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Secondary cleft palate correction with 3D-printed thermoplastic polyurethane film – a case report

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ABSTRACT. Cleft palate is an oronasal communication that can affect the area comprehending the lips and the soft palate. Its clinical signs vary depending on the degree of the defect and the age of the animal, ranging from nasal secretion, coughing, sneezing, halitosis, respiratory difficulty, aspiration pneumonia, and loss of body condition. Its diagnosis is based on inspection of the oral cavity and imaging tests. Palatal defects must be surgically corrected as quickly as possible, using mucosal flaps, grafts, or implants. A desire to evolve alternative treatments for cleft palates drives the search for ways to manufacture customized pieces. 3D printing and biomaterials have enhanced in detail and applicability; combined with design tools and imaging exams, they allow for the making of precise implants and anatomical models for the planning and execution of surgical procedures. This report describes the case of a female, mixed-breed feline treated at a veterinary clinic; it was diagnosed with secondary cleft palate, had a history of falling, and underwent previous palatoplasties with recurrence. A surgical reintervention was performed to implant a 3D-printed TPU film to close its secondary cleft palate.

Keywords: cleft palate; film; thermoplastic polyurethane; 3D printing.

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Introduction

The palate is located dorsally on the roof of the oral cavity; it is divided into 3 parts: primary palate (lips, incisal alveolar crest, and premaxilla), secondary palate (palatine, maxillary and incisor bones) and soft palate, separating the nasal cavity from the oropharynx (Hette & Rahal, 2003; Silva, Magalhães, Oliveira, Coelho, & Saldanha, 2009; Bezerra et al., 2019).

The hard palate is formed by the palatine processes of the incisor bones, jaw, and palatine bone. It elongates caudally, without external demarcation with the soft palate, where there is an internal replacement of bone by an aponeurosis of connective tissue. Delimited by the palatine grooves on the sides, caudally by the greater palatine foramen, and rostrally by the palatal fissures, the hard palate is characterized by a stratified, keratinized or parakeratinized squamous epithelium, presenting a very firm union with the periosteum (Hette & Rahal, 2003; Silva et al., 2009; Bezerra et al., 2019).

The soft palate, in its turn, is located caudally to the hard palate and has a nonkeratinized stratified squamous epithelium. It is covered dorsally by a respiratory mucosa, which is reinforced ventrally with a resistant aponeurosis, and by the oral mucosa.

The blood supply to the hard and soft palates originates from the branches of the common carotid arteries. The greater palatine arteries emerge in the greater palatine foramen, at the level of the fourth premolar tooth, and continue rostrally through the respective groove, being responsible for the main blood supply to the hard palate, oral mucosa, periosteum, and alveolar processes. The lesser palatine arteries are smaller branches of the maxillary artery and vascularize the soft palate and the caudal portion of the hard palate; they are inserted close to the last premolar and located laterally and caudally to the greater palatine foramen (Hette & Rahal, 2003; Silva et al., 2009; Fossum, 2014; Bezerra et al., 2019).

Cleft palate is a pathological oronasal communication resulting from a change in the hard and/or soft palates, allowing the passage of food and liquids into the nasal cavity (Hette & Rahal, 2003; Silva, Aleixo, Sá, & Coelho, 2006; Silva et al., 2009). Depending on the structures compromised, a cleft palate can be classified as primary, if it occurs in the lip and alveoli, secondary, when it affects only the secondary palate, or both (primary and secondary palates) (Paraguassu, Joffily, Moreira, Freitas, & Malm, 2019; Silva et al., 2009).

The causes of palatal defects are congenital and acquired factors. Among congenital causes, the most reported are nutritional deficiency (riboflavin, folic acid, vitamin A deficiency, or excess vitamin D), fetal injuries at specific stages of development, hormonal changes, intoxication, hereditary factors, and emotional stress. In dogs, the most affected breeds are: Boston Terrier, Pekingese, Bulldog, Schnauzer, Beagle, Cocker Spaniel, and Dachshund. Among cats, the most affected breeds are: Abyssinian, Siamese and Persian (Hette & Rahal, 2003; Silva et al., 2009).

Acquired cleft palates do not present racial, sexual, or age predisposition. They can occur due to trauma, chronic infections, tooth extractions, radiotherapy, and neoplasms (Silva et al., 2009; Cook & Thomson, 2014).

The clinical signs of cleft palates vary according to the degree of the defect and the age of the animal. Mucous or mucopurulent nasal secretion, coughing, sneezing, halitosis, respiratory difficulty, aspiration pneumonia, and loss of body condition may occur (Silva et al., 2006; 2009; Sousa Filho, Sampaio, Evangelista, & Cunha, 2016).

Cleft palate is diagnosed first through inspection and visualization of the condition in the oral cavity. In patients with primary cleft palate, the diagnosis is simple due to its easy visibility, being evident soon after the animal is born (Silva et al., 2006; 2009).

In cases of secondary cleft palate, it is necessary to inspect the oral cavity during physical examination. Despite being a more common condition than primary cleft palate, secondary cleft palate is usually identified when the animal begins to show some clinical signs of the disease (Silva et al., 2006; 2009).

In different cases, it may be necessary to carry out additional examinations, such as x-rays, for diagnosis and visualization of the complete separation of the palatine bones, if necessary (Silva et al., 2009).

Palatal defects, regardless of whether they result from trauma, chronic infections, congenital changes, or neoplasms, must be surgically corrected as quickly as possible, given the risk of aspiration of food and liquids into the respiratory tract (Sousa Filho et al., 2016).

Cleft palate correction in baby animals must be done when they are old enough for safe anesthesia and their tissue has fully matured, which is possible at 45 days of age, when the animal can better tolerate anesthetic risks. Initially, the patient must be fed via a tube, having its nutritional status maintained until it is old enough for surgical procedure (Sousa Filho et al., 2016).

The choice of the most recommended surgical technique for each case is determined by the patient's condition, size of the lesion, and ease of access to the affected region. Most surgeries are based on mucosal flaps, grafts, polypropylene meshes, self-polymerizing acrylic resin prostheses, biomembranes, and pre-shaped titanium alloys, the most common techniques being mucosal flaps (Hette & Rahal, 2003; Silva et al., 2009; Cook & Thomson, 2014; Sousa Filho et al., 2016; Isaka, Viveiros, Carpovicz, Lautert, & Villanova Junior, 2020).

In all surgical techniques for correcting palatal defects, some principles must be followed carefully, such as preserving the palatal arteries, delicately manipulating the structures, and preventing tension on suture lines (Fossum, 2014).

For narrow cleft palates (1 to 2 mm wide) in the hard palate, bipedicled sliding flaps (Von Langenbeck technique) are used, with an incision at the margins of the cleft and bilateral release incisions along the dental arch, with the mucoperiosteal flaps being medially slid and sutured (Fossum, 2002; Sousa Filho et al. 2016).

For clefts wider than 2 mm, the overlapping flap technique can be used, always with careful attention to the vascularization of the region. This is an advantageous technique, as it does not position the flap suture line over the palatal defect and provides less tension on the suture line (Fossum, 2002).

Other techniques described are transposition, advancement and U-stitch, which consist of debriding the margins of the epithelium around the cleft, making incisions in the mucosa, and creating a rotational or advancement flap (Fossum, 2014).

The success of cleft palate reconstructive surgery depends, to a large extent, on the preservation of vascularization and the ability of the graft to resist mechanical stress induced by chewing, swallowing, and permanent traumatic movement of the tongue in the regional palate (Fossum, 2014).

Palatoplasties present several complications such as wound dehiscence (which may be associated with movement, tension, or tight sutures), hemorrhage, infections, retraction of the surgical wound, and palatal fistulas (an occurrence of 11 to 35% of cases). Despite well-described conventional surgical techniques, in cases of large bone defects and recurrences, the result is not very efficient (Kirschner et al., 2006; Steele & Seagle, 2006).

Postoperatively, the most common complication in this type of condition is wound dehiscence, which usually occurs between 3 and 7 days after surgery. To prevent this type of complication from happening, pasty foods for a minimum period of two weeks is recommended, and hard objects such as bones and chew toys must not be provided, preventing direct contact with the surgical wound (Fossum, 2014).

The use of an esophageal or gastric tube for approximately 14 days can facilitate the handling of the animal during feeding and administration of postoperative medications (Fossum, 2014).

It is recommended that the owner re-evaluate the animal within two weeks to check tissue healing. If dehiscence of the surgical wound is found, a new repair procedure must be scheduled in four to six weeks, in order to allow revascularization and recovery of tissues that are friable (Fossum, 2014).

Given this scenario, a desire to evolve and develop alternative treatments to reconstruct cleft palates has encouraged professionals and researchers to search for means of manufacturing customized and biocompatible parts (Rengier et al., 2010).

The use of 3D printing (3DP), applied in medicine since the end of the 1990s, in combination with computer design programs and specific imaging tests (computed tomography, magnetic resonance, and x-ray), allows the production of pieces, surgical planning biomodels, and customizable implants. These medical devices are characterized by different requirements and properties that require a good selection of the material to be used and a specific 3D printing technology for the case (Rengier et al., 2010; Haryńska et al., 2018).

Fused deposition modeling (FDM) is one of the methods used in 3DP; it works by depositing fused polymeric materials, layer upon layer, forming a complex three-dimensional structure, enabling the production of objects with different shapes, sizes, and diverse internal architectures (Jung et al., 2016; Kristiawan, Imaduddin, Ariawan, Ubaidillah, & Arifin, 2021).

A great effort has been made on the development of new 3D printed artificial matrices and scaffolds using both inert biomaterials and dynamic biomaterials (which interact with the organism). A three-dimensional model must provide a platform on which cells can adhere and proliferate. As main characteristics, it must be biocompatible, have mechanical stability, and be easy to produce, sterilize and manipulate at the surgery site (Haryńska et al., 2018).

Biomaterials are natural or synthetic materials used in contact with biological systems; their purpose is to repair or replace tissues, organs or functions of the organism, with the aim of improving the patient's quality of life (Sinhoreti, Vitti, & Correr-Sobrinho, 2013).

Biomaterials are classified in two different ways, depending on their origin and their response to the body. They can be of biological origin (autogenous – from the patient; allogenic – from a donor; or xenogeneic – from an animal), or synthetic origin, such as metals, ceramics, and polymers. Through induced response to the biological environment, a biomaterial can be bioinert, bioabsorbable, or bioactive (Sinhoreti et al., 2013).

Bioactive materials have the ability to interact intimately with biological tissue (bioadhesion), unlike bioinert and bioabsorbable ones, since the response induced by the latter occurs through the formation of a layer of fibrous tissue between the material and the biological tissue, thus making direct interaction between material and fabric impossible, which could lead to instabilities and failures (Sinhoreti et al., 2013).

Elastomeric materials, such as thermoplastic polyurethane (TPU), widely used in 3D printing, have a unique combination of biocompatibility, toughness, biostability, and surface functionality. These characteristics of TPU have led to its widespread use in implantable devices such as vascular grafts, pacemaker leads, bags, catheters, and artificial bladders and hearts (Davis & Mitchell, 2008; Vogels et al., 2015; Haryńska et al., 2018; Tao, Shao, Li, & Shi, 2019).

Thermoplastic polyurethane is a highly elastic linear polymer composed of soft segments, usually polyester or flexible polyethers, and hard segments, usually diisocyanates with a benzylic structure. As characteristics, TPU presents good biocompatibility and excellent mechanical properties, such as good resistance to abrasion, elasticity, traction, and compression (Pinchuk, 1995; Davis & Mitchell, 2008).

Polyurethane can be formed either by a high degree of crosslinking (bonding between linear molecules producing three-dimensional polymers), resulting in a thermosetting polymer, or by long linear chains, giving rise to a thermoplastic polymer (melts at high temperatures) (Sonnenschein, 2014).

Thermosetting polyurethanes are mainly known in the form of foams, which can be rigid or flexible and do not melt. Thermoplastic polyurethanes are those that can be cast and molded, and are generally found in products manufactured by injection molding, 3DP, and calendering (Sonnenschein, 2014).

Depending on its formulation, TPU may exhibit elastomeric behavior, having a great stretching capacity due to chain extenders in its synthesis (short-chain diols that are linked between isocyanates and polyols) (Pinchuk, 1995; Davis & Mitchell, 2008).

A study conducted by Vogels et al. (2015), comparing *in vivo* polypropylene (PP) suture with thermoplastic polyurethane suture, showed that TPU sutures have better biocompatibility compared to PP suture, with a reduction in the number of macrophages around the material after 21 days. The TPU thread, in addition to a lower inflammatory reaction, also showed a significantly lower number of apoptotic cells after the first week compared to PP.

Material and method

A feline patient was referred for specialized respiratory care (in October 2021, Manaus – Amazonas State); it was female, mixed-breed, neutered, approximately 2 years old, and weighed around 5 kg. The patient came with a history of falling and a diagnosis of secondary cleft palate. It had undergone three previous palatoplasties, in an unreported veterinary clinic, through the advancement flap technique, which was followed by successive postoperative complications and subsequent recurrences of the cleft palate (Figure 1).

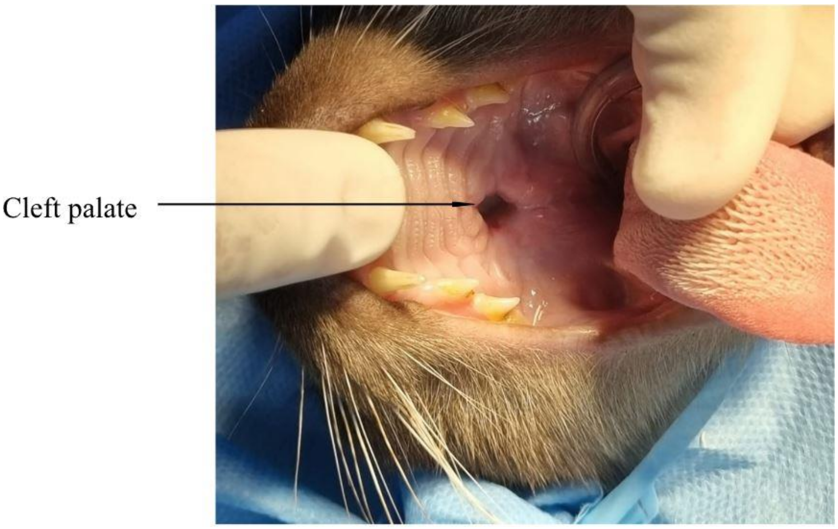

Figure 1. Feline patient with secondary cleft palate in the caudal region of the hard palate caused by fall. Source: the author, 2021.

Due to this situation, its owner and the veterinarians responsible for the case sought alternatives to improve the quality of life of the patient, which presented clinical signs and complications from the condition.

The animal was in good physical condition, with no notable changes in laboratory tests. Its physical examination revealed oronasal communication through a cleft palate located in the caudal region of the hard palate, with an approximate diameter of 8 mm, and the presence of oral and nasal mucopurulent secretion. There was a large amount of fibrotic tissue around the lesion, resulting from previous surgical interventions.

Its owner was proposed with, and then authorized, an innovative and experimental surgery for the implantation of a thermoplastic polyurethane film, customized and produced using a 3D printer, to occlude the cleft. The film was planned to be implanted below two bilateral bipedicled mucosal flaps and fixed with sutures to the palatal mucosa, with the aim of closing the communication between the oral and nasal cavities.

The film was produced with the thermoplastic polyurethane biomaterial, with 100% closed mesh, 0.7 mm thick, and with a size of 40 x 40 mm (Figure 2 and 3). The size of the film was determined based on the size of the palatal cleft, and could be cut and adjusted to the implantation site during surgery. The film was produced using 3D printing, through the Fused Deposition Material technique.

Preoperatively, to treat oral and nasal mucopurulent secretion, the use of amoxicillin with potassium clavulanate (20 mg kg^{-1}) was started, and went on for 10 days. To treat oral alterations, Stomorgyl and Omeprazole (1 mg kg^{-1}) were administered for 3 days.

As pre-anesthetic medication, methadone (0.25 mg kg^{-1}) and acepromazine (0.01 mg kg^{-1}) were administered intramuscularly (IM). During anesthetic induction, propofol (1.2 mg kg^{-1}) and ketamine (1 mg kg^{-1}) were administered intravenously (IV), and orotracheal intubation was performed. Anesthesia was maintained with isoflurane.

After fasting from solids and liquids, the animal was taken to surgery. The surgical procedure was carried out on November 30, 2021, one month after clinical evaluation with the owner's approval.

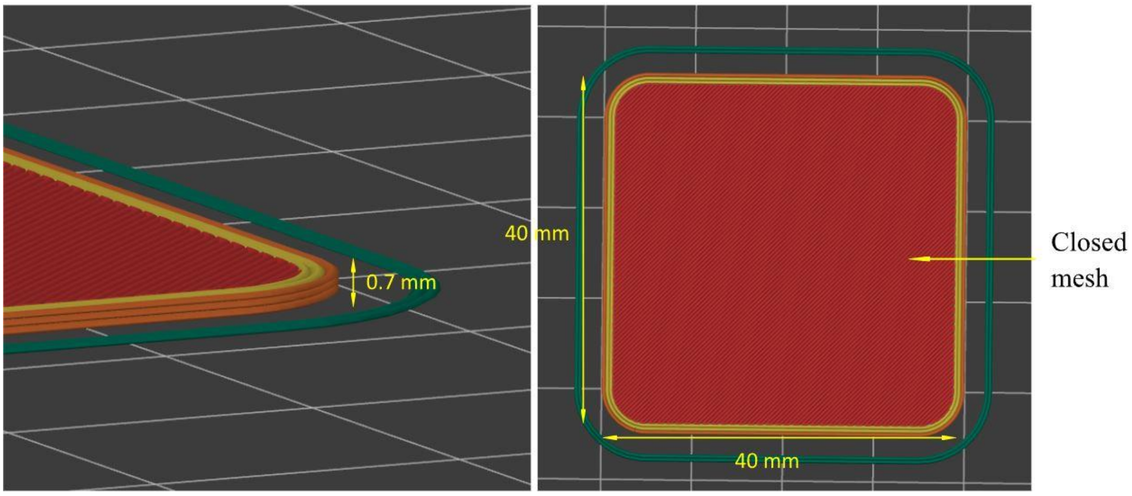

Figure 2. Image of the film in the 3D printing software with the apropriate device measurements. Source: the author, 2022.

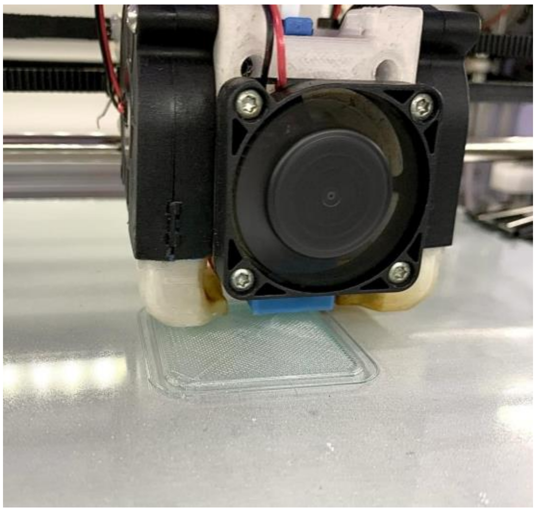

Figure 3. 3D printing of the film with the thermoplastic polyurethane biomaterial using the FDM technique. Source: the author, 2022.

The patient was placed in the supine position, and antisepsis of its oral cavity was performed with 0.2% nonalcoholic chlorhexidine gluconate. After the operative field was prepared, incisions were made in the palatal mucosa, as previously planned (Figure 4), with two bilateral incisions bordering the dental arch (from the first premolar to the last molar), and two incisions close to the palatal cleft.

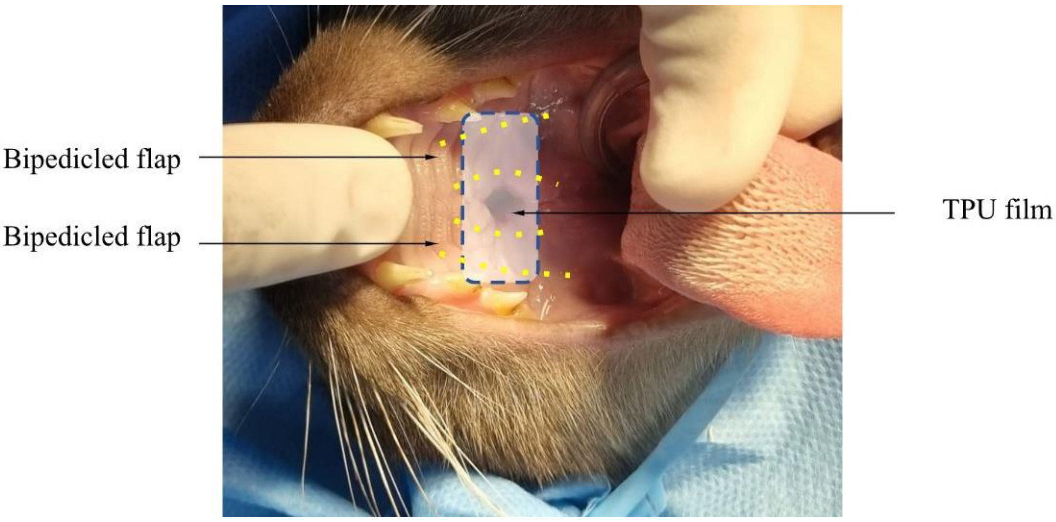

Figure 4. Image of the patient's surgical planning, which allowed determining the size of the TPU film (blue dotted line) and where the palatal mucosa incisions (yellow dotted lines) would be made for implantation of the film. Source: the author, 2021.

Bilateral dissection of the mucosal flaps was performed through elevation of the mucoperiosteal layer of the palatal bone so that the TPU film could be inserted below them (Figure 5). The palatal cleft was measured, and the mesh was cut to the appropriate size and inserted between the palatal mucosa and the bone.

The edges of the palatal mucosa were fixed to the thermoplastic polyurethane film, with simple interrupted sutures using 3-0 monofilament polydioxanone thread (Figure 6).

After the surgical procedure, the patient was discharged and prescribed ondansetron (0.3 mg kg^{-1} $oral^{-1}$) for 5 days, prednisolone (0.5 mg kg^{-1} $oral^{-1}$) for 5 days, and dipyrone (25 mg kg^{-1} $oral^{-1}$) for 7 days. Some recommendations, such as the use of an Elizabethan collar, pasty food, and toy restriction, were informed at the time of discharge.

Figure 5. Measurement (A) and implantation (B) of the TPU film in feline patient with cleft palate in the caudal region of the hard palate. Source: the author, 2021.

Figure 6. Final appearance of the lesion after implantation of the TPU film in the cleft palate in a feline. Source: the author, 2021.

The patient presented a good evolution of the case, without postoperative complications, with spontaneous oral feeding on the same day of the procedure. One month postoperatively, it returned for evaluation, when it was possible to observe the TPU film well adhered to the mucosa, without biofilm growth, color change, odor, inflammatory reaction, or presence of secretions, indicating that the TPU film successfully performed the cleft filling function (Figure 7). After 10 months of follow-up, no changes or complications were observed.

Results and discussion

According to Hette and Rahal (2003), cleft palate can be congenital or acquired. In the case in question, the patient arrived with a history of falling and a diagnosis of acquired secondary cleft palate.

Secondary cleft palates require inspection of the oral cavity during physical examination for diagnosis, being usually identified only when the animal begins to show some clinical signs of the disease (Silva et al., 2006; 2009). The case was diagnosed through its history and an inspection of the oral cavity, revealing the presence of a cleft palate in the caudal region of the hard palate (Figure 1), with no need for an x-ray to confirm the diagnosis. It was possible to observe mucopurulent oral and nasal secretion in the patient's physical examination, which are clinical signs mentioned by Fossum (2014).

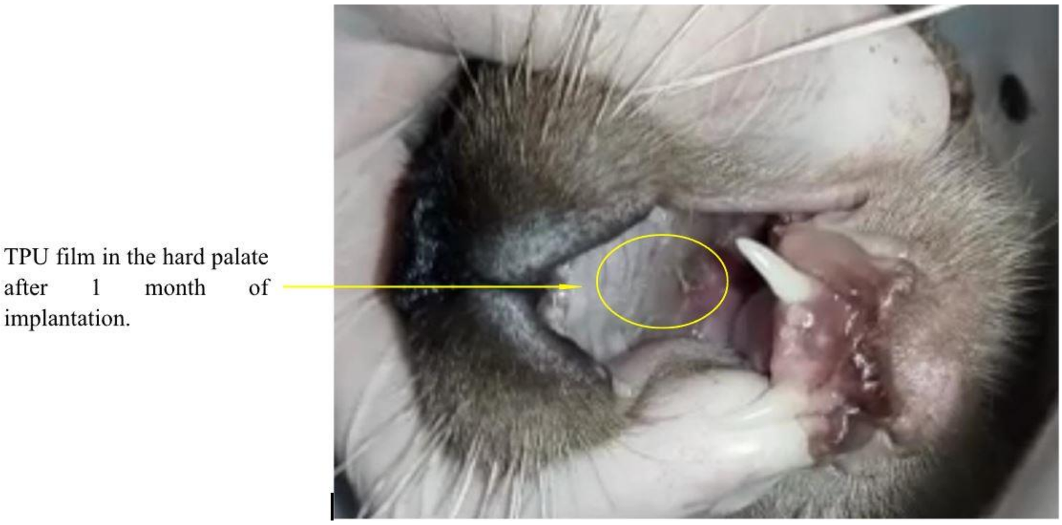

Figure 7. Appearance of the TPU film and the feline's hard palate after 1 month of procedure and implantation to obturate the lesion and reconstruct the palate. Source: the author, 2021.

According to Sousa Filho (2016), palatal defects, regardless of their causes, must be surgically corrected as quickly as possible, given the risk of aspiration of food and liquids into the respiratory tract. In the reported case, the patient had undergone three previous palatoplasties by means of the advancement flap technique, which resulted in postoperative wound dehiscence and recurrence of the cleft palate – common complications reported by Silva (2006; 2009) and Fossum (2014).

Due to postoperative complications and cleft recurrence, the choice was to perform a surgical reintervention with the implantation of a 3D-printed thermoplastic polyurethane film to close the cleft palate (Figure 4). The decision was based on the failure of conventional techniques, as the use of implants (mesh, films, or resins) has been suggested to correct the lesion (Silva et al., 2009; Isaka et al., 2020). Another significant point for the success of the case is the choice of a biomaterial, due to its characteristics (Haryńska et al., 2018).

According to Silva (2009), polypropylene (PP) mesh, a material widely used in routine veterinary surgery, is an alternative for recurrent cleft palates. However, Vogels et al. (2015) states in his research that TPU has better biocompatibility, good resistance to tension and traction, and a lower inflammatory reaction compared to PP. Due to the strengths presented, thermoplastic polyurethane was chosen as the material for producing the film to be used in this case.

The biomaterial of choice (TPU) has the main characteristics of being biocompatible, having good elasticity, a lower inflammatory reaction, traction resistance, total adhesion of the granulation tissue and, above all, low potential for bacterial adhesion, which allows the film to be used in contaminated lesions such as the oral cavity, the region of interest in the reported case. These characteristics could be observed in the patient in question, as it showed good implant acceptability, corroborating several authors who report that TPU is an excellent biomaterial for medical devices (Pinchuk, 1995; Davis & Mitchell, 2008; Sonnenschein, 2014).

The choice of the surgical technique was based on the sliding bipedicled flap technique, creating two flaps in the palatal mucosa, which overlapped the thermoplastic polyurethane film and were fixed with simple interrupted stitches (Figure 6) (Fossum, 2014).

For adequate coaptation of the device to the lesion site, the film was easily cut to fit the size of the cleft palate (Figure 5). Due to the film's FDM production method (Figure 3), the material is fused, keeping the printed layers together (Jung et al., 2016; Kristiawan et al., 2021), allowing the film to keep its shape when cut and not shred.

To fix the device to the mucosa, a 3-0 polydioxanone suture was used – a monofilament, absorbable and synthetic thread (Silva, 2009). It is recommended to use thin suture threads, # 3-0 to 5-0, with molded reverse cutting needle; in the case reported here, this recommendation was followed.

Antibiotic prophylaxis, such as amoxicillin with potassium clavulanate and metronidazole, carried out in the present case report, is in agreement with Fossum (2014), who mentions that using broad-spectrum antibiotics effective against anaerobic bacteria is more adequate in conditions in which the patient presents purulent secretions.

The patient, in the first 24 postoperative hours until complete tissue healing, ingested water and pasty food, as recommended by Fossum (2014) and Silva (2009), and hard toys and materials were not provided until the stitches were removed, preventing possible wound dehiscence.

Conclusion

This case report exemplifies the possibility for veterinarians to provide a better quality of life to patients with large and recurrent cleft palates through customizable and biocompatible devices. Based on the results of the reported case, it can be stated that the thermoplastic polyurethane film produced in a 3D printer is a viable option for cleft palate correction, being considered an easy-to-execute product, with an affordable price, adequate elasticity, and good durability. Despite the encouraging results, given the scarce literature found, a more in-depth experimental study is necessary in order to determine the stability of the implant and its safety.

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