



Innovation in liposuction cannula to harvest fat graft to use in breast reconstruction

Inovação em cânula de lipoaspiração para coleta de enxerto de gordura para uso em reconstrução mamária

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■ ABSTRACT

Introduction: The evolution of liposuction and fat graft technique with the oncologic safety allowed to use the fat as autologous filler in patients with breast cancer and submitted to breast reconstruction. The objective is to introduce an innovation in the instrument used to harvest fat grafts for breast reconstruction. **Methods:** Search of anteriority and trademarks were performed at international and national databases, and a prototype was built as a fat harvest instrument with 35cm in length, 4cm in diameter, with 10 holes at the distal extremity, with 2mm diameter each. It was experimented with a harvest of a viscous substance, comparing the prototype with two regular industry cannulas types: three holes Mercedes' type and five holes Pitanguy's type. **Results:** Four high-relevance patents and one medium-relevance patent were found, which differ from the proposed utility model when comparing the type of design of the distal end of the studied cannulas and the function of the instruments identified. When the prototype's efficiency was compared with the other cannulas, the cannula with five holes in Pitanguy's type was the most efficient, and it was no statistical difference between the prototype and the cannula with three holes in Mercedes' type. **Conclusion:** The innovation presented to harvest fat graft for breast reconstruction had the same efficiency in harvesting the viscose substance as the cannula Mercedes type with three holes in this experimental model.

Keywords: Subcutaneous fat; Breast; Breast neoplasms; Cannula; Graft survival; Adipocytes.

■ RESUMO

Introdução: A evolução da técnica de lipoaspiração e da enxertia de gordura associada a segurança oncológica permitiram utilizar a gordura como preenchedor autólogo em pacientes com neoplasia de mama que eram submetidas a reconstrução mamária. O objetivo é apresentar uma inovação no instrumento de coleta de gordura que será utilizada como enxerto, para uso em reconstrução mamária. **Métodos:** Foi realizada a busca de anterioridade nos bancos de dados internacionais e nacional e a confecção de um protótipo de cânula de coleta de gordura de 35cm de comprimento, com diâmetro do tubo de 4mm, com 10 furos redondos na sua extremidade distal com 2mm de diâmetro. Foi realizado um experimento de aspiração de substância viscosa comparando o protótipo com dois modelos de cânulas com desenho padrão da indústria, de três furos tipo Mercedes e de cinco furos tipo Pitanguy. **Resultados:** Foram encontrados quatro patentes de alta relevância e uma patente de média relevância, que diferem do modelo de utilidade proposto quando se comparam o tipo de desenho da extremidade distal das cânulas estudadas e a função dos instrumentos identificados. Quando comparou-se a eficiência do protótipo, a

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cânula de cinco furos foi a mais eficiente na aspiração da substância viscosa, e não houve diferença estatística na velocidade de aspiração entre o protótipo e a cânula de três furos tipo Mercedes. **Conclusão:** A inovação apresentada para a coleta de enxerto de gordura para uso em reconstrução mamária apresentou a mesma eficiência que a cânula Mercedes de três furos neste modelo experimental.

Descritores: Gordura subcutânea; Mama; Neoplasias da mama; Cânula; Sobrevivência de enxerto; Adipócitos.

INTRODUCTION

The use of fat as an autologous filler in breast reconstruction began in 1895 with Czerny, who used a patient's lipoma to reconstruct the breast¹. Its use has fallen into disuse due to morbidity in the donor area when large tissue volumes are used. However, with the description of the fat extraction technique with cannulas, called liposuction, plastic surgeons were offered an important tool for fat collection as an autologous filler with low morbidity².

However, due to the technical limitations of the time, a high number of complications such as graft loss and steatonecrosis that led to breast calcifications, and the available diagnostic imaging technology resources that were unable to differentiate between steatonecrosis calcifications and breast microcalcifications, the new procedures by the American Society of Plastic Surgery in 1987 contraindicated breast fat grafting due to the possibility that steatonecrosis calcifications could compromise the diagnosis of early breast neoplasms on mammography.

From 2005 onwards, with the evolution of the liposuction and fat grafting technique, associated with the technological evolution of diagnostic imaging methods, new studies showed the evolution of the technique of fat grafting in the breasts, with a lower incidence of complications locally³⁻⁶.

In 2011, the first studies were published showing the oncological safety of fat grafting in patients with breast cancer and undergoing breast reconstruction, increasing its use in patients with breast cancer⁷⁻¹³.

Despite the ease of collecting fat grafts, the main obstacle to its use is the high absorption rate, which varies from 20 to 90%¹⁴⁻¹⁷. In order to improve fat graft integration rates, with a smaller number of surgical interventions in patients, innovations in each step of the fat tissue preparation method were proposed¹⁸.

The most important characteristics for the success of fat grafting are patient age, choice of the donor area, the technique of fat collection, the instrument for fat collection, fat processing, the injection technique and the preparation of the recipient area.^{19,20}

The use of liposuction cannulas with a larger diameter alone has higher collection rates of viable adipocytes in experimental models^{14,21}.

In addition to the diameter of the cannula tube, the size and number of holes are important for the collection²². 2-mm-diameter cannulas with four 600- μ m holes and multi-perforated cannulas with 1-mm holes were proposed for micrografts on the face²³.

Apart from the 3mm diameter Coleman™ fat graft collection cannula with two holes, which is not designed for breast fat grafting, there are few proposals for innovation in the fat collection instrument to reduce trauma in adipocytes and improve the rates of viability and integration of fat grafts when it is desired to collect larger volumes of fat graft for use other than the face^{24,25}.

OBJECTIVE

To present an innovation for liposuction cannula to collect fat micrografts for use in patients undergoing mastectomy who wish to reconstruct their breasts and optimize their final aesthetic result.

METHODS

This is a primary, experimental, prospective, comparative and controlled study, carried out from March 2016 to March 2017 at the Universidade Federal do Estado de São Paulo (UNIFESP), presented to the Ethics and Research Committee of UNIFESP, having received the number 6331150116. A search for prior patents was carried out in international databases: Espacenet, The United States Patent and Trademark Office (USPTO), World Intellectual Property Organization (WIPO), China National Intellectual Property (CNIPA) and Japan Patent Office (JPO), the National Institute of Intellectual Property (INPI) database, the PatBase software and Google Patents, with the keywords and classifications: cannula, liposuction, orifice, neoplasia, A61B, A61M.

For the experimental study, a prototype of a surgical steel cannula for the fat collection was developed and made with 10 holes at the distal end of

2 mm in diameter each, in a hollow tube with a luminal diameter of 4 mm and 35 cm in length, with a coupler at its proximal end for a 60ml syringe with a catheter tip and for an adapter for a suction device for storing the fat to be used, to collect fat grafts in blocks of fat tissue up to 2mm in diameter (micrografts) (Figure 1).



Figure 1. Detail of the design and arrangement of the orifices of the 10-hole cannula prototype.

The experiment was carried out by comparing the aspiration efficiency of the prototype with two models of liposuction cannula with a luminal diameter of 4 mm and a length of 35 cm, with an industry-standard design and of the same brand (three holes with a Mercedes-type design, and five holes with a design type PitanguyTM) all made by the same company (Richter®, São Paulo, Brazil), considering the same material and the same resistance of the tubes (Figure 2).

A pilot was carried out with a model of water aspiration under continuous pressure of 30mmHg, 20mmHg, 10mmHg, and the aspirated weight of four measurements of the three cannulas at 30", 60" and 90" were compared. The Aspirotec III surgical aspirator (Sismatec company, Curitiba, Brazil) was used, with a digital scale model EHA251 of 0.1gr accuracy and 500gr capacity (Camry electronic, Guangdong, China). As there was no statistical difference in the volume of water aspirated between the different pressures in the different types of the cannula, the aspiration pressure was defined at 10 mmHg in 10 measurements of the three cannulas in 30", 60" and 90".

The experiment of aspiration of viscous substance (soybean oil, density 0.891gr/cm³) under continuous pressure of 10mmHg was then performed, and the aspirated weight of 10 measurements of the three cannulas at 30", 60" and 90" was compared. The Aspirotec III surgical aspirator (Sismatec company,

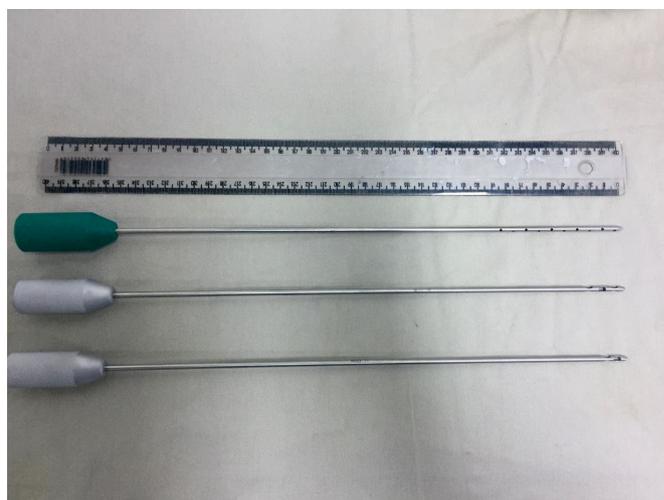


Figure 2. 10-hole cannula (prototype), Mercedes-type three-hole cannula, and PitanguyTM five-hole cannula.

Curitiba, Brazil) was used with a digital scale model EHA251 with 0.1gr accuracy and 500gr capacity (Camry electronic, Guangdong, China)²⁶.

To analyze the results, Friedman's analysis of variance was applied to each of the cannula designs, studying the aspiration speed of grams of soybean oil/second at times 30", 60", and 90"; and the Kruskal-Wallis analysis of variance to compare the three types of cannula designs, at 30", 60", and 90" times separately²⁷.

In all tests, the significance level was set at 0.05 or 5%.

RESULTS

Four highly relevant patents were found (product catalog of the company Tulip Medical - "Sorensen Harvested" and "Sforza Harvester" cannula; WO 2014074606 (A1) - adjustable liposuction cannula; US 8333740 B2 - tissue transfer cannula; and US 2008/0167613 - closed system and method for atraumatic, low pressure, continuous harvesting, processing, and grafting of lipoaspirate) and a patent of medium relevance (US 5817050 A - liposuction cannula), which differ from the proposed utility model when comparing the type of design of the distal end of the studied cannulas and the function of the instruments identified.

The weight in grams of soybean oil aspirated per second was higher in the five-hole cannula group (Table 1), followed by the three-hole cannula group, and the 10-hole cannula group at times 30", 60" and 90" when performing Friedman's analysis of variance (30" x 60" x 90") (Figure 3).

When comparing the aspirated weight of soybean oil per second between the five-hole cannula X three-hole cannula X 10-hole cannula groups, the five-hole

Table 1. Comparison of the weight of soybean oil aspirated at 10mmHg in the different types of drilling of 4mm cannulas of 35cm in length.

Cannula 3 holes			Cannula 5 holes			Cannula 10 holes		
30"	60"	90"	30"	60"	90"	30"	60"	90"
17.2	52.5	70.1	20	39.5	62.3	15.9	31.4	47
17.9	36.1	54.9	18	37.5	58.8	16.1	31.9	47.5
19.4	37.6	57	17.3	36.4	55.7	16.1	31.7	47.7
19.1	37.6	56.5	19	37	55.6	16	31.9	47.4
17.4	34.4	51.1	18.6	37.1	55.4	15.7	31.4	48.3
17.4	32.9	50	18.8	38	55	15.7	31.4	47.2
16.7	32.9	49.3	19	37	54.6	15.7	31.3	46.9
18.5	35.9	53.9	20	39	57.4	15.4	30.6	46.6
17.3	35.3	51.4	18.8	37.4	56.5	15.4	31.5	47.1
12.1	23.4	45.9	19.1	37.7	57.5	21.4	42.9	57.4
Average 17.3	35.9	54.0	18.9	37.7	56.9	16.3	32.6	48.3
Median 17.4	35.6	52.7	18.9	37.4	56.1	15.8	31.4	47.3

Friedman's analysis of variance (30"x60"x90")		
Cannula 3 holes	Cannula 5 holes	Cannula 10 holes
$X^2_r = 20.00$	$X^2_r = 20.00$	$X^2_r = 20.00$
($p < 0.0001$)	($p < 0.0001$)	($p < 0.0001$)
90" > 30"	90" > 30"	90" > 30"

Kruskal-Wallis analysis of variance (30"x60"x90")		
30"	60"	90"
H= 12.69	H= 12.70	H= 13.89
p=0.0018	p=0.0017	p=0.0010
Cannula de 5 holes > 10 holes	Cannula de 5 holes > 10 holes	Cannula de 5 holes > 10 holes
Cannula de 5 holes > 3 holes	Cannula de 5 holes > 3 holes	Cannula de 5 holes > 3 holes

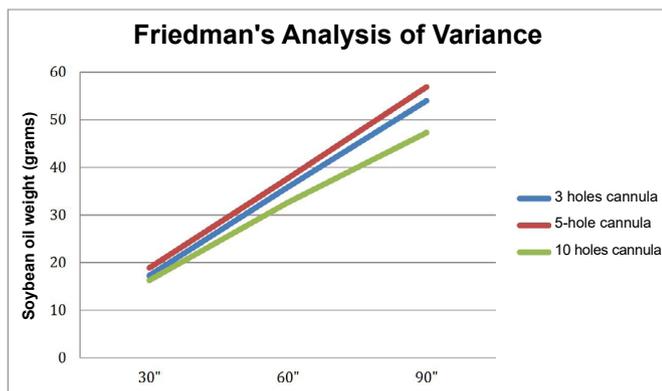


Figure 3. Friedman analysis of variance for each of the cannula designs studying the aspiration speed of grams of soybean oil/second at 30", 60" and 90" times.

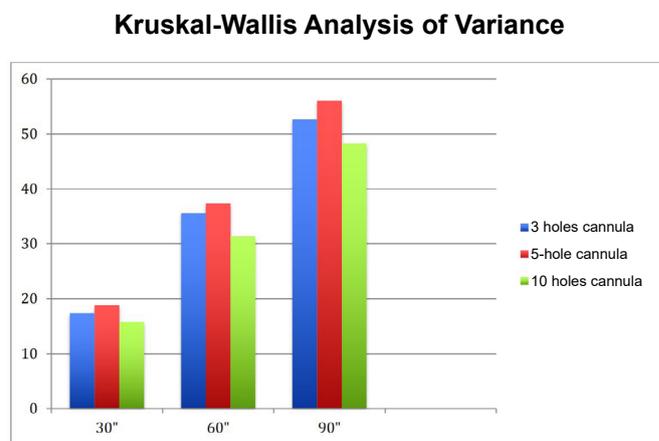


Figure 4. Kruskal-Wallis analysis of variance comparing the three types of cannula designs, at 30", 60", and 90" times separately.

cannula aspirated a greater amount of soybean oil per second. However, there was no statistical difference between the weight of soybean oil aspirated per second between the three-hole cannula and 10-hole cannula groups by the Kruskal-Wallis test (Figure 4).

DISCUSSION

Breast cancer is the second most common type worldwide after non-melanoma skin cancer. It is the

most common among women, accounting for 25% of new cases yearly. In men, it represents 1% of all cases of the disease. In Brazil, the estimate was 66,280 new cases for the year 2020. In 2019, the number of deaths from breast cancer was 18,285, with 227 men and 18,068 women²⁸.

Mastectomized patients undergoing breast reconstruction have a better quality of life, self-esteem, and improved sexuality compared to non-reconstructed patients^{29,30}.

Fat grafting alone or associated with the reconstruction technique with autologous or alloplastic tissue aims to improve reconstruction quality, especially in irradiated skin¹³.

In 2015, a systematic review on fat grafting was published, which concluded that although there is a difference in the survival of adipocytes according to the collection with liposuction cannulas of different types and diameters in experimental models, when performed in humans, this difference is not significant¹⁸.

In 2016, a new systematic review did not identify differences between the different types of cannula diameter for the same design in the viability of fat grafts³¹.

The development of new cannulas for fat graft collection is necessary to reduce the incidence of local complications such as volume reduction and the need for new surgical interventions to volumize the breasts.

The definition of the collection of more symmetrical blocks of fat up to 2.0 mm in diameter for use as a fat graft, which would be collected and stored in syringes or a larger reservoir with the use of a vacuum cleaner, in a less traumatic way and with low morbidity in the donor area, with the possibility of fewer surgical interventions in this group of patients to achieve the planned result, and that did not significantly prolong the surgical time with increased morbidity of the procedure in patients, were the main motivations that led to the elaboration of a utility model proposal for the INPI patent MU 6602563-0 U2.

It features a new design at its distal end, with 10 holes with a fixed diameter of 2.0mm, an internal diameter of the cannula of 4.0mm and a length of 35cm, with the sole objective of less traumatic and more efficient collection of fat, possibly with a greater number of viable adipocytes and an increased possibility of integration into the recipient bed, for use in breast reconstruction.

The thickness of the graft and its geometric shape are inversely proportional to the survival of the fat graft if the graft diameter exceeds 3.0 mm in diameter (radius of 1.5 + 5 mm). Therefore, the size of the chosen block of fat of up to 2.0 mm in diameter has a greater chance of being integrated into the recipient bed when

this criterion is analyzed separately in the collection, defined by the type of cannula to be used³²⁻³⁷.

The dimension of the fat block of micrografts up to 2.0mm is determined by the diameter of the 2.0mm hole at the distal end through which the fat enters the collection cannula in a smooth and less traumatic tube and, in addition to promoting a greater possibility of survival of the adipocyte in the recipient bed and greater possibility of integration of this fat, the dimensions of the cannula (length, diameter, number and positioning of the holes) allow to collect a greater amount of fat in a shorter surgical time, and, therefore, a smaller number of surgical interventions required for volumization of the reconstructed breast with autologous fat graft. There was no difference in the speed of aspiration of soybean oil between the three-hole Mercedes cannula and the 10-hole prototype cannula.

CONCLUSION

The innovation presented with the making of a prototype with 10 holes of 2mm in diameter at its distal end was developed for the efficient collection of fat blocks up to 2mm for use in breast reconstruction and presented the same aspiration efficiency of the viscous substance oil of soybean when compared to the industry standard three-hole Mercedes design cannula design.

COLLABORATIONS

- MSLO** Analysis and/or interpretation of data, Statistical analysis, Acquisition of funding, Data collection, Conceptualization, Conception and design of the study, Resource Management, Project Management, Investigation, Methodology, Conducting operations and/or experiments, Writing - Preparation of the original, Writing - Proofing and Editing.
- EBG** Final Manuscript Approval, Project Management, Methodology, Supervision.
- LB** Methodology, Supervision.
- CSS** Methodology, Supervision.
- LMF** Supervision.

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