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Orthotics and prosthetics by 3D-printing: Accelerating its fabrication flow

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ABSTRACT

Orthoses and socket prostheses are rarely used orthopaedic devices in veterinary medicine. Recently, more pet owners have sought these treatments for pets with orthopaedic conditions. However, veterinarians often lack substantial scientific evidence on device outcomes and may expect high costs, the main limiting factor, if human orthopaedic market prices are assumed. This discrepancy creates an imbalance between pet owners' expectations, veterinarians' recommendations, and actual patient benefits. To address economic constraints and enhance knowledge about these devices, this study used 3D technology—namely 3D scanning and printing via fused deposition modelling—to design, modify, and manufacture orthoses and socket prostheses for ten patients, including nine dogs and one calf. An equation was devised and applied to all printed devices to streamline the resizing process for sockets and orthoses. The 3D-printed devices were fitted to the patients, and their adaptation was assessed using three novel scales based on prior scientific literature in the small animal orthopaedic field. The orthoses were well-tolerated, with successful and straightforward adaptation. Although socket prostheses were tolerated, the dogs' adaptation was suboptimal, while the calf demonstrated excellent and immediate adaptation.

1. Introduction

Orthoses and socket prostheses are medical devices attached to the body to help patients with orthopaedic pathologies, which hinder the use of their extremities (Mich, 2014). Their effectiveness depends on both their design and owner diligence to restore function, improve patient acclimatisation, and maintain tissue integrity (Bertocci et al., 2017; Lee et al., 2021).

Orthoses assist the limb functionality by aligning, positioning, preventing, or correcting deformities; assisting weak muscles; or enhancing function (Mich, 2014). They can also be used as a complementary treatment after surgery, as owners may prefer an orthosis over surgery due to concerns such as surgery, cost, elder dogs, inability to provide postoperative care, other health issues of their dogs, and concerns regarding anaesthesia safety (Bertocci et al., 2017). Successful use of orthoses and braces have been described for isolated cases in various ligamentous pathologies, neuropathies, and pad wounds (Bertocci et al., 2017).

Prostheses substitute part or the entire limb after amputation, assisting with weight-bearing during standing and walking (Marcellin-Little, 2018). However, positive outcomes limited to patients where at least 30% of the thoracic limb and the tibia and fibula remain, respectively (Séguin, 2018). Several retrospective studies have reported better dog adaptation to these medical devices, as shorter stumps have inconsistent outcomes (Carr et al., 2018; Desrochers et al., 2014; Phillips et al., 2017; Wendland et al., 2019). Regardless, other factors must be considered as the resulting stump of a partial amputation such as angulation of the limb, patient's breed and affected limb (Carr et al., 2018; Phillips et al., 2017).

Research on device affordability has been only conducted in the USA, where pet owners spend $1000 to $6000 on veterinary orthoses and prostheses, with devices costing an average of $600 to $1000 (Lee et al., 2021; Mich, 2014). Despite the literature about the primary adaptation of animals to both medical devices from the owner's point of view (Lee et al., 2021), however, no results of the animal's adaptation have been reported from the veterinarian's point of view using an orthotic device adaptation scale.

Additive manufacturing (AM) offers a low-cost option for producing medical devices, particularly in human medicine and to a lesser extent in veterinary medicine (Wang et al., 2020). While 3D-printed orthoses and

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socket-prostheses for various animal species have been reported in recent literature, their postoperative outcomes have either not been reported (Antonana et al., 2019) or have been limited (de Freitas et al., 2011). However, commercial 3D-printed orthoses are available for human medicine from renowned orthopaedic companies (Ottobock, 2023). These technologies reduce fabrication cost (Hopkinson and Dicknes, 2003), might occur with orthoses and prostheses. Fused Deposition Modelling (FDM) technology, the most affordable branch of AM (Hopkinson and Dicknes, 2003), has not yet been described as an option for manufacturing orthoses or prostheses in veterinary medicine, but offers an acceptable finish.

3D scanning of the limb for capturing stump/limb morphology reduces the time to obtain a design of these orthotic devices on human medicine, particularly for experienced clinicians (Farhan et al., 2021). However, there are currently no studies on the use of 3D scanning in veterinary medicine for its clinical application.

The present work describes the fabrication process for animal orthoses and prostheses using 3D scanning and FDM technology and presents three adaptation scales for orthotic devices.

2. Materials and methods

2.1. Case selection

The study included 9 dogs and a calf, divided into two groups based on their need for socket-prosthesis or orthosis (Table 1). This study was approved by the Animal Care and Use Committee of the Veterinary Faculty of Madrid (n° 05/2019, Clinical Veterinary Hospital. University Complutense of Madrid, Spain).

Socket-prosthesis patients came to consulting room with a partial amputation at the proximal or distal antebrachium, distal tibia and distal metatarsus, and with different lengths of their residual limbs. Orthosis patients had pathologies that prevented the normal function of their affected limb.

2.2. 3D scanning and adjustment of dimensions

The 3D-scanning was conducted with a handheld surface scanner (3D SENSE Scan, 3D systems Inc., South Carolina, USA) in the examination room. The animals were placed in a comfortable position to allow them to remain still while a 360° scan was performed. The patients were either standing or lying down laterally.

3D Systems Sense software (version 2.0.321, 3D systems Inc., South Carolina, USA) was used to analyse the raw images and to obtain a STL file. The STL file was cropped and smoothed to obtain the three-dimensional stump/limb with Autodesk Meshmixer freeware (Autodesk, California, USA). Stumps/limbd were loaded on SolidWorks 2020® (SW) (SolidWorks Corp., Waltham, MA, United States) for designing their sockets. For all 3D stumps, CATIA V5 (Dassault Systèmes, Vélizy-Villacoublay, France) software was needed to obtain a file which would better handle the 3D model by SW.

To verify that the dimensions of the 3D-stump matched those of the animals, measurements of the stump were taken on the consultation room. Measurement on the animal depended on the affected limb and the future orthotic device. For socket prostheses, measurements were taken of the diameter of osseous reliefs of the upper joint of the affected limb (Fig. 1A), stump length, distance of the stump from the ground, and length of the contralateral limb from the upper joint to the ground. For orthoses, other measurements were considered like diameter of osseous reliefs of the joints of the affected limb (Fig. 1B and C), long bone length, two perpendicular diameters of the paw and two perpendicular diameters of each upper and lower limb section—dorsocaudal and mediolateral diameters (Fig. 1B,C and D)—of the affected joint. The same experienced veterinarian performed all measurements.

These measurements from 3D scanner directly related to the stump and the affected limb were taken on the 3D model in SW. These data were compared with the measurement of the real stump to obtain a ratio coefficient (Eq. (1)).

$$Coef = L_{real} / L_{scan3D} \tag{1}$$

Where Coef is the ratio coefficient, L_{real} is the measure taken at the animal and L_{scan3D} is the measurement taken from SW.

2.3. Prosthesis and orthosis design

Six socket prostheses and five orthoses were designed using SW. Six designed socket-prostheses were manufactured using FDM technology. Socket-prosthesis consisted of socket and limb parts. The socket part held the stump and aimed to be anchored firmly to the residual limb (Fig. 2A and D). The limb part extended from the distal end of the socket part to the ground, replacing the lost limb part (Fig. 2B). On the other hand, five orthoses were designed following the same procedure for socket prostheses (Fig. 2C).

For designing socket parts and orthoses, the scanned stump was taken as a reference. Also, the width of a soft infill between the stump/limb and the rigid part (W_{sf}) and a clearance between the stump and the infill (C). Using (Eq. (2)), the 3D-scanned stump/limb was scaled.

$$Scaling\ Factor = L_{real} + W_{sf}{*}2 + C{*}2 / L_{scan3D} \tag{2}$$

The scaled model was thickened until 2–3 mm, except for the bovine socket prosthesis which was increased to 6 mm (Fig. 2A). A specific stem for coupling the limb part was designed for all prostheses and one orthosis, except for the orthoses which were not necessary (Fig. 2D).

Other general considerations were taken for the design like an aperture for easing the introduction of the stump or limb in the socket and holes for the straps to attach the device to the residual limb (Fig. 2A and D). Finally, sockets designs were split for manufacturing with different materials.

The anatomic stand position was used as a reference for each species. Contralateral joint angles and length of the limb sections were considered for the design. In case of orthoses, part of a tyre was use as sole.

Table 1
Patient data: Species, breed, weight (kg), affected limb, type of device manufactured and pathology.

Patient	Species	Breed	Age	Weight (kg)	Limb	Device	Pathology
1	Canine	Warren hound	2 years	25	LTL	Prosthesis	Thoracic limb amputation at proximal third of the radius-ulna
2	Canine	Greyhound	6 years	20	PPLL	Prosthesis	Bilateral amputation at tarsus
3 (Kahla)	Canine	Pitbull terrier	3 years	25	RTL	Prosthesis	Thoracic limb amputation at proximal third of the radius-ulna
4	Bovine	Simmental	1 week - 2 moths	78–116	PPLL	Prosthesis	Bilateral amputation at phalanges
5 (Titan)	Canine	Spanish Mastiff	3 years	45	RTL	Prosthesis	Thoracic limb amputation at distal third of the radius-ulna
6	Canine	Miniature Pincher	4 years	11	LTL	Orthosis	Radial nerve paralysis
7	Canine	Mongrel	3 years	9	LPL	Orthosis	Limb shortening and unable of digit extension
8	Canine	Rottweiler	12 years	32,2	LPL	Orthosis	Tarsal instability and standing modification of digits
9	Canine	Mongrel	6 years	41	LTL	Orthosis	Pancarpal arthrodesis failure
10	Canine	Greyhound	8 years	19	RPL	Orthosis	Metatarsal-phalangeal luxation of four fingers

* LTL = left thoracic limb, RTL = right thoracic limb, RPL = right pelvic limb, LPL = left pelvic limb and PPLL = pelvic limbs.

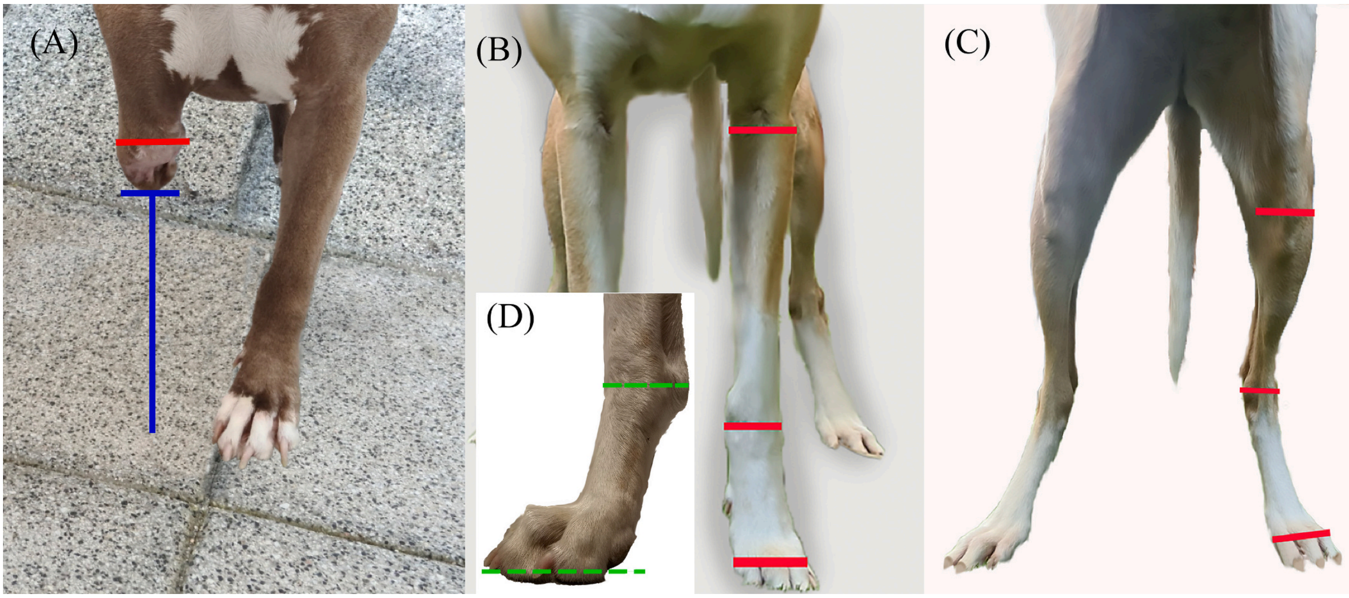

Fig. 1. Thoracic limbs of an amputee dog (A) and a dog before the 3D-scanning for an orthosis (B, C and D). Red lines indicate areas of osseous reliefs for measurements the mediolateral diameter. Green dotted lines indicate areas of osseous reliefs for measurements dorsocaudal diameter. Blue line points to the distance of the stump apex to the ground. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

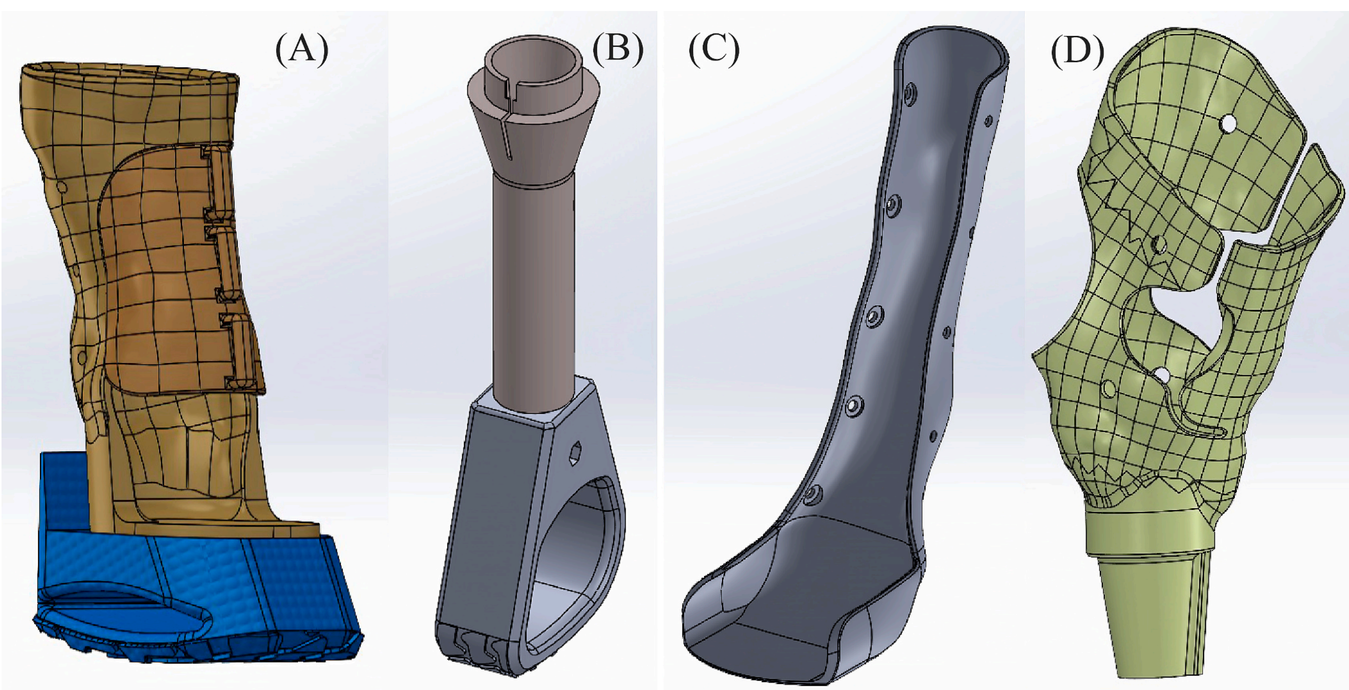

Fig. 2. A prototype of the socket prosthesis designed for the bovine (A), an example of a limb part design of a socket prosthesis (B), an orthosis design (C), and an example of a socket part design of a socket prosthesis (D).

2.4. Manufacturing socket prostheses and orthoses by 3D printing

Socket prostheses and orthoses were made mainly in rigid polyethylene terephthalate glycol modified (PETG, SmartMaterials, Jaén, Spain), and some models in flexible thermoplastic polyurethane (TPU, Filaflex A82, Recreus Industries, Valencia, Spain). Socket part for stumps were printed with both materials at the same time with a dual extruder printer (Fig. 3).

The direction of the main force that the 3D models would bear was considered to orient them on the printing bed. Devices were printed at a FDM printer with one or two extruders (PRi5 or PRi5 DEX, Abax Innovation Technologies, Madrid, Spain). Both printers have a build volume of 310 × 310 × 300 mm (x, y, and z). The printers have brass nozzles of 0.4 mm diameter. The nozzle of PRi5 was changed to Ø 0.8 mm for printing the calf's prostheses and the orthoses of large-breed canine patients (weighing above 30 kg). These printers reach a nozzle temperature of up to 260 °C and a bed temperature of up to 120 °C. Before printing, 3D virtual models were sliced with Simplify 3D software (Cincinnati, USA).

PETG parts of sockets were printed with 0.3 mm layer height, while

Fig. 3. An example of Patient 3's 3D-printed socket prosthesis with socket and limb parts assembled. PETG (black) and TPU (white) material can be seen at the socket part, with infill material within. Additionally, straps, ratchet buckles and the stump-limb part union can be seen.

TPU parts were printed with 0.2 mm layer height. After printing, models were cleaned of oozing defects and scaffolds. Straps and soft infill (Poron or/and PPT, OKM Química Ortopédica, Girona, Spain) were attached to the socket with 4-pronged tee nuts and screws or universal contact adhesive, respectively. A ratchet buckle-strap was used for fastening the socket to the limb.

The orthoses and limb sections of the socket prostheses were printed in a horizontal orientation with a layer height of 0.3 mm. Two model orientations - horizontal and vertical - were attempted during the printing process, considering the mean force direction during weight-bearing. For limb parts, quash balls were used either as carpal joint-like cushioning or as a substitute for the animal's pad. An 3D-printed A95 TPU cushioning, or squash balls were utilized as substitutes for the animal's pad. Polypropylene straps and their ratchet buckle were then assembled. Finally, soft infill (Poron Performance or 94, OKM Química Ortopédica, Girona, Spain) was added. For orthoses, rubber sole was glued on the printed part using universal contact adhesive and allowed it dry. One of the orthoses had a heel made of A82 TPU to compensate for a shortened limb of 4.5 cm in length.

The most relevant printing parameters of PETG were printing speed of 30–40 mm/s, nozzle temperature of 245–250 °C, bed temperature of 65 °C, and no cooling fan. Printing parameters of TPU were printing speed of 30 mm/s, nozzle temperature of 235 °C, bed temperature of 50 °C and no cooling fan.

2.5. Fitting exoprosthesis and orthosis

Fitting trials were conducted at the consulting room. Animals were helped to stand up if they required it and allowed to interact with the device and walk. Animals were not sedated. During the visit, the fitting of the device was evaluated using three original scales (Tables 2, 3 and 4) based on the scale for an online survey of Wendland et al. (Wendland et al., 2019).

Fitting of the 3D-device to the stump/limb (Table 2) was measured immediately after the orthotic device was placed on the patient. 'Downsized' referred to a smaller device compared to the stump/limb of the patient, which did not cover the limb completely. 'Loose-fitting' referred to a larger device than the patient's stump/limb, which covered the limb, but the osseous reliefs were not set and/or were too baggy. 'Movable' referred to a better-adjusted device than the other two, but the stump/limb was still moved with a slight rotation of the veterinarian's hand. 'Perfect fitting' referred to a preliminary tight-fitting of the device to the stump/limb. Each level of fitting was assigned a numeric value from 0 to 3, with 0 being 'downsized' and 3 being 'perfect' fitting.

Once the device was attached, the patient was allowed to stand up and to walk inside the consultation room. As the patient interacted with its surroundings, its behaviour was observed and recorded to obtain a general fitting assessment of the device (Table 3). Depending on how the animal adapted to the device, a score from 0 to 3 was assigned. A score of 0 meant the animal did not use the device at all, 1 indicated the animal rested the limb on the ground but did not bear weight or remained still without motion, 2 denoted the animal used the limb with the device most of the time but held it up for a few steps, and 3 signified the patient used the device almost in every step.

Owners were asked to take the device and monitor its use by their pets at home. They were contacted every one to two weeks for a follow-up revision (Table 4). During the revision, the clinician observed the animal with the device and asked the owner about its use. Evaluated tasks included running, getting up from lying position, using the device for stairs, holding toys or other objects/scratching ears and digging with the device.

2.6. Data analysis

Type of orthopaedic device, 'Real L (mm)', '3DSc L (mm)', 'Infill width (mm)', 'Clearance (mm)', 'L differences' and the three scales were analysed using principal component analysis (Snedecor and Cochran, 1980), extracting factors with an eigenvalue greater or equal to 1.0. All factors were analysed by multivariate analysis to show correlations between factors with a significance level $P \leq 0.05$ (Snedecor and Cochran, 1980).

Type of orthopaedic device and prosthesis/orthosis fitting scale for other task were analysed by Kruskal-Wallis, as the variances for both groups did not follow a normal distribution. For this analysis, results of patient 4 were not considered, as it was a different species. The null hypothesis (H_0) was 'both types of orthopedic device have no difference in the fitting scale'. The significance level was set at $P \leq 0.05$. When the *P*-value of the test was significant comparison of medians was made by Fisher's Least Significant Difference (LSD) multiple range test (Snedecor and Cochran, 1980).

All analyses were made using the STATGRAPHICS program (XVII Centurion. Ver. 17.2.00, StatPoint, Inc., Herndon, VA, USA).

Table 2
Scale to evaluate the fitting of the manufactured device to the patient's limb/stump.

Fitting of the 3D-device to the stump/limb
0. Downsized
1. Loose-fitting
2. Movable
3. Perfect fitting

Table 3
Scale to evaluate the fitting of the manufactured device once the patient wore it in the consultation room.

Prosthesis/orthosis General Fitting scale (adaptation of Wendland et al.(Wendland et al., 2019))
0. The patient never uses the prosthesis
1. The patient uses the prosthesis for some steps but most of the time he/she holds up the prosthetic limb
2. The patient uses the prosthesis most of the time, but holds the prosthetic limb up for some steps
3. The patient uses the prosthesis almost every step

Table 4
Scale to evaluate the fitting of the manufactured device once the patient wore it after 1–2 weeks.

Prosthesis/orthosis Fitting scale for other tasks (multiple answers) (Wendland et al., 2019)
a. Running (places prosthesis and uses it as part of gait pattern). Yes = 1, no = 0
b. Getting up from a laying position (using prosthesis for support). Yes = 1, no = 0
c. Ascending or descending stairs (uses and occasionally leads with prosthesis). Yes = 1, no = 0
d. Holding toys or bones with prosthesis/scratching its ears. Yes = 1, no = 0
e. Digging with the prosthesis/orthosis. Yes = 1, no = 0

3. Results

3.1. Prosthesis and orthosis design

Six socket prostheses and five orthoses were designed using SW. Model scalation varied depending on soft-infill width and the desired clearance to obtain an acceptable fitting on the patient. Table 5 shows patients with different measures for each version of their device. Device version depended on modifications of measure values. For each version, the diameter of the limb measured on the first day of the visit is shown at 'Real L' column. The '3DSc L' column contains the same measurement for the 3D-scanned model. The 'Infill width' column represents the thickness of the infill material between the printed device and the limb. 'Clearance' refers to the value used for the real-3D coefficient equation (Eq. (1)), and 'Scaling Factor' shows the real-3D coefficient obtained by Eq. (1).

Table 5
Different versions of patients' devices with their measurement on the animal and on the 3D-model with other factors to obtain the Scaling Factor for each patient.

Patient	Device Version	Real L (mm)	3DSc L (mm)	Infill width (mm)	Clearance (mm)	Scaling Factor
1	-V1	36,15	42,78	5,00	0,50	0,85
1	-V2	36,15	42,78	5,00	0,25	0,85
1	-V3	36,15	42,78	5,00	0,00	0,85
2	-V1	34,05	34,94	5,00	0,50	0,97
3	-V1	52,85	56,44	5,00	0,50	0,94
3	-V2	52,85	56,44	5,00	0,25	0,94
3	V3	52,85	56,44	5,00	0,00	0,94
4	L-V1	68,00	104,06	5,00	0,50	0,65
4	L-V2	68,00	104,06	9,00	0,00	0,65
4	R-V1	68,00	104,06	5,00	0,50	0,65
4	R-V2	68,00	104,06	9,00	0,00	0,65
5	-V1	47,75	51,70	5,00	0,25	0,92
6	-V1	25,41	26,95	4,00	2,00	0,94
7	-V1	19,32	23,11	4,00	2,00	0,84
8	-V1	35,80	764,41	4,00	2,00	0,0625
8	-V2	35,80	764,41	4,00	0,00	0,0573
9	-V1	51,80	58,34	4,00	2,00	0,89
10	-V1	31,99	33,62	4,00	0,50	0,95
10	-V2	31,99	33,62	4,00	0,00	0,95

* Real L is the taken measurement of patient's osseous relief. 3DEsc L is the measure of the before-mentioned relief, but on the 3D-scanned model. Clearance is the tolerance margin of the whole device to allow a better device placement.

As seen in Table 5, the scanning files were oversized comparing with animal's measurements, except for one orthosis. 3D-scanned models were 10% larger than the animal's limb, except for the orthosis of patient 8, where its enlargement was 10-fold more. For patient 8, the 'Scaling Factor' was shown with more decimals than other patients to capture a difference on its design.

Original scanning files were cleaned and repaired to obtain a proper 3D stump/limb to use with the CAD software used in this study. Holes, anchoring, openings, and part separation were precisely designed with the CAD software. Part separation was planned for double material use during 3D printing for socket prostheses.

3.2. Manufacturing socket prostheses and orthoses by 3D printer

Orthoses printing procedure lasted approximately 1–4 h. Orthoses weight ranged between 42 and 306 g of PETG depending on the patient's size (Table 6). Vertical and horizontal orientation models were tried on patients, with horizontally oriented models being preferred because vertical models failed earlier than horizontal ones on patients. Vertical models failed at their layer union. These medical devices should withstand two main stresses: compression stresses along the largest axis of the model and flexural stress during the stance phase of the gait.

3D-sockets of exoprostheses were printed in 12–27 h depending on the stump size. Stump socket weight ranged between 100 and 940 g of material, related to the patient's size (Table 6). Vertical or crosswise orientations were chosen based on the principal tightening effort and fitting the model into the printing volume.

Limb parts were printed in 6–36 h depending on the patient's size. The weight of the limb parts ranged between 125 and 546 g of material, related to the patient's size (Table 6). These parts were printed in a horizontal orientation. Support removal was made without problems for any manufactured device.

3.3. Fitting exoprosthesis and orthosis

Table 7 shows the fitting assessment for protheses and orthoses using the three scales and a total sum from values of each scale. Prosthesis patients limited their usage of the device to the consultation room, except for the ruminant patient.

The limb part of the socket prostheses required a reduction of 1–5 cm, for an easier prosthesis adaptation on the visiting day. A sensation of 'instability' was observed in the patient when a spherical sole was chosen. That sensation seemed to reduce when a curved sole was designed (Fig. 4).

Patient 1 used three different versions of its prosthesis because corrections over the clearance parameter were made to improve the fitting. Initially, the first version could not be assessed by two of the three scales because the model was too loose. Decreasing the clearance made the second version capable of being evaluated by all three scales. Patient 1

Table 6
Weight of printed orthopaedic devices for each patient and their respective printing time.

Patient	Type of orthopaedic device	Weight of the Orthopaedic device (g)	Printing time (h)
1	Prosthesis	122.62 + 124.67	12 + 6
2	Prosthesis	103.59	15
3	Prosthesis	122.93 + 143.94	9 + 6
4	Prosthesis	932.10 + 393.16	12 + 36
5	Prosthesis	379.78 + 545.88	27 + 13
6	Orthosis	42.76	2
7	Orthosis	62.18	4
8	Orthosis	306.19	4
9	Orthosis	303.12	4
10	Orthosis	141.08	2

Table 7
Patients 'scores obtained with the three scales, and their total summatory.

Patient	Fitting of the 3D-device scale	General Fitting scale	Other Task Scale	Total
1-V1	2	1	1	4
1-V2	3	2	1	6
1-V3	0	0	0	0
2	1	0	0	0
3-V1	2	1	0	3
3-V2	3	1	1	5
3-V3	0	0	0	0
4L-V1	2	3	2	7
4L-V2	3	3	3	9
4R-V1	2	3	3	8
4R-V2	3	3	3	9
5	2	1	2	5
6	3	2	5	10
7	2	1	1	4
8-V1	1	0	0	1
8-V2	2	3	2	7
9	3	1	3	7
10-V1	1	1	1	3
10-V2	2	2	3	7

was able to walk on the visiting day without the device falling off after a few minutes of slight adaptation (Fig. 4A). The third version was too small to be stable for walking.

Canine patients gradually reduced their lameness and began to use their affected limb when the prosthesis was attached, progressing from no weight-bearing to minimal weight-bearing. The socket and preferred soft-infill were adjusted during two to three visits. However, patients' owners did not use the device at home, observing their animals' reluctance to walk with it or its tendency to fall off after galloping. They felt unable to train their animals with the device and none of the amputees with socket prosthesis followed a rehabilitation program for adaptation to the prosthesis.

The calf (patient 4) used the prostheses during several weeks until they broke because of patient's weight. During this time, the bovine could reduce the appearance of wounds on the stumps and allowed existing wounds to heal. The first versions of prostheses were movable, but by including a bandage with two layers of cotton and one of cohesive bandage, they remained fixed. As the patient used them, the stump slipped slightly downwards; however, the bovine walked, and the models did not fall off (Fig. 4C). After a month of usage, the devices caused two pressure ulcers in the areas of the distal tee nuts. The two last versions were fabricated with double infill and no looseness was shown, resulting in better attachment. However, the two last prosthesis versions produced small pressure ulcers on osseous reliefs on tarsi (or hocks).

Three of four orthoses patients continue to use the devices at home without problems. All patients used the affected limb with an evident lameness but reduced their lameness from no weight-bearing to minimal. Up to three trials with a scale-modified orthosis in each trial were needed to obtain the final orthosis.

Patient 6 was the first to recieve a 3D-printed orthosis and for application of Eq. (1) (Fig. 5A). Other 3D-printed orthoses were used but a properly fitting was not achieved until the equation was applied. Patient 7's follow-up was limited due to living in a different city, but the orthosis fit similarly to preliminary orthoses of other patients (Fig. 5B). However, the owner of patient 7 observed chafing on the calcaneus and was reluctant to put the orthosis again. Patient 9 was hesitant to use the device in the consultation room but gradually became weight-bearing at home (Fig. 5D). Patient 10 had similar adaptation as patient 9, but version 2 of the device achieved better limb adjustment (Fig. 5E). Patient 8 had excellent outcomes after specifying an accurate 'Scaling Factor' on the second trial (Fig. 5D).

Principal component analysis (PCA) confirmed that all factors were distributed in three groups. The first three components accounted for 34.52%, 61.70% and 82.20% of the total variation, respectively (Fig. 6). All scales were correlated between them, and the type of device was correlated with clearance, infill width and 'Real L' as could be observed on Fig. 6 and on the multivariate analysis (Supplementary file_Correlations). Kruskal-Wallis test and multiple range test showed statistically differences between both types of orthopaedic devices for Prosthesis/orthosis Fitting scale for other tasks scale ($P = 0.047$).

4. Discussion

The fabrication process of animal orthoses and prostheses using 3D scanning and FDM technology had been described. The results showed better adaptation for orthoses compared to prostheses in canine patients, as demonstrated by the Kruskal-Wallis test. There are multiple explanations for these differences.

Fig. 4. All 3D-printed socket prostheses: (A) thoracic prosthesis of Patient 1, (B) thoracic prosthesis of Patient 3, (C) pelvic prostheses of Patient 4, and (D) thoracic prosthesis of Patient 5.

Fig. 5. All 3D-printed orthoses: (A) thoracic orthosis of Patient 6, (B) pelvic orthosis of Patient 7, (C) pelvic orthosis of Patient 8, (D) thoracic orthosis of Patient 9, and (E) pelvic orthosis of Patient 10.

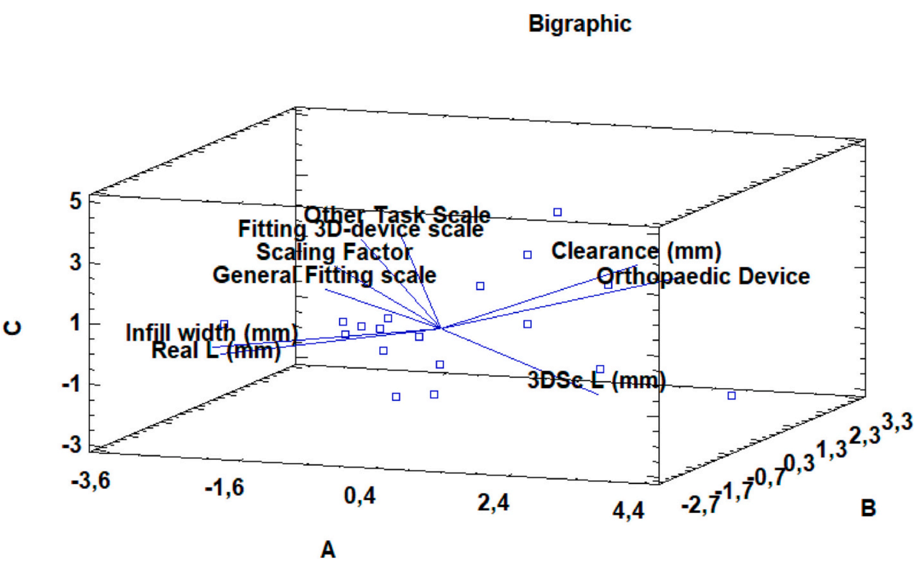

Fig. 6. Principal component analysis for Type of Orthopaedic Device, Real L (mm), 3DSc L (mm), Infill width (mm), Clearance (mm), L differences and the three scales. The first three components accounted for 34.52% (A), 61.70% (B), and 82.20% (C) of the total variation, respectively. "Orthopaedic Device" denotes the type of orthopaedic device, "Real L (mm)" refers to the diameter measured on the animal, "3DSc L (mm)" denotes the diameter measured on the 3D-model. "Infill width (mm)" refers to the width of the soft infill. "Clearance (mm)" denotes the area between the stump and the infill. 'Scaling Factor' refers to the one used to resize the 3D-scanned stump. 'Fitting 3D-device scale', 'General Fitting scale' and 'Other task scale' are the three scales.

All canine patients had stumps shorter than the recommended 30% of limb length (Marcellin-Little, 2018) and were close to the elbow joint. All canine socket prostheses were for thoracic limbs, which have been shown to have lower adaptation than pelvic limbs (Carr et al., 2018; Phillips et al., 2017). Furthermore, the small surface area and conical shape of these stumps made attachment of the socket difficult and a circumferential strapping around the patient's thorax should have been considered. In contrast, orthoses showed better adaptation after two weeks of use than canine prostheses, possibly due to more attachment area for the devices than the amputees. Additionally, small displacements of the orthoses on the limb would have affected less than those of the canine prostheses. Because of these differences in attachment, biomechanical analysis of these devices could improve their design and efficiency, particularly for socket prostheses (Wang et al., 2020).

The chosen infill material for both orthoses and socket prostheses may have influenced the fit, and alternatives with more grip or the use of a liner should be considered (Carr et al., 2018). Canine patients of socket prosthesis only used them on the visiting day, and it was suggested that a device-specific rehabilitation programme may improve their usage (Carr et al., 2018; Wendland et al., 2019). However, others have shown that it might not be necessary (Phillips et al., 2017). Regarding bovine patient, the observed better fitting results might be attributed to its longer stump length and higher pain threshold compared to canines (Desrochers et al., 2014; Kavaliers, 1988; Phillips et al., 2017).

The limb part of the socket prostheses generally appeared longer for the patient than the dimension obtained on the first visit. These dimensional errors could be attributed to fact that measures were taken in a standing position and socket-ground distance variations were not considered initially (Galindo-Zamora et al., 2016).

3D manufacturing still required at least two trials before obtaining a well-fitting device. However, the authors observed a reduction in the number of trials as they gained experience in 3D scanning, 3D manufacturing and determining the preferred tolerance value. As a previous study noted, even experienced veterinary orthopaedics require more than two adjustments to obtain the perfect medical device in the first few months (Mich, 2014). Wang et al. observed the absence of a 3D manufacturing procedure limits the expansion of this technology (Wang et al., 2020). Eq. (1) was described to objectify and accelerate the resizing of the 3D-scanned models. The usefulness of this equation was demonstrated in the results of the fitting scale, the statistical results and in the 'Scaling Factor', especially in patient 8.

A proper election of printing orientation for fabricating functional objects was demonstrated for withstanding the principal strains during use, as forces are better supported along the main filament rod direction rather than by layer unions in 3D-printed objects (Mendaza-DeCal et al., 2021).

A larger nozzle diameter (0.8 mm) was used to improve the mechanical strength of 3D-printed bovine prostheses and larger orthoses, thickness reduction, making them ligther and reduce printing time. Studies have shown that increasing the printed filament diameter significantly improves the mechanical strength of FDM-printed models as it covers a larger area with bulk filament, reducing the number of printed layers (Czyżewski et al., 2022; Solomon et al., 2021), resulting in cost savings on manufacturing (Czyżewski et al., 2022; Le et al., 2022). This is important because FDM-printed models are weakened on the layer unions. According to Lim et al., a 0.8 mm nozzle diameter provides the best mechanical strength compared to narrower or wider ones for 3D printing a human prosthetic socket (Lim et al., 2022).

5. Conclusion

Orthoses and socket prostheses devices were fabricated with FDM technology with better results on orthoses. The scaling equation improved the fit of the devices, and orthoses patients were able to use them in their daily lives without issues. Further research is required to optimise material selection for socket prostheses manufacturing.

Ethical approval

Not applicable.

Authorship

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

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Declaration of Competing Interest

None of the authors has any financial or personal relationships that could inappropriately influence or bias the content of the paper. The Regional Government of Madrid has not involved in any decision about the development of this study.

Data availability

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

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Appendix A. Supplementary data

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