were made on the surfaces in contact with the vertebral endplate, which now exhibit roughness and entrails in order to allow greater primary fixation and subsequent osseointegration. The horizontal surfaces of both P1 and P2 were also adjusted with the creation of a central groove between the screw holes to allow greater adjustment if there is a need for molding in the vertebral body.

Table 2 - Dimensions (mm) of the main structural parts of the first, second, and third generations of the PVTM Cervical Disc prosthesis.

----------Prosthesis structure----------		----------Generations----------		
		First generation	Second generation	Third generation
P1	Vertical plate	17.0	14.0	14.0
	Horizontal plate	29.0	23.0	12.0
	Width of the vertical plate	17.0	11.4	11.4
P2	Vertical plate	15.0	14.0	14.0
	Horizontal plate	20.0	20.0	11.0
	Width of the vertical plate	17.0	11.4	11.4

surgeries (WANG et al., 2020). However, catastrophic wear may occur in unfavorable conditions, such as subsidence, migration, undersizing, adjacent levels that can become fused, and osteolysis (ROBERTS et al., 2018). Interbody subsidence is defined as the settling of an interbody into the adjacent vertebral bodies and is a known complication of their utilization throughout the spine (PINTER et al., 2021; XU et al., 2020). The complication rate represented especially by late prosthesis subsidence into the vertebral body, which varies from 14% (ADAMO et al., 2014b) to 92% (FALZONE et al., 2022), of the currently commercially available canine cervical prostheses stimulated the authors of the present study to develop a modified cervical disk prosthesis. This novel implant proposes improvements in the prosthesis-vertebra interface considering the vertebral endplates' morphometric-based geometry with additional screw fixation, aiming to implant stability and; consequently, reducing the post-surgical morbidity rates described in the literature.

Several factors are involved in cervical disc arthroplasty design (KORECKIJ et al., 2019). Despite the considerable range of arthroplasty designs, virtually all mechanical discs share identical goals: (1) to eliminate the painful degenerative/dysplastic elements of the joint; (2) to preserve or restore, to some extent, the natural range of spinal motion; and (3) to mitigate stresses on adjacent spinal segments, thereby theoretically limiting adjacent segment disease (ROBERTS et al., 2018). The main structural and morphological difference in the design of the PVTM Cervical Disc prosthesis in relation to the only prosthesis currently available in the veterinary market is the fact that each of its parts has specific extensions that fit the ventral parts of the vertebral bodies and allow the insertion of locked screws, and probably the better distribution of stress on the vertebral bodies, directing such stress to the screws. According to HAKATO et al. (2003), subsidence occurs when a structure with a high modulus of elasticity (cage, spacer) penetrates into another structure with a low modulus of elasticity (vertebral body), with the magnitude of subsidence being directly proportional to the load pressure and stress concentration at a single point. Meanwhile, according to LINK, et al., (2004), force distribution and subsidence into the vertebral body are possibly the leading biomechanical considerations for an artificial disc. The idea is to distribute the forces involved as evenly as possible over a large area. In addition to the possibility of allowing better stress distribution with likely less subsidence and loss of distraction, the screws probably allow for a better fixation power of the prosthesis, which can reduce loosening failures (PARISH et al., 2020). WIGFIELD et al. (2003) reported that the fixation of the articular components in the vertebral bodies with locked screws, in addition to allowing greater fixation in the prosthesis, preventing its migration, also distributes the tensions with more quality in several points of the prosthesis.

Regarding the stability of fixation of the PVTM Cervical Disc prosthesis, it is important to note that its screws are locked and monocortical. This allows the screws to be fixed to a plate, acting as an internal fixator (FERRIGNO et al., 2011). Thus, this locking plate-screw system enables angular stability and is not dependent on the frictional force between the plate and bone and, thereby, eliminates plate contouring and allows proper blood supply (BEISHUIZEN et al., 2021). Additionally, the use of monocortical screws prevents inadvertent penetration into the spinal canal. Theoretically, in non-locked systems, the stability is significantly higher when using bicortical screws (FERRIGNO et al., 2011). However, monocortical screw/PMMA constructs were biomechanically equivalent to bicortical pin

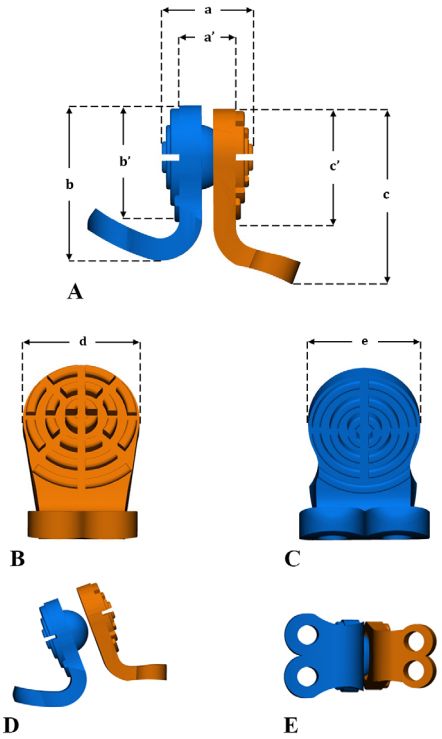

Figure 5 - Picture of the schematic rendered by Ansys Worksbench® representing the third generation of the PVTM Cervical Disc prosthesis showing its respective dimensions. (A) Lateral view (a= 10.98mm, a'= 6.81, b= 19mm, b'= 14mm, c=21.6mm, c'= 14.6mm). (B) Caudal view of P2 (d= 11.4mm) and (C) Cranial view of P1 (e= 11.4mm). (D) Lateral view with parts (P1 and P2) separately; (E) Ventral view. The modifications were made to the horizontal surfaces, with a reduction in length, in addition to an increase in the concave and convex articular surfaces.

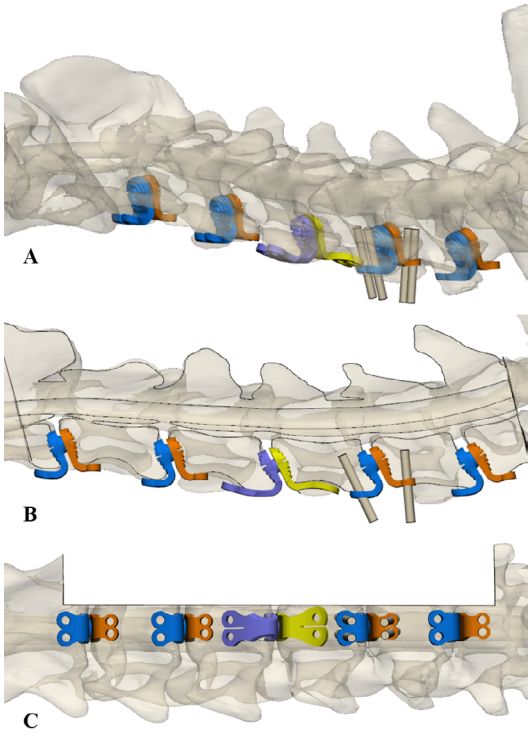

Figure 6 - Picture of the schematic rendered by Ansys Worksbench® representing the second (yellow and purple) and third (blue and orange) generation of the PVTM Cervical Disc prosthesis applied in a three-dimensional model of real computed tomography of a large-sized dog's cervical spine. (A) Craniolateral view; (B) Lateral view after sagittal sectioning, and (C) Ventral view. Note the versatility of application of the prosthesis in the intervertebral spaces from C2-C3 to C6-C7.

constructs in a study with cadaveric canine cervical spines (HETTLICH et al., 2013).

Keels, spikes, rails, ridges, and screws have all been used to achieve immediate stability of cervical prostheses, and each method presents advantages and disadvantages, but long-term stability usually occurs by osteointegration (CUNNINGHAM et al., 2010). With the PVTM Cervical Disc prosthesis, it will be possible to modify the material used in the contact point between the prosthesis and the endplates by coating the points with a bone growth stimulant. This will allow the bone in the vertebral body to integrate with the implant, thus preventing subsidence of the implant into the bone (ADAMO & FORTERRE, 2015).

The design of the PVTM Cervical Disc prosthesis using the Rhinoceros® and SolidWorks® programs and 3D printing was essential to allow the prosthesis to bypass bone surfaces in order to fit properly between the vertebral bodies. Upon the development of the prosthesis, the use of 3D printing and prototyping emerged as a significantly important tool to facilitate both the creation of a final model based on real three-dimensional vertebral spine models acquired through computed tomography and the development of the multiple preceding prototypes. All prosthesis generations were sequentially virtually tested in the intervertebral space, enabling sizing and fitting to be evaluated directly. The prosthesis design was refined to that of the final model by using the tests on all model generations to identify specific points for improvement and correction. 3D printing technology is becoming widely used in veterinary medicine

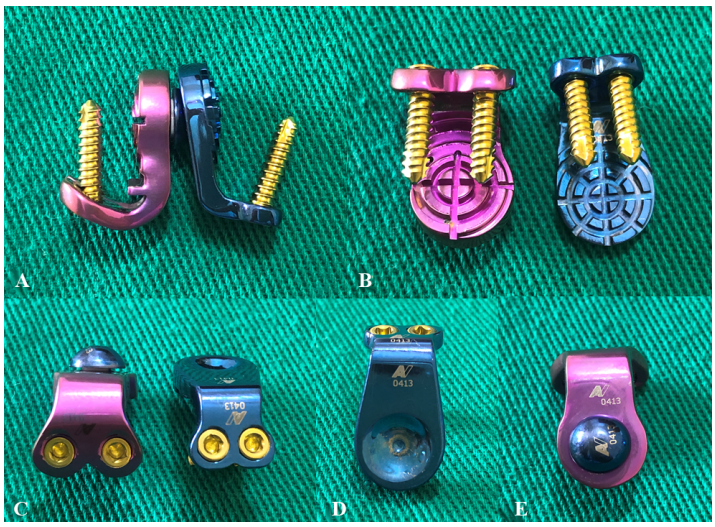

Figure 7 - Picture of the third generation of the PVTM Cervical Disc prosthesis machined in titanium. (A) Lateral view; (B) View of the faces that come into contact with the vertebral endplates of P1 and P2; (C) Dorsal view; (D) View of the cranial face of P2, and (E) View of the caudal face of P1.

because it eases surgical planning, enhances student teaching, and allows medical device prototyping (HESPEL et al., 2014).

On the basis of these 3D shapes of the cervical IVD space of dogs, it appears that the cervical IVD was a semimobile structure, with the central part having an unchanging IVD width, whereas the dorsal and ventral portions of the disc change significantly throughout motion (KNELL et al., 2019). This means that the center of vertebral rotation is located exactly at the midpoint of the intervertebral space, the same place where the center of rotation of the developed prosthesis is positioned, considering the dog's anatomy and respective acting forces.

Three materials are commonly used in arthroplasty: titanium alloys, stainless steel, and cobalt. In the present study, the prosthesis was machined in pure titanium. This biocompatible material has a modulus of elasticity that is more similar to bone and more MRI compatible (PHILLIPS & GARFIN, 2005; SEKHON et al., 2007); although, it offers less ductility than stainless steel (PHILLIPS & GARFIN, 2005). Pure titanium exhibits interesting aspects, such as good corrosion resistance and high biocompatibility, but its use is limited to applications where the mechanical requirements are not high (MELLO, 2004). Stainless steel is biocompatible and less expensive for manufacturing implants; however, it has a high modulus of elasticity, which may be preferable regarding the problem of prosthesis subsidence into the soft cancellous bone of the vertebral body (BENZEL, 2015). These implants can generate magnetic field interactions, heat, or artifacts in computed tomography or magnetic resonance imaging (MRI), making them inadequate for assessing healing and other parameters (LINK, et al., 2004; SEKHON & BALL, 2005; ADAMO et al., 2007; GJESTEBY et al., 2016).

The implant-bearing surface materials are another important factor to be considered in any arthroplasty device. The most commonly used material is the metal-on-polymer design because it uses ultra-high molecular weight, such as polyethylene or polyurethane, coating compounds that influence the extent and rapidity of bony in-growth (SEKHON & BALL, 2005; ROBERTS et al., 2018). In the present study, the PVTM Cervical Disc prosthesis was developed using a metal-on-metal contact surface as a substitute for the intervertebral disc; however, in some studies, there is evidence that debris release may occur due to the wear of metal-on-metal contact surfaces on prostheses, and may result in some inflammatory biological processes, including soft-tissue reactions, debris corrosion, osteolysis, and sinking of the prosthesis (ANDERSON & ROULEAU, 2004). In Total Hip Arthroplasty (THA),

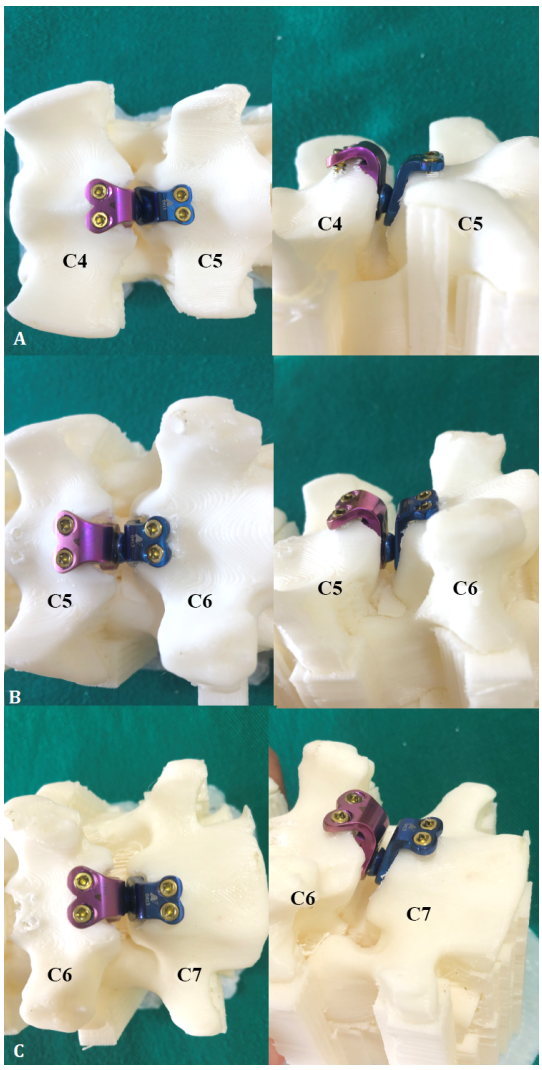

Figure 8 - Picture showing the ventral and lateral aspects of the third generation of the PVTM Cervical Disc prosthesis machined in titanium and implanted into the intervertebral spaces of (A) C4-C5; (B) C5-C6, and (C) C6-C7.

the classic combination of metal surfaces (femoral component) and ultra-high molecular weight polyethylene (acetabular component) continues to be the most widely used method. However, the most significant advantage of using metal-on-metal contact surfaces in total hip prostheses is the reduction in the wear rate when compared to metal-on-polyethylene surfaces; the volumetric wear rate of metal-on-metal joints is approximately 200 times lower than that of metal-on-polyethylene joints (SCHWARTSMANN et al., 2012). Since dogs have a shorter lifespan than humans, it is believed that, based on the aforementioned studies, the wear of the metallic surfaces of the PVTM will be unharmful. There is not enough research on metal-to-metal cervical prostheses in veterinary medicine. Thus, more studies are necessary to provide knowledge and understanding of the biomaterials and biomechanics recommended to ensure the development of safe and effective prostheses.

One limitation to be considered in the present study was not having performed computed tomography examination instead of orthogonal radiography to exclude anatomical abnormalities. Another limitation was the fact that biomechanical tests were not conducted. This was because the key objective of this preliminary study was to develop a prosthesis based on the anatomy and morphology of the intervertebral space. It is known that the cyclical biomechanical efforts to be considered in orthopedic implant projects are very important. These efforts generate cyclic fatigue in the implanted materials, which is one of the most critical flaws observed in prostheses, causing the total replacement of the intervertebral disc (CAMPELLO et al., 2009). Therefore, biomechanical analysis and longitudinal clinical research are required in order to determine the influences and consequences of stress on implants and adjacent structures, as well as the anatomical and soft-tissue interferences that vary from animal to animal (BARBIER et al., 1998).

CONCLUSION

The third-generation PVTM Cervical Disc prosthesis presented a satisfactory design and good fit in the intervertebral spaces between C4-C5, C5-C6, and C6-C7. *Ex vivo* and *in vivo* studies with the developed prosthesis models are necessary to evaluate the actual degree of distraction and mobility and to assess the long-term results in treated intervertebral spaces and adjacent functional vertebral dog units.

ACKNOWLEDGEMENTS

The authors thank the Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq), Brasil for granting a Master scholarship in Animal Science to the corresponding author and the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), Brasil – Finance code 001, for their financial support. Special thanks should be given to Henrique Eduardo Vilela Oliveira (Veterinary Resident at Londrina State University, Londrina-PR, Brazil) for his immense contribution in facilitating the collection and dissection of the cervical vertebral columns used in this study. We would like to thank the company Aldrivet, Campinas-SP, Brazil, for all the support and partnership in manufacturing the prosthesis for the development of the study.

DECLARATION OF CONFLICT OF INTEREST

The PVTM Cervical Disc implant was designed by Dr. Paulo Vinícius Tertuliano Marinho.

AUTHORS' CONTRIBUTIONS

All authors contributed equally to the conception and writing of the manuscript. All authors critically revised the manuscript and approved its final version.

BIOETHICS AND BIOSSECURITY COMMITTEE APPROVAL

This study was approved by the Londrina State University Ethics Committee on Animal Use (CEUA-UEL), under Protocol No. 155/2013, and followed the Brazilian Government principles for the utilization and care of vertebrate animals.

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