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Chapter 7

Prosthesis for Flow Control in the Esophagus as a New Technique for the Treatment of Obesity

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Additional information is available at the end of the chapter

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1. Introduction

Obesity is becoming increasingly common, with at least 400 million obese adults worldwide and the World Health Organization (WHO) projecting that this statistic will reach 700 million in another five years [1]. The body, which is altered by excessive weight, has its biological process modified. This results in several diseases. Different diseases such as heart disease and strokes, high blood pressure, type 2 diabetes, cancer, asthma, sleep apnea, osteoarthritis are all related to obesity [2].

According to a recent survey by the Brazilian Society of Endocrinology and Metabolism (SBEM) obesity in Brazil has increased, on average, 240% over the past 20 years. Today, methods of treatment for obesity are: a) diets; b) non-pharmacological treatments; c) pharmacological treatments; d) surgeries. All the aforementioned methods have the same principle –an energy deficit is necessary to cause weight loss.

Among the techniques available for treating obesity, surgical techniques are more efficient. It is known that surgical methods offer effective results, maintaining 50% weight loss for 10 years. Two types of surgical treatments are practiced: a reduction of the stomach volume to diminish food ingestion and the use of a stomach-intestine bypass to produce practically no absorption of nutrients [3].

In type 2 diabetes mellitus (T2DM), treatment with pharmacologic therapies in order to control blood sugar only slows progression of the disease. Bariatric surgery has been implicated in the complete resolution of type 2 diabetes mellitus in several clinical studies [4].

Multidisciplinary studies for treating obesity and type 2 diabetes mellitus have been developed. Doctors and Engineers are working together to deal with the problem and find

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solutions. This is being carried out especially with biomaterials and in biomedical engineering where new devices are being developed.

GI Dynamics® is developing a novel endoscopic treatment for obesity and T2DM. The EndoBarrier™ gastrointestinal liner is a removable implant that resides in the proximal intestine [3]. Toga, from Satiety, Inc., still in its trial stages, inserts flexible stapling devices through the mouth and into the stomach, and then uses suction to gather stomach tissue and staple it together, creating a small stomach pouch near the esophageal junction and thereby increasing satiety [1]. Furthermore, the methods used neuroregulation activation and gastric implants for activation of the vagus nerve as a way to control hunger [1,4].Thus, it is worth noting that there are difficulties in proposing an efficient obesity treatment. In other words, the control and cure of the multiple causes of obesity associated with eating habits is a difficult problem.

In this study, we designed an esophageal flow control module (CFE) made from a biosynthetic material based on natural latex (extracted from the rubber tree *Hevea brasiliens*). The intended purpose of the CFE is to help to control the speed and the volume of food ingested, and, as a result, to help in treatments to reduce weight.

The CFE proposed is classified as a restrictive surgical procedure. It is inserted into the esophagus (3 cm after the passage of the upper sphincter) and filled with gas. Experimental animal research has shown satisfactory results. The device has the mechanical characteristics necessary for use inside the esophagus. Furthermore, the animals did not have problems with gastric and behavioral changes, nutrition, blood disorders or irritation because of the CFE. Therefore, this unprecedented technique, which can solve the obesity problem, allows a decreased food intake by decreasing the flow through the esophagus.

Therefore, even though the device needs to be tested on humans, the efficiency of this procedure has been ratified, especially given the success of the evaluation in dogs. Weight loss was confirmed (and validated) between two groups of animals tested. One group had the module and the other did not (however both maintained the same dietary and environmental routine). A biomaterial, latex, is used in its development, given its prominence (in Brazil). There are non-gummy, rubber, hydrocarbon particles in the composition of natural latex. The particles are suspended in an aqueous solution phase in which there is on average 36% hydrocarbons, 1,4% proteins, 1,6% carbohydrates, 1% neutral lipids, 0,6% glycolipids plus phospholipids, 0,5% inorganic components, 58,5% water and 0,4% of other substances. For this reason, *Hevea brasiliensis* latex is a complex cytoplasmic system in which the rubber particles and the non-rubbery particles (also called non-gummy) are dispersed in an aqueous cytosolic phase. It is a national low-cost product, which is also easy to handle. Latex, plus other substances, was initially used as a material that induces healing in damaged esophageal walls. Results showed that a natural latex biomembrane with polylysine has biochemical characteristics that make it capable of interfering in the process of tissue repair thus promoting the rapid and regular formation of new tissue. It is also easy to handle, dispensing with complex techniques for manufacturing and use [5, 6, 7]. Based on these data, other studies utilizing latex have been done, such as using latex for myringoplasty in humans [8] and applying latex biomembranes

for treating ischemic leg ulcers. Here, the goal is for the biomembrane to act as an inducing agent for healing tissues [9]. In [10], this membrane was employed in recurrent umbilical hernias and its effectiveness was established in twelve dairy cows.

In orthopaedic research aimed at more effective bone regeneration, latex was efficient in repairing tibial fractures in a rabbit, demonstrating great potential for this kind of application. In skull fractures in rats, the results were similar and the researchers believe that new investigations indicate its use in osteoporosis, odontology and facial bone reconstruction [11]. In [12], they developed a new microperforated vascular prosthesis model, made of tissue covered with a compound derived from rubber tree natural latex (*Heveabrasiliensis*) and used an expanded a polytetrafluoroethylene prosthesis as control in the contralateral pelvic limb in the same animal. The study was done applying two prostheses in 15 dogs. The microperforated latex and fabric graft showed satisfactory structural qualities (adaptability, elasticity, impermeability and possibility of suture) as a vascular substitute. It stimulated endothelial growth, beyond contact regions with the artery in anastomoses and was bicompatible with the dog's arterial system, showing adequate tissue integration. In [13], they evaluated using a natural latex mould in the postoperative surgical preparation of the neovagina with the objective of inducing healing and to keep the cavity functional in nine patients with Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome. The results confirmed the properties of tissue replacement and regeneration of natural latex derived from *Hevea brasiliensis* and acceleration of the healing process with no rejection. In [14], they developed a topical latex membrane for controlled drug release. In other medical areas, latex has been studied and successfully utilized in the healing process of ulcers, and in burned areas on the body's surface and in conjunctiva reconstruction [8]. Due to these promising results, using latex was the basis for making the new device proposed here for treating and controlling diabetes and obesity.

A study was conducted concerning esophageal diseases in order to propose a device and its placement technique. It was found that patients with obstructive diseases of the esophagus (caustic stenosis, chagasic megaesophagus and esophageal cancer) have high weight loss as a result of reducing the flow of food,which can be seen in [15,16,17,18]. Because these esophageal diseases cause a reduction of the esophageal lumen or obstruct the emptying of the organ, they lead to the patient losing weight. In this context, the CFE® module was developed for helping in the treatment of obesity and it also can be used for diabetes treatment due to the significant weight loss achieved with its use. This chapter describes the engineering and design used in the development of the device and the tests already carried on it aiming at its efficacy and security evaluation in order to offer to the global community a new option for obesity and diabetes treatments.

2. Materials and methods

Whereas a decrease in food consumption may be secondary to esophageal obstruction and considering that there is the possibility for inserting devices that may alter its diameter (which takes place in the treatment of bleeding due to esophageal varices), it was plausible

to suppose that developing the CFE® module may lead to reducing food intake.The objective is to evaluate the possibility of CFE® insertion into the esophagus which causes, during its use, resistance to the passage of food bolus. This makes food ingestion slower due to a reduction in the lumen of the esophagus, resulting in the need for prolonged chewing.

2.1. Latex preparation

The latex used here had already been through the centrifuging process, with sulfur and resin suspensions, having the objective of providing elasticity and the necessary strength for the final compound. From this preparation process, the latex is configured as a compound which upon contact with the skin, vulcanizes, making it adhesive. To be removed, however, just pure water is used. On glass surfaces, its removal is facilitated due to the low friction that glass provides.

When handling the latex, glass rods were used for mixing, as well as a glass container for storage, plastic wrap to protect it from contact with the air and cotton flannel for cleaning. An important point for any application that uses raw latex is the uniformity of its properties, since this is an essential characteristic. To obtain this characteristic, the latex source should be the same, i.e. the latex should come from trees of the same clone.

2.2. Manufacturing the CFE® module

The CFE® module was manufactured aiming to develop a mechanical device, with biocompatible and flexible material, in the shape of an 8 cm long cylindrical balloon, inflatable with gas by a valve system with an approximately 1 cm diameter conduit. The dimension established for length refers, approximately, to the size of the upper third of the esophagus. Incorporated into the module were radiography visualizations and fixing devices, containing within them a barium contrast indicator for controlling the position for x-rays. At one of the ends, there is a thread for fixing the module to a dental crown, which should be attached to the superior molar with the aim of preventing the module from migrating to the stomach in the event of accidental disinflation.

Manufacturing the CFE® module begins with preparing the environment, the raw material and the moulds and then follows a series of steps, such as: immersion of the glass moulds into a container containing liquid latex, drying the moulds in an oven, analyzing the thickness, removing the solidified latex from the moulds, assembly of module and final inspection.

2.3. Cadaver test

An experimental feasibility study was conducted, testing the placement and removal of the CFE® device in the esophagus of a cadaver at the Institute of Forensic Medicine (IFM). After being applied, the module was inflated with the aid of a manometer adapted to a pressure of 120 mm Hg. Its placement was made with delicate maneuvers aimed at preventing alterations to the module to be examined.

2.4. *In-vitro* study

With the objective of estimating the minimal time to carry out an intervention, in the event that it descends to the stomach and in order that it not cause intestinal obstruction, an experiment was conducted in the Laboratory of Engineering and Innovation – LEI at the Gama Campus of the University of Brasília. This experiment compared the volume of BIB (400 ml to 700 ml) and (CFE 146 ml) with the goal of comparing its volumes and its emptying capacity in the case it is punctured. The calculation employed for obtaining the CFE volume used a technique based on solids of revolution and the time was obtained from simple arithmetic means. There were four CFE modules used as samples and these were immersed into an environment similar to the stomach. The method utilized was to inflate the CFEs with the same pressure to be applied in humans (60 mmHg – minimum), withdrawal of the scalp[1] number 27, immersion of the CFE in the environment with the hole made in the sample by the scalp on the upper part of the module thereby forcing partial emptying, since if it were not punctured, it would not empty as in the test done in [7].

2.5. Preparation for clinical trial

The choice for using a dog – as an animal for testing and for weight loss and/or as a validator of the CFE module – was made in light of findings raised with medical veterinarians. It was verified that the animal would be an excellent subject for analysis in this study keeping in mind the anatomical-physiological similarity between human and canine esophagi. Allied with this, above all, factors that denote affability with such animals and also, the facility of controlling their eating routine, as well as the food ingestion speed of the animal, associated with little chewing and the absence of psychological pressure (as opposed to what a human develops when the goal is losing weight). To conduct the experimental procedure, eight adult dogs, of no specific breed, males and females, with body weights varying between 9.2 and 17.8 kg were selected. Before the experiment, the animals were kept at the Veterinarian Hospital kennel at the Federal University of Goiás to be submitted to quarantine procedures that include: vaccination (Duramune Max, single dosage), application of ecto and endoparasiticides (administered through 100 mg of mebendazole, twice a day for three days), in addition to laboratory exams like blood count, urinalysis, hormonal and blood biochemical evaluations. Furthermore, improvements in the nutritional conditions of the animals was sought, through the implementation of a daily diet of dry dog food, supplemented with semi-moist dog food rich in nutrients (Dudog®). The animals were vaccinated against rabies and DHLPPC (distemper, hepatitis and adenovirus, leptospirosis, parainfluenza, parvovirus, and coronavirus) and dewormed with a broad spectrum dewormer. Ectoparasites were eliminated with a two-dose application of pour-on parasiticide. Blood was taken from all the animals and when hemoparasitoses was present, doxycycline was applied for 21 days, and diminazene in two applications with an interval of 15 days.

[1] The scalps peripheral intravenous comprise: siliconized needle stainless steel bezel with thin walls and biangular and three faceted; wings malleable and flexible, adjustable anatomically as handling (known as "butterfly"); transparent vinyl tube.

2.6. Experimental model for analyzing weight loss

It has been suggested that application is the placement and utilization of the CFE® module in the upper third of the esophagus (3 cm after the passage of the upper sphincter) of the dogs through video-endoscopy over a period of seven days as a weight loss method. The research protocol was previously submitted and approved by the Ethics Committee for Human and Animal Medical Research at the Federal University of Goiás (UFG) (process number 060/2008, registered on SAPP-WEB number 33256). To conduct the experimental procedure, eight adult dogs, of no specific breed, males and females, with body weights varying between 9.2 and 17.8 kg were selected. Before the experiment, the animals were kept at the Veterinarian Hospital kennel at the Federal University of Goiás to be submitted to quarantine procedures in addition to laboratory exams like blood count, urinalysis, hormonal and blood biochemical evaluations.

2.6.1. Plan for placement

The technique proposed for this new method is based on the mechanical decrease of the esophageal lumen, which directly influences a decrease in the speed and volume of food consumption, without altering the digestive tract or bringing about physiological and nutritional alterations: the outcome of the technique is weight loss. To achieve this, the CFE module was tested experimentally on animals, with the objective of verifying its capacity for accomplishing weight loss in the animal.

2.6.2. Definition of the groups

For this experiment, six dogs of no special breed, males and females, with body weight varying between 9.780 to 18.100 kg were selected. The process for recruiting and handling the animals followed the same norms described in the previous experiment. At this point, note that the animals were divided into two groups – the weight control-group (GCp) and the test-group (GT). In the weight control-group, the animals received the same dietary treatment and the same routine as the test-group; however, the module was not placed in the subjects in the first group. In the test-group, the module was placed following the same steps as the previous experiment, as shown in Table 1.

Groups (n=2)	Weight (kg) $\overline{x}$	Sex		Pressure applied (mmHg)
		F	M	
GC	12.84	1	1	60
GT1	11.56	1	1	100
GT2	12.10	0	2	120
GT3	14.63	0	2	140

Table 1. Group Distribution.

2.6.3. Video-endoscopy placement

The video-endoscopy procedure was conducted according to the same steps as described in the previous experiment.

2.6.4. Post-placement care

The post-placement period and the routine of the animals were carried out similar to the previous experiment.

2.6.5. Evaluation parameters

The parameters used in the evaluation were volume, speed, ingestion time, nutritional, hormonal and complete blood count, in addition to weight loss.

2.6.6. Volume, speed and ingestion time

The same diet (nutritional, quantity, and schedule characteristics) was chosen for evaluating the behavior of the dogs while eating, as well as for measuring the food left over (which was weighed and recorded). Another point evaluated was the time spent eating in both groups – which is approximately proportional to the volume ingested – through clinical observation, a timer and a precision scale.

2.6.7. Nutritional, hormonal and complete blood count

The nutritional, hormonal and complete blood count was investigated by blood tests done before and after the placement. The tests done were classified as nutritional and blood count tests.

2.6.8. Weight loss

Weighing of the animals was done before the placement and after every two days until the module was withdrawn. Weights in the beginning and in the end of the experiment were compared, and comparisons were also made between the control and test groups.

2.7. Evaluation instruments

2.7.1. Clinical observation

Clinical observation was one of the evaluation instruments used, in which a daily chart was filled out with data referring to the following data bases: 1) reaction of dog before and after meals; 2) reaction of dog during ingestion of water; 3) stool consistency; 4) amount voided; 5) behavior (irritated, agitated, normal); 6) gagging, cough, vomit, choking; 7) signs of dysphagia; 8) behavior in the presence of other dogs; 9) blood tests; 10) weight at the end of the day.

2.7.2. X-rays

Radiographic follow-up of the animals was done of the cervical region on the lateral-right (in decubito) side, immediately after placement of the module, and every two days until its removal. The test was done in the radiology laboratory at the Veterinary School at UFG, according to the following protocol: 55 kV, 300 mA, 0.04 second of exposure in a right-lateral ducubitus position. A normal esophagus is not visible radiographically, because it is a close to collapsing organ and the module behaves like a foreign body (filled with gas), making it possible to visualize it radiographically. Thus, due to the radiopacity of the gas, it is possible to determine location by means of image.

2.7.3. Video-endoscopy

A video-endoscopy was performed on the 15th day, after withdrawal of the module. The procedure was analogous to that used during placement, utilizing the same endoscopic material.

2.8. Exclusions

There were no exclusions of the dogs, including those that expelled the modules. All of them, at the end of the experiment were evaluated.

2.9. Statistical study

The statistical hypothesis t-student test was used here to make a comparison between the groups (small samples). All discussions of the present study were carried out with a 99% confidence interval.

3. Results

In Figure 1, the CFE module developed with its morphological macroscopic appearance can be observed.

Figure 1. Picture of the esophageal flow control module – CFE; from left to right: upper and side views

The materials used in the manufacturing and packaging of the module that did withstand high temperatures, were sterilized with ethylene oxide. The materials (moulds) that withstand high temperatures were sterilized by steam autoclave.

3.1. Cadaver test

In this study, a guide needed for pulling the device through to the inside of the esophagus was developed. During the removal procedure, the external wall of the module was perforated for deflation and it was removed with endoscopic forceps.

3.2. *In-vitro* study

It was found that if the module is inflated with the volume and pressure as described above,upon reaching the stomach it would take, via simple arithmetic mean, 49 hours to partially empty. With this partial emptying, it could pass through the pylorus and into the intestine, a situation similar to what occurred in the experiment presented in [7]. On that, note that among the restrictive techniques already in practice, endoscopic intervention is done to remove the object from the stomach before it descends into the intestine. In the case of the CFE – in the event that it becomes lodged in the stomach between one radiography and another, meaning during a 24-hour period, we would have ample time for removing it endoscopically without causing intestinal obstruction. It is worth mentioning in a detailed analysis carried out, it was noted that studies apply synthetic prosthesis in patients as temporary substitutes for the esophagus, and they are made of diverse materials such as: silicone, *Marlex*®, Teflon®, collagen, and a mixture of collagen and silicone. The amount of time the prosthesis remained inside the body was on average from four to five weeks, from its placement until its exit which corresponds to the end of this treatment, when expelled in the feces after this period without causing intestinal obstruction. In [6], which is used as a basis for this work, among the groups evaluated, cases occurred where the latex prosthesis was expelled by the animal, without causing intestinal obstruction. Thus, the scope of radiographic evaluations adopted (every 24 hours) was done to prevent the possibility of it passing from the stomach to the intestine.

3.3. Weight loss analysis experiment

This analysis sought to verify if the diet offered was bringing about weight loss in the animals. Considering this, the food provided was initiated ten days before placing the module: the animals accepted the food well given that the ingredients used were appealing. With this procedure, weight loss did not take place in any dog. On the contrary, some animals experienced weight gain.

3.3.1. Volume, speed and ingestion time

The food provided was semi-moist, made for each dog individually with measurements calculated according to the animal's weight, as indicated by the manufacturer. When preparing the food, solid dog food was used along with meat pâté for dogs and a dietary supplement called Dudog®. With the assistance of a veterinary doctor plus the manufacturer's instructions, the dietary composition was established for each dog which is presented in Table 2.

	Dog weight (kg)	Solid dog food (g)	Meat (spoonful)	Dudog® (slices)
GCp	13,100	331	2	4
	13,400	339	2	4
	15,780	410	3	6
GT1	9,780	247	1	2
	10,120	256	1	2
	18,100	470	3	6

Table 2. Amount of food offered to each dog, mixed with 1 liter of water.

The containers used were identified with name of each dog, being "deducted" from their weight at each meal offered. All meals provided were weighed after having been mixed with water in a blender. During feeding, the dog was monitored. When done eating, the container was removed and weighed again, so that the exact amount of the volume ingested, per meal per dog, was obtained.

However, it was observed that the volume of food ingestion in group GT1 was less than the volume in group GCp. The accumulation of leftovers was observed in the feeding of all subjects in group GT1, having at times volumes up to 1 kg. This fact indicated that the method restricted the volume of food consumed by the dogs, but without causing apparent discomfort. Another point that should be put forth is that in the observation, there was great care taken to verify if there was evidence of satiety after eating in the dogs with the module. To this end, the container was left longer to confirm the dog's level of satiety. Faced with this situation, the animals did not go back and enjoy the rest of the contents, even when it was offered directly to them. This fact is a strong indicator that the dogs felt satiated. The speed and the time for ingesting the food were two other items observed, given that in the first two days, it was clearly noted that in group GT1, both (time and ingestion) were greater than those in group GCp.

During the eating process, the dogs in group GT1 made pauses in their food ingestion. This decreased and later it normalized over the subsequent days. It is believed that this situation occurred due to the esophagus module accommodating itself. After, it was observed that there was an inversion, since the food ingestion time of group GT1 was reduced and the amount of food consumed became gradually less. It must also be put into evidence that each dog was offered two meals a day – one at 09:00 and another at 18:00.

3.3.2. Nutritional, hormonal and complete blood count

The complete blood count was collected through the Vacutainer® system, taken from the arteriovenous group in a tube with four drops of anti-coagulant (10% EDTA solution), then performing the homogenization of the samples with slow and regular movements. From the samples, hemoglobin, hematocrit (the percentage occupied by red blood cells or erythrocytes in total blood volume, because a decrease in it may indicate anaemia), and total plasma protein (TPP) were evaluated. The data collected was analyzed statistically following the Tukey test ($p<0,05$), in the ANOVA module of STATISTICA software, with repeated measurements and a non-parametric test, for qualitative variables. The data obtained from the blood count are described in Table 3 below, thus allowing evaluation of the effects of the esophageal module, as well as evaluating how it affects the blood tissue.

	Hemoglobin (g/%)		Hematocrit (%)		TPP*(g/%)	
	Average	DP(±)	Average	DP(±)	Average	DP(±)
GCp	8,16	0,83	30,19	3,02	7,21	0,37
GT1	8,08	0,95	30,25	3,36	7,33	0,54

Table 3. Evaluation of the hemoglobin, hematocrit and total plasma protein. Values do not differ ($p > 0,05$). *TPP = Total plasma protein.

It was also verified that the average values obtained from the evaluation do not differ. Therefore, it may be suggested that the method does not promote alterations in the blood tissue, since when the hemoglobin concentration was evaluated, there was no difference between the groups ($p > 0,05$), considering that the same result was obtained in the hematocrit and TPP evaluations.

However, it is known that blood count evaluations may suffer variations according to the nutritional condition of the animals, climatic factors, infections and release of blood components. Nevertheless, in this study the parameters were maintained within the physiological values.

3.3.3. Weight loss

Specifically in relation to weight loss, in all of the experiments conducted in this study which involved dogs, the animals' weights were monitored. Weight loss took place to a slight extent (≈1,3%), as well as to a great extent (≈6,3%), for the weight of the dogs in the analysis presented in item 7.3 of this study, which used the module. Lower indices were observed in recently arrived dogs from the Center for Zoonoses, and the higher indices were exhibited in the dogs that had already been at the Veterinary Hospital for a longer period of

time. It is believed that this occurred because the dogs that had recently arrived were under their ideal weight.

In this analysis in which the two groups GCp (without module) and GT1 (with module) were compared, it was observed that the group in which the module was applied (for seven days), weight loss took place. This fact is attributed to a decrease in the volume of food ingested, brought about by the module placed in the esophagus. In Table 4, data related to the dogs submitted to the test are presented. For ten days, semi-moist food, before the module's placement, was provided to the two groups and after the module's placement, the dogs remained for seven more days on the same dietary routine.

The data in Table 4 are described next. In the Start column, the original weight of the dog is presented. The GCp lines correspond to the weights of the dogs in the control group that did not use the module and the GT1 lines are of the dogs in which the module was placed. The dogs were fully fed over a period of 10 days without the module. The weight of the dogs at the end of 10 days is shown in the "10 days (final)" column. Then, the modules were installed only in group GT1, and remained in the dogs for a period of 7 days, and the final weights, after 7 days, are presented in the "7 days (final)" column. The column furthest to the right indicates the weight loss percentage in relation to the weight of the dogs in both groups on the date of the module's placement.

	Dog weight (kg) Start	Dog weight (kg) 10 days (final)	Dog weight (kg) 7 days (final)	Weight change (%)
GCp	13,100	13,480	14,000	(+) 3,71
	13,400	13,400	13,590	(+) 1,39
	15,780	16,200	16,630	(+) 2,58
GT1	9,780	9,900	9,540	(-) 3,63
	10,120	12,180	11,140	(-) 8,54
	18,100	19,800	17,950	(-) 9,35

Table 4. Animal weight variation[2].

[2] The values shown in the table are an average of the weights.

3.4. Clinical trial

After placing the module, the animals were evaluated over a period of 15 days. No dog died and there was no exclusion. At the end of the procedures associated with the experiment, the dogs received hygiene care, food and the necessary clinical-laboratorial evaluations, in order that they be donated to owners registered in the Veterinary Hospital data bank (which in fact did take place).

3.4.1. Lack of appetite

No grave alteration in appetite was observed, such as anorexia. However, all of the groups ate less than what was observed before placing the module, thus characterizing a state of hyporexia. The semi-moist food provided was of the same consistency and quantity, and accepted by all of the animals, who also did not show any clinical manifestation suggesting dysphagia. None of them had clinical alterations during the period following.

3.4.2. Absence of voiding and/or defecation

In all groups, voidance was normal, present and without difficulty. But defecation took place with less frequency, was not daily, and had a soft consistency.

3.4.3. Range of pressure values

Concerning the range of pressure values, based on the results observed here and in the pilot study in dogs, a pressure range from 60 mmHg up to 120 mmHg is suggested for modules with construction characteristics similar to those applied in this experiment. As such, an exact definition of applied pressure should be made based on the diameter of the dog's esophagus, since the greater the diameter, the greater the pressure must be. This fact must be taken into consideration and evaluated prior to the endoscopy because there is a reasonable dimensional variation, given the vast number of breeds that are found in this species, each having distinct anatomical features.

Clinical observation shows that the expected outcome was achieved with the placement and fixedness of the module for GC and GT1, while preserving the dog's welfare and only minimally altering its physical condition. In groups GT2 and GT3, which used greater pressure, the dogs' state remained normal after a long period of adaptation, which altered the condition of the animal for a longer period.

3.5. Damage to the esophageal wall

The esophagus was analyzed in all of the animals, including the dog belonging to group GT3 that expelled the module 20 hours after placement, and one dog in group GT2 in which the module descended to the region caudal region of the stomach 9 days after placement. It must be emphasized that in all groups, there was no visible alteration to the esophageal wall. This finding was made after endoscopic macroscopic evaluation of the dogs'

esophageal wall, after removal of the module, which was compared with the endoscopy that had been previously done. Nonetheless, after the endoscopic exam, it was observed that the entire esophageal wall was intact, i.e. a normal appearance of the esophageal wall was preserved having a bright and rosy coloring, without food residuals or ulcerations. The folds were normal as was the frequency of the peristaltic waves.

4. Discussion

At this point, it needs to be restated that obesity is a disease that affects an individual as a whole. It interferes with mental, physical and social aspects, and is not a direct result of psychological disorders, but it is a target for prejudice and discrimination [19]. Hence, when obese people seek out a doctor for treatment, they are in search of not only a healthy body, but also to "discover themselves". However, there are many problems that these individuals face. Standing out from these issues are marital problems, mental disorders, anxiety, depression, excessive eating, low self-esteem, guilt complex and no self-acceptance [20].

There are many factors that cause obesity as already described in this study. But in general, the main cause of obesity remains to be an altered or inadequate eating behavior. From this point of view, it is of fundamental importance that those who are obese are not only seeking solutions in order to control their weight: it is essential to provide conditions for re-educating such people.

When researching currently available treatments for all ranges of obesity, one point in common was observed – decreasing food intake - because depending on how the treatments are carried out each technique in its own way, seeks to achieve this goal. However, the failures, having unfavorable consequences to the patient, amongst other drawbacks, point to the need for finding new techniques.

In light of such a necessity, a new device was designed in this study for treating such cases. The device presented in this study is called an esophageal flow control module (CFE). It must be emphasized that this is a totally original method using a natural raw material extracted from the *Heveabrasiliensis*. An extremely simple, handmade method is used for manufacturing it, which is based on observations and products that already exist in this surgical field.

In this sense, it is important to consider that in terms of the surgical procedures utilized here, the method (proposed here) qualifies as a restrictive technique. This is particularly because the objective of the procedures is to reduce the volume of food ingested. Acknowledging that the esophagus is the organ for placement, it should be pointed out that this technique has disadvantages and restrictions for placement, which have also been described in this study.

The basis for this proposal then is founded upon presenting a proposal for reducing food intake, however, with some significant differences that are listed here: 1) the organ for

placement is the esophagus – in its upper third; 2) reduction of the lumen in the esophagus works mechanically, which blocks the quantity of food going from the mouth to the stomach, limiting the ingestion speed of solid foods; 3) placement takes place by means of endoscopy; 4) no alteration to the digestive tract is made, which neither brings about dysfunction nor compromises the absorption of nutrients; the procedure does not cause esophageal lesions, compared to the "gastric band" method which causes lesions in 10% of cases; 5) similar to the other methods, there is the necessity for chewing correctly, however, upon ingesting food of improper consistency, the food comes back up (before reaching the stomach), a positive point in this treatment, since in the other methods, vomiting crises triggered by incorrect mastication may develop into anorexia and bulimia; 6) similarly to the other methods, multi-professional treatment, dietary planning and exercise are also necessary.

In this study, the results show that placing a module inflated with gas in the esophagus, does not lead to behavior alterations in the animals. In humans, this feature had already been observed in studies that use esophageal balloon applications. In [21], short esophageal balloons are used (3 cm length and 1 cm in diameter) and long balloons (16 cm in length and 0,8 cm in diameter) for measuring the pressure of the esophageal wall. In [22], notations on the pressure inside the esophagus with a long balloon led to reports that the best results are reached when measurements are made at the middle third, showing that in this region the shape of the pressure *versus* volume curve is not affected by changes in body posture. Another application to be shown is aimed at tubular prostheses used to maintain patent malignant strictures of the esophagus and seal tracheo-esophageal fistulae, when they are fully expanded, reaching 18 mm to 25 mm in diameter and 8 cm to 14 cm length [23]. In the procedures that are involved in this study, no macroscopic damage was observed in the esophageal wall where the module was placed, or in the entire length of the esophagus. A great advantage of this module in relation to the other BIB® methods and the gastric band is how simple it is to manufacture, with the raw material "latex" estimated to be low-cost, easy to handle and highly biocompatible.

As for flow control in the esophagus, there are no reports in literature of studies with this objective. This may be because no one correlated a common denominator between esophageal illnesses that reduce the diameter of the esophagus and marked weight loss. To this end, the model presented in this study seeks to promote a reduction in the esophageal lumen to achieve weight loss.

So, mainly based on the results obtained and in the experiments conducted in dogs, a new procedure is revealed here for treating cases of obesity, derived from a natural source, which imbues it with a low-cost. But, it is probable that alterations and improvements will take place in the module aiming at obtaining better results for applying it in humans.

Thus, the results reached suggest the possibility of controlling the volume of food intake by means of a mechanical system placed in the esophagus. In obtaining results associated with weight loss – without causing significant harm or nutritional changes or alterations

in the blood, and furthermore without altering the digestive tract –, through a minimally invasive procedure, is a fact that is appealing within the current context of society. But, in validation of the conclusions reached in the experiments that support this study, it was revealed that a desire such as this has not yet been achieved from the scientifically proven premises.

5. Conclusion

The effects of mastication exert an influence on the mechanisms that trigger satiety. It implies nutritional re-education in individuals with obesity and also weight loss, as observed in previous studies. One can read in studies by many authors that new studies regarding procedures for treating obesity are necessary, particularly with the goal of improving the results and decreasing the costs and morbidity of obese patients. But, the basic, necessary characteristics for comprising a new treatment should be founded. On a minimally invasive procedure, without side effects, that would not interfere or modify gastro-intestinal anatomy.

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