

RESEARCH ARTICLE

Comparison between Laser-Cutting or Molded Polyoxanone Thread in Facial Lifting

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Abstract:

There is no literature comparing the effectiveness of laser-cutting or molded barbed polydioxanone (PDO) threads when used in protocols for facial lifting. The objective of this study was to compare the efficiency of laser-cutting ($n=10$) or molded ($n=15$) threads in facial lifting procedures. Adverse events, quality of treatments, and self-perception facial improvement were investigated immediately and after 90 days of the clinical procedures. Data pointed that the most prevalent adverse events reported by the patients, for both threads, were pain and sensation of skin traction at the intervention sites (56%). According to the Numeric Visual Scale (NVS), the molded thread received score 10 in 42.8% of the patients. It was observed more reports of major ($n=32$) and noticeable ($n=46$) facial aesthetic improvement by patients who received laser-cutting threads. The results suggest that both, laser-cutting or molded threads, cause few adverse events, allow good acceptance by patients, and permit to treat successfully different facial areas.

Keywords: Threads; Polydioxanone; Facial Lifting Aesthetic

Introduction

Aging is an inevitable and progressive process that compromises skin, superficial or deep fatty, ligaments, muscles and bones [1-3]. The main oral and facial aging consequences are loss or tooth wear, resorption of periodontal bone tissue and gingival retraction, supraciliary prolapse, palpebro-malar groove, nasal groove, sagging jowls, submental fat, and ptosis of the nose tip[4,5].

Protocols for facial aging correction vary greatly according to the clinical case. They can be invasive or minimally invasive. Among the invasive procedures are the plastic surgeries, which usually require hospitalization and general anesthesia. Minimally invasive procedures are done in ambulatorial place and under local anesthesia. Usually, cosmetic treatment of the dermis, chemical and mechanical peelings, photobiomodulation, injectable dermal fillers, neurotoxins, lipolysis of fatty compartments, and thread implants [6-8].

Threads for lifting, in general, are non-absorbable and absorbable. The most used absorbable threads materials are of polylactic acid (PLLA), polycaprolactone (PCL) and polydioxanone (PDO), whose effects last from 6 months to four years, depending on the material [9].

Polydioxanone (PDO) threads are used routinely and safely for more than three decades as suture threads in surgical procedures [10-12]. They are composed of a very flexible synthetic polymer that is biodegraded by non-enzymatic hydrolysis and excreted mainly by urine, with absorption rate around 180 days [13]. Their rupture resistance is 53% at 42 days, and act as neovascularization agents and in the regeneration of collagen (Col α 1 and Col α 3) [14,15]. Barbed (or spiculated) threads have good tensile strength and anchorage resistance on the implanted tissue 15 and may promote facial lifting effects. It happens because they fix the tissues and keep them in position through the action of their bidirectional spicules, which are opposed to the movement of tissue traction [16].

Thread spicules can be made by laser-cutting or can be molded by injection of the material into molds. The chances of spicules to fail when submitted to efforts appear to be lower when they are molded, especially if the threads present larger diameter. However, there are few information about the clinical efficiency of PDO threads with laser-cutting or molded spicules.

The main of this randomized preliminary study in humans, was to compare the effectiveness of bidirectional spiculated absorbable polydioxanone (PDO) threads in facial lifting protocols when the spicules has been laser-cutting or when molded.

Materials and methods

Twenty-five Caucasian women, aged between 41 and 57 years, were selected to participate in this study. Exclusion factors were: allergy, lesions or infections at the implantation sites, plastic surgery on the face; have done or be doing another treatment for facial rejuvenation; tendency to scar or keloid; exaggerated bleeding or some blood pathology; neurotic or psychological disorders; acute and systemic infectious diseases or any contraindication factor to the use of PDO thread, iodine and anesthetic; pregnancy and lactation. Inclusion factors were: female gender, finished any dental treatment, agreement with the implantation of facial lifting thread, sign the terms of consent to interventions, and agreement to conduct the postoperative care. The study was conducted after its approval by the Human Research Ethics Committee (# 4181091).

Ten randomized patients received 19G bidirectional barbed PDO laser-cutting threads (HMC-FCL19-01/160mm of thread; Hyundae Meditech© Co., Ltd; 80, Cheongjeong-ro, Jijeong-myeon, 26347; Wonju-si, Gangwon-do. South Korea). The other fifteen patients received 18G bidirectional barbed PDO molded threads (FML 18100G185/185mm thread; Hyundae Meditech© Co., Ltd; 80, Cheongjeong-ro, Jijeong-myeon, 26347; Wonju-si, Gangwon-do. South Korea).

The implantation of the threads were done with 100mm cannulas introduced in the subdermis skin, through a single perforation, in linear vectors, and without any fixation per node or per point in muscle fascia. Briefly, after signing all terms and documents pertinent to the procedure, as well as conducting the preoperative photographic documentation, the patients were prepared to receive the procedures. All possible dirt on the face was removed with alcohol 70°. The path of insertion threads were done with dermal pen, according to the treatment planning to be carried out, and iodine antiseptic solution (Povidine®), Rua Willis Roberto Banks, 487; Parque Maria Domitila, Sao Paulo; SP; Brazil) was applied throughout the patient's face. Infiltrative anesthesia was performed with a 1mL syringe and a 12mm needle throughout the thread insertion planned path (1.8mL of Articaine 4% / epinephrine 1:100,000, diluted in 10mL of saline). A perforation was performed with a 18G needle at the site of the origin of the thread implantation. It was inserted in the line and direction of the planned vector with a cannula, that was introduced, by continuous antegrade movement, into subdermal, in parallel to the surface of epidermis, up to the expected point of thread complete implantation. The thread was kept under pressure in the implanted position, and the cannula was gently removed from the path of its insertion point, where the thread remained inside the tissue. The portion of the thread out of the perforation skin was cut with rounded-tipped surgical scissors. On average, 3 to 4 threads were implanted per treated region. The distance among the thread was about 10mm[17].

The clinical procedures were performed at the authors' private clinic and at the MedBeauty© Training Center (Sao Paulo, SP, Brazil) by professionals qualified and trained in the use of PDO thread under the supervision of the authors (CMRB and JRAB), and in accordance with the protocols defined by the MedBeauty©.

After the first 24 hours of threads implantation, the first questionnaire was applied to evaluate the postoperative adverse events. Then, the patients returned weekly, during the first month, and monthly until the last clinical evaluation of three months postoperatively. In this period, the questionnaires were applied to evaluate and compare the results.

The used questionnaires were modified from Arizola et al (2012)[18] (Figure 1, 2 and 3) investigating about post operatory adverse events (pain, swelling, skin purplish, skin redness, itching, skin traction); subjective treatment satisfaction degree on a numerical visual scale (NVS) from 0 to 10 (considering 0 the worst result, and 10 the best result); and subjective patients evaluation regarding the degree of facial changes realized by the patients, according to their own reports by the a Self-Perception Questionnaire. The application of the questionnaires was conducted by two calibrated professionals (CMRB and JRAB).

ADVERSE EVENTS	YES	NO
<u>None</u>		
<u>Pain</u>		
<u>Swelling</u>		
<u>Purplish skin</u>		
<u>Reddness</u>		
<u>Itching</u>		
<u>Skin traction</u>		
<u>Other*</u>		

*(If you defined "Other", please, describe it here)

Figure 1. Description of Adverse Events modified from *Ariola et al, 2012*

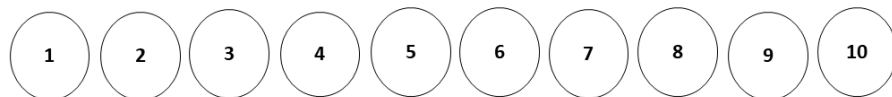


Figure 2. Numeric Visual Scale modified from *Ariola et al, 2012*

SCORE	1 (Major changes)	2 (Noticeable changes)	3 (Minimal changes)	4 (No changes)
FACIAL REGION				
Wrinkles around the eyes				
Wrinkles around the lips				
Cross forehead wrinkles				
Glabella wrinkles				
Nasolabial groove				
Mental groove				
Dark circles				
Cheeks				
Lips				
Facial symmetry				
Skin shine				
Facial relaxation				
Double chin				
Nose				
Mental region				
Jaw's definition				
Neck				

Figure 3. Self-Perception Questionnaire modified from *Ariola et al, 2012*

After obtaining approval from the Human Research Ethics Committee, the study lasted eight months from the implantation of the threads and their final evaluation, including three months of screening compliance period, and about two additional months for data processing and preparation of written work. The study were only considered completed when no adverse events or remaining symptoms were observed, and after a final evaluation of 90 days postoperatively.

All collected data were stored in the Excel program database. The tabulation of the obtained data was performed in tables, through numerical and percentage values. The data did not allow statistical differences between the pattern threads or the among periods, and were presented as individual and percentual values.

Results

All collected data are expressed on Table 1.

Table 1. Number of patients that presented Adverse Events* after anesthesia effect; individual patient score of treatment quality in the Numeric Visual Scale (NVS)[§], and number of patients who noticed facial modification in the Self Perception Questionnaire[£] after 90 days implantation, for Molded Threads (MT) (n=15) and Laser-cutting Threads (LT) (n=10).

Adverse Events*	None	Pain	Swelling	Purplish skin	Redness	Itching	Skin traction	Other							
MT	6	7	5	1	1	3	6	2							
LT	2	7	2	3	1	3	8	1							
%	32	56	28	16	8	24	56	12							
Patient's numbers															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
NVS score [§]															
MT	9	10	9	10	9	7	10	5	10	8	7	10	10	8	-
LT	7	8	8	9	9	7	7	6	7	7					
Self Perception Questionnaire [£]															
						1		2		3		4			
Number of patients															
Facial Region	LT	MT	LT	MC	LT	MT	LT	MT	Sum						
Wrinkles around the eyes	2	-	1	1	3	1	-	2	10						
Wrinkles around the lips	2	-	2	1	2	-	1	1	9						
Cross forehead wrinkles	2	2	2	1	2	3	1	4	17						
Glabella wrinkles	2	1	4	-	1	1	1	2	12						
Nasolabial groove	2	-	4	2	1	2	1	-	12						
Mental groove	-	-	3	1	4	5	4	8	25						
Dark circles	-	-	5	1	5	5	3	8	27						
Cheeks	1	-	5	1	2	1	-	1	11						
Lips	2	1	3	-	2	1	-	2	11						
Facial symmetry	1	-	3	2	4	6	2	6	24						
Skin shine	4	2	4	1	1	-	1	6	19						
Facial relaxation	3	-	-	2	4	3	1	9	19						
Double chin	3	-	2	1	3	6	1	6	22						
Nose	3	-	2	2	3	7	1	4	22						
Mental region	2	-	3	1	4	6	-	3	19						
Jaw's definition	3	1	3	-	3	6	-	3	19						
Neck	-	-	-	-	-	-	-	-	-						
Sum	32	7	46	17	44	53	17	65							

Number of patients who reported Adverse Events* after anesthetic effect. Number of the score assigned in the NVS[§] per each patient, and number of patients that signed self-perception improvement of the treated face region (Self Perception Questionnaire[£]: 1= Major changes, 2= Noticeable changes, 3= Minimal changes, 4= No changes) after 90 days of thread implantation.

The individual and percentual data about the adverse events after finishing anesthetic effects, showed that some patients reported more than one postoperative symptom. The immediate postoperative signals and symptoms most reported by patients (56%) for both threads were pain and sensation of skin traction at the site of interventions. Eight patients (32%) reported no different sensation after the interventions, six of which were related to molded thread and two, with the laser-cutting thread. The same number of symptoms (n=25) were reported for both threads template, excluding the report of no postoperative symptoms.

The values of NVS, defining the degree of patient satisfaction regarding their facial appearance after treatment from 0 to 10, showed that the lowest indexes were 5 for the molded threads, and 6 for the laser-cutting threads. The molded threads received maximum index (10) by six patients (42.8%), and index 9 by three patients (21.4%). The laser-cutting threads received a maximum index of 9 by two

patients (20%). One molded thread patient did not give opinion on the level of satisfaction with the treatment, and was not considered.

In the Self-Perception Questionnaire, there were a higher number of reports of major changes ($n=32$), and noticeable changes ($n=46$) by patients who received laser-cutting threads. Most patients who received molded threads reported minimal changes ($n=53$) or no changes ($n=65$). The areas of greatest self-perception of changes were nasal grooves ($n=25$), dark circles ($n=27$) and facial symmetry ($n=24$), when both threads were considered. The areas of lower perception of changes were wrinkles around the lips ($n=9$) and wrinkles around the eyes ($n=10$). No patient reported changes in the neck, because wire implants were not performed in this region

Discussion

This study allowed preliminary evaluation data from patients who received implantations of laser-cutting and molded threads in different regions of the face, in order to improve facial aesthetics. Although the data did not allow statistical comparisons, they admitted some observations for clinical trials when considering the two threads comparison, or in individualized thread comparisons over time.

In general, lifting threads are good options to correct facial aging. They have often been used due to the facility and safety,[17] the efficacy in pull up fallen tissues,10 because they are excellent collagen stimulators,[15] and because of the short period required for postoperative recovery [16]. The implantation of both threads used in this study took an average of 40 minutes, and the recovery of patients was also rapid and efficient with few adverse events. In general, the threads provided softness to the facial contours, complementing the aesthetic desired at the beginning of the treatment, which lasted during the ninety days of postoperative follow-up. The results were perceived by all patients. We observed a long durability, even after the period of threads complete resorption, probably due to their property in stimulating collagenase [15]. Barbed threads stimulate more collagenase than monofilament ones, probably due to spicules and tissue trauma. This contributes not only to the lifting persistence but also to improve the quality of the skin. We do not observed the postoperative skin quality. However, we consider this is a variable that can be evaluated in a clinical trial comparing the threads used in this study, because is it possible to assume that the molded threads could stimulate fibroblasts to produce collagen for longer, and this could be a reason for choosing this thread model for clinical use.

Due to the attaching competence of their bidirectional spicules, both barbed threads also provided good tissue fixation. The great length and the spikes of the used threads, certainly contributed to a larger amount of captured tissue, and also, defined better traction stability. Both pattern are two-way spiculated threads. The difference between them is that, in molded threads, the spicules are more stable over time [16]. As a result, the tendency is that these spicules change less over time than the laser-cutting threads. Despite this, both threads allowed traction and support of the tissues involved in grooves and wrinkles, and provided a very favorable aesthetic result over time. It was possible to verify that the threads revealed favorable results for their lifting promotion attributions in different regions of the face during the postoperative 90 days. In a clinical trial, we suggest this period be longer than that used in this study (around 180 days, for example), to

observe if this effect is the same for both threads, or if, clinically, the fact that the spicules are laser-cutting, really promote shorter duration for the lifting effect.

When postoperative signs and symptoms were investigated as soon as the anesthetic effect ceased, it was observed that pain and the sensation of skin traction at the intervention sites were the most prevalent adverse events. Few patients reported complications to contraindicate the use of the threads in question. Tissue pain and skin traction are two symptoms expected in postoperative thread implantation. In our point of view, these symptoms should not be considered as adverse events or even interurrences, since the implantation of barbed threads, requires perforation of the integument, and the thread is implanted in the subdermal region. The most sensitive nerve endings for pain are in superficial dermal layer, and are, therefore, involved in the procedure that happens in subdermal. Pain can be controlled with non-steroidal analgesics during the first 24 postoperative hours. Also applications of cold compress soon after the procedure tend to decrease postoperative pain.

Similarly, skin traction sensation is common after thread implantation. This is due to the action of the thread spicules. The main function of spiculated thread is to promote the traction of fallen tissues. This traction can be done with thread anchored in fascia of muscles or only by the action of the spicules. In this study, no anchoring of the implanted thread was done. The traction was only by the spicules action. In a recent work developed by our team, we demonstrated that laser-cutting threads have good tissue anchoring competence and ability to promote lifting [15]. We suggest that, for clinical trials, implantation of laser-cutting and molded threads should be done with and without anchoring in fascia. It will prove the best protocol for anchored threads, independent of the model.

There was no difference among the number of adverse events reported by patients who received both threads ($n=25$). In general, the implantation of resorbable threads does not develop expressive side events. Under this condition, 32% of the patients did not report any symptoms, and 6 of them received molded thread, which are thicker, and with higher chances of trauma. Although not investigated in this study, infections may arise as late postoperative events. It happens when asepsis and antiseptic care are not careful during the pre, trans and postoperative periods. In this study, care with asepsis and antiseptic was adopted in all procedures. It is advisable this must be an usual procedure and always performed with criterion. It is common for the operator to touch the cannula during the implantation of the threads. We consider important to be careful concerning this procedures, because, even if the handling of the cannulas is done with sterile gloves, the glove material itself may bring impurities inside the hypodermis and compromise the entire procedure. Similarly, postoperative care recommendations are critical to the success of the procedure. The patients of this study were instructed do not touch the sites of implantation of the threads, as well as do not remove the protective bandages before 7 days postoperatively. These factors, probably, contributed to decrease interurrences, migration and exposure of the threads, and must be maintained in clinical trials in order to do not add bias in the experiment.

When we investigated the satisfaction index of the treatment performed through the index attributed by the patients in the NVS, we observed that there was good acceptance regarding the treatment. Only one of the patients attributed index 5 to molded threads, and another that attributed index 6 to laser-cutting threads. The other ones attributed values above 7, and a good part, attributed scores 9 or 10 for both threads. These reports are important because the search for aesthetic solutions complementary to dental treatment has increased significantly in recent decades.

The intervention with spiculated threads can represent a good option the face lift and to collagen production. This alternative may add aesthetic quality to the dental treatments, especially when there is a facial rejuvenation component. In face lifting, probably the correction of the nasolabial groove and the erecting of the sagging jowls have a very close relationship with dental treatments, and requires studies about the interaction of dental and facial interventions. Through the observed in these preliminary results, we suggest that facial aesthetic treatments should be done after oral rehabilitation, orthodontic or orthognathic treatments with the threads used in this study for facial aesthetic improvement. The results should provide resources to select more securely the best thread to complement dental treatments.

In this study we defined the analysis of Caucasian adults' women, because of the higher prevalence of seeking face interventions. We did not consider standardization of age, ethnicity, parity of subjects between groups, neither concerning to implantation sites. All procedures we deemed necessary during case planning were performed, without selection of treated region. Also, we followed the results for 90 days; if the patients were followed up for more than 180 days, surely the results would be different.

Despite of the literature presents some trials done with few patients and without the necessary criteria for the selection of independent variables, in our opinion, some methodologic standardizations are necessary to provide reliable data for clinical applicability. Although it is more difficult to perform, experimental designs involving defined independent variables allow more appropriated results.

To measure the real effects of threads in a clinical trial, it is important to increase the number of patients. We observed that 25 patients are not enough to perform properly an experiment with this characteristic. Anyway, this study contributed to the sample calculation of a clinical trial, as it shows a tendency for data analysis.

The questionnaires were modified from that of literature¹⁸ and showed effectiveness in the composition of the study. When the data were investigated together, they gave confidence to suggest regarding a good efficiency of the used threads. According to the responses, the laser-cutting threads admitted great alterations in the treated areas. One of its advantages is the lifting of the structures, in addition to its fixation competence, where the result of traction depends directly on the material employed, the quantity and quality of the spicules, and specially its ability to promote collagen formation by the presence of spicules.¹⁵ Clinical trials to investigate the action of both thread for a longer period of time should be conducted, in order to further investigated the results of collagen formation and facial lifting quality. The ideal are studies in which biopsies be performed in tissues, and, through histochemical analysis, in addition to other variables that define tissue recompositing, the real formation of collagen can be observed. This study contributed to observe some limitations that can be followed or avoided in clinical trials.

Conclusion

The results suggest that both, laser-cutting or molded threads, allow good acceptance by patients, cause few adverse events and allow to treat different areas of the face successfully.

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