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Research Article

Autologous Fat Grafting for Women with Post-Partum Perineal Pain: A Pilot Study

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Abstract

Introduction: During delivery, the perineum is prone to develop lesions that could lead to dyspareunia. Perineal Autologous Fat Grafting (PAFG) appeared to be a promising solution to treat this symptom. Our study aimed to evaluate the safety and efficacy of this technique.

Methods: We conducted an observational retrospective study on patients who benefited from PAFG at the CHU de Limoges in France between from 2017 to 2021. Our primary objective was to evaluate pain before and one year after PAFG using a Numerical Rate Scale (NRS). The secondary objectives were pain evaluation at 3 and 6 months, and PISQ-12, Mac Gill Pain Questionnaire, Euro Qol, and Saint Mark's score.

Results: 55 patients were included. At one year, we observed a decrease in NRS in 45 patients (82%) with a decrease in mean NRS from 7.3 (CI 95% [6.86 - 7.78]) to 2.89 (CI 95% [2.05 - 3.72] ($p<0.001$). No serious adverse events were reported. At 3 and 6 months, results were favorable and clinically relevant.

Conclusion: PAFG seems to decrease perineal pain caused by labor. Further investigations should be carried out to evaluate impact on efficacy, pain, Euro Qol and anal incontinence.

Keywords: Autologous fat grafting; Dyspareunia; MacGill Pain Questionnaire; Perineal tear; PISQ-12; Saint Mark's score

Introduction

During childbirth, the perineum experienced stressors that could damage soft tissues. These lesions can have significant impact on the women's daily activities and could affect her social life and metal health. Dyspareunia, chronic perineal pain, urinary and anal incontinence are all symptoms that can result from a complicated vaginal delivery [1-8]. Dyspareunia was noted in up to 25% of women at one year following childbirth [5,9] and is defined as a painful or difficult sexual intercourse. The therapeutic arsenal for dealing with these symptoms remained limited. Fortunately, the Perineal Autologous Fat Grafting (PAFG), a technique mainly performed in breast reconstructive surgeries, seems to be a promising solution for patients suffering from post-partum dyspareunia and pelvic pain. The aim of our study was to evaluate the interest of the Perineal Autologous Fat Grafting (PAFG) for

the treatment of post-partum pain and to assess any possible complication of this procedure.

Materials and Methods

This was a retrospective observational study conducted at the University of Limoges (France). In order to be included, patients had to be French speakers, above eighteen years, complaining of post-partum pain greater than 4 /10 on the NRS, unresponsive to medical treatment, and have undergone the PAFG intervention at the CHU of Limoges (France) in the intention to treat post-partum chronic pain. The decision to perform PAFG for each case was discussed at the Multidisciplinary Consultation Meeting. The exclusion criteria were coagulation disorders, the absence of fatty sampling sites, patients under tutelage, and contraindication to general anesthesia. The main objective of the study was to have an improvement in perineal pain at or beyond one year of the PAFG. We listed all women who underwent PAFG from 2017 to 2021. Medical records were all retrieved from the University of Limoges's database. The questionnaires were distributed on papers. All the information and data collected were kept confidential. The ethics committee approved this study in December 2020 (No. 436-2020-92). We used MEDCAL© and R© software for statistical analysis. The comparison of patients before and after PAFG was done by Wilcoxon test for two pairing samples because our population did not follow a normal law. The significance threshold was defined by a $p < 0.05$. A logistical analysis was done to predict the influence of other variables like: age, Body Mass Index (BMI), time between childbirth and intervention, and re-injected fat volume.

During the discussion with the patients in consultation, we looked for difficulties and complications during childbirth. In the patients' records, we searched for the mode of delivery, the occurrence of an episiotomy, perineal, vaginal or anal sphincters injuries. An estimation of the pain was made on the pain Numeric Rating Scale from 0 to 10. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) was one of the validated questionnaires that we used to assess patients' feelings about sexuality and sexual intercourse. This aspect is often neglected while it appears to be crucial in the case of patients with dyspareunia. The MacGill Pain Questionnaire was likewise used to assist us in perceiving symptomatology and severity of chronic pain. Euro Qol was used to assess patients' quality of life. The Saint Mark's score allowed us to estimate anal incontinence. Complications were graded according to Clavien's Dindo classification. In the event of missing data for over a year due to the loss of follow-up, patients were contacted by phone and then mailed the questionnaires all over again. The similar scenario was also applicable during CoVID-19 pandemic. The primary outcome to judge the success of the treatment was to assess the pain Numeric Rating Scale for dyspareunia dating of one year or more. A decrease in pain on the NRS of 3 levels or more was considered a success. A complete improvement or reduction of fifty percent on the pain scale was also assessed. Likewise, worsening of dyspareunia was also evaluated.

The secondary outcome was the evaluation of the pain scale at 3 and 6 month interval, and the following questionnaires and classifications: Euro Qol, the PISQ-12, the Mac Gill Pain questionnaire, and the Saint Mark's score. The fat sampling follows the Coleman's technique [10]. The patient received 1g of cefazolin as antibioprophylaxis, and she had to be up-to-date regarding the antitenanic vaccination. Fat tissue was taken from the abdominal level, the inner side of the thighs, hips or knees. A specific suction cannula of 3 or 4 mm was used, with foam ends and openings, wide enough to allow the suction of adiposal tissue. This cannula was then connected to a vacuum Redon bottle. Passages were made in a superficial way and across the entire sample area being the least traumatic for the cells and the most regular on the affected area. Once the material was collected, it was purified by centrifugation. [11-14] The first step was to spread the fat in 10 mL shut-up syringes. They were placed in a sterile rack before centrifugation. The equipment was centrifugated at 1000 rpm for 1 minute. At the end of the procedure, we could identify 3 phases in the syringes of 10 mL: The overflow made of triglycerides and damaged adipocytes was simply removed by drain. The bottom of the syringe contains figurative elements of blood that were not preserved. The middle part contains the noble elements: stroma, adipocytes, growth factors. Gently and without pressure the purified sample was distributed in 2 m L syringes before reinjection.

The adipocytes were reinjected using a 9 cm long transfer cannulas. The end of the cannula was foamed to avoid further trauma or to create a hematoma at the scar level. The injection was done through the lateral side of the cannula to avoid an intra-vascular injection, which could be lethal. The size of the cannula and hole was large enough to inject adipocytes without damaging them. The caliber should not be too wide to limit the injection of too much fat and create a secondary necrosis of the graft. The area where fibrosis prevails was detected by palpation. A cutaneous incision was made using a catheter needle. The cannula was inserted and the injection was done by removing the cannula. It was important to create a multitude of tunnels that cross each other in order to deposit the fat in the form of mesh or parallel tunnels. Once the procedure was completed, the scar's laxity was checked. A solution of local anesthetic was injected into the sampling sites before closing the skin with a Prolene® 2-0. Procedures could be repeated if the results were incomplete. The main advantage was the fully biocompatible and non-toxic character of fat tissue, the comfort of fat, its ability to implant, and to persist over time even despite some initial losses.

Results

From january 1st, 2017 to january 1st, 2021, ninety three patients received PAFG. Of which 9 patients had pain in the perineum that was not related to childbirth (pain after perineal surgery, physical activity or cause not found), 5 had never received a questionnaire, 14 patients were followed for less than a year and 10 had a PAFG in order to prepare the perineum for sphincteroplasty or for causes of anal incontinence. Fifty five patients were included in our study (Figure 1).

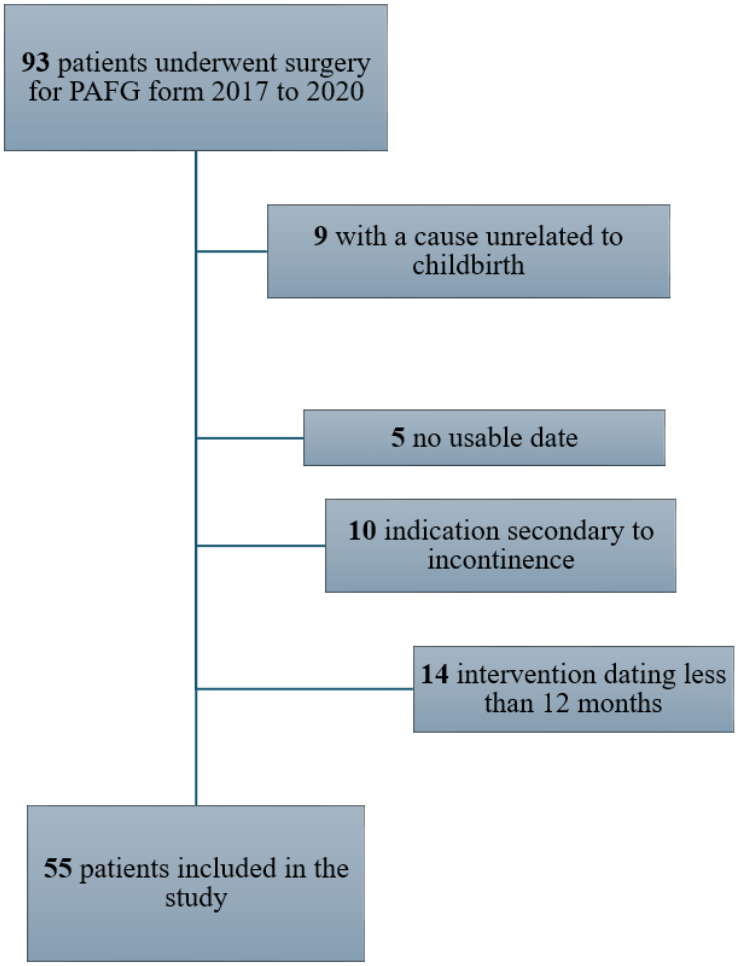

Figure 1: Flow chart.

The characteristics of our population were shown in Table 1: 56% were primiparous. Twenty tow percent of the patients were smoker and forty seven percent had an operative vaginal birth. Thirty nine patients (71%) had a pre PFAG pain score ranging from 7 to 10. The most common perineal lesion type was episiotomy present in 58% of patients. Nine women had two PAFG sessions, and one had 3 sessions.

	Mean (SD)	CI 95%	Median [SD]	Minimum	Maximum	N
Age	31.6 (5,1)	[30.2 - 33]	31 [27.5 - 35]	20	44	55
NRS dyspareunia pre PAFG	7.3 (1.7)	[6.86 - 7.78]	8 [6 - 8]	4	10	55
BMI (Kg/m²)	24.7 (4.62)	[23.4 - 26]	24 [21 – 27.8]	18	41	55
Time between childbirth and intervention (month)	29.5 (28.7)	[21 - 36.8]	18 [14 - 31]	7	148	55
Euro Qol	43.4 (24.3)	[36 - 50.8]	40 [20.0 - 61.2]	5	100	44
PISQ 12	18.4 (6.15)	[16 - 21]	17 [15.2 - 20.8]	9	41	26
MacGill Pain Questionnaire	29.1 (13.1)	[23.7 - 34]	29.5 [19.2 - 41]	6	56	26
Saint Mark's score	12.3 (3.5)	[10.3 - 14.1]	12 [7.75 - 12.39]	5	19	15
Volume reinjected PAFG (mL)	34 (14,2)	[30 - 37.8]	32.5 [23.2 - 40]	12	71	54

Table 1: Characteristics of the populatin.

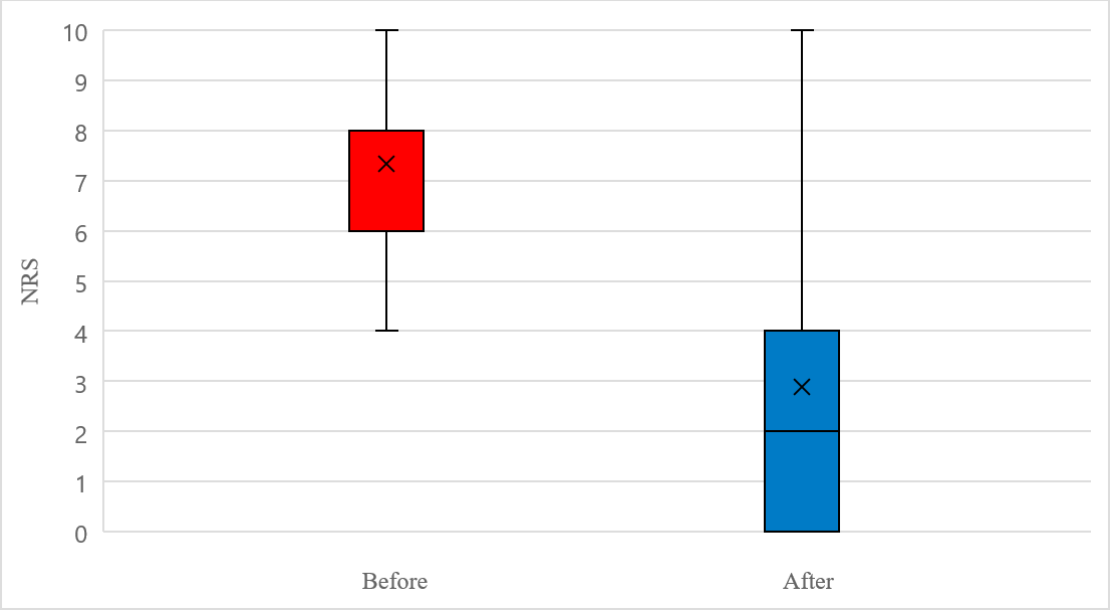

Figure 2: Evolution of NRS in the population at 12 months.

The mean pain value on the NRS after 1 year was decreased from 7.3 (95% CI [6.86 - 7.78]) to 2.89 (95 % CI [2.05 - 3.72]) in a sample of 55 patients. The decrease of mean pain value was statistically significant between the period before and after PAFG, with a decrease of 4.41 points [3.60 - 5.27] ($p<0.001$) (Figure 2). A decrease of the pain greater or equal to 3 points was found in 76% (n=42) of patients, and 67.3% (n=37) had an NRS less than 3/10, of which 17 had no pelvic pain (NRS=0), and 81.8% (n =45) had an improvement in their pain. Forty-one patients benefited from a 50% reduction in their pain, and 7.3% (n=4) of patients reported increased pain (Figure 3 and 4). One should note that this last analysis was not done 1 month after the procedure and was focused on the complications directly related to the surgery.

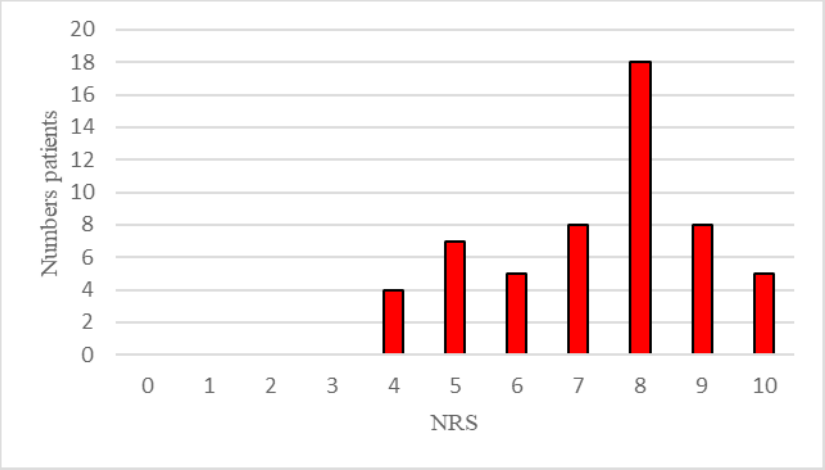

Figure 3: The distribution of patients according to their NRS before PAFG.

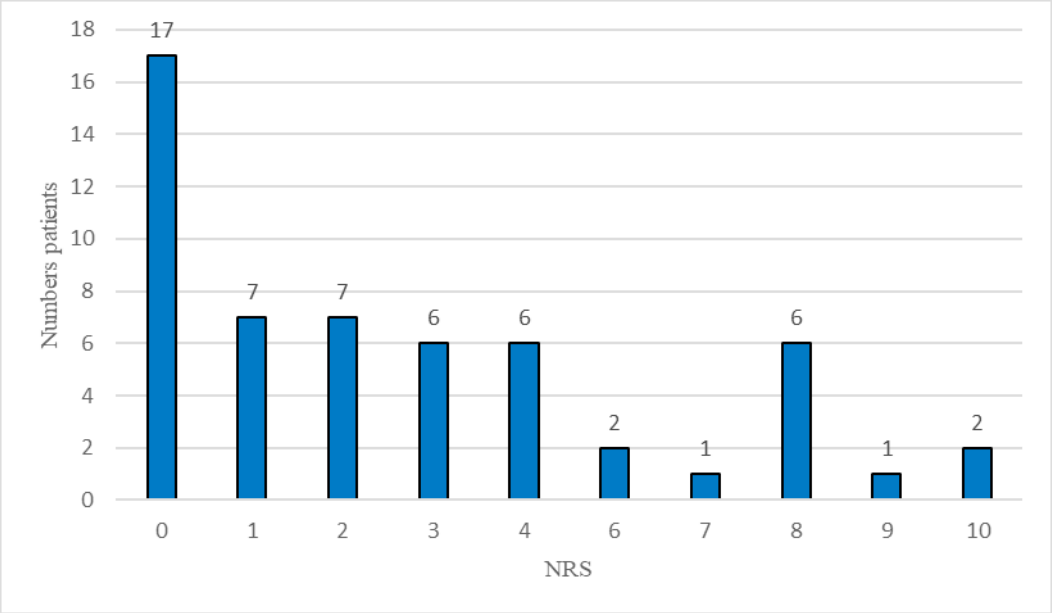

Figure 4: The distribution of patients according to their NRS 12 after months.

The main complications were postoperative pain in the sampling areas. Two required hospitalizations: one for monitoring of rectal pique suspicion without subsequent repercussions (simple monitoring/ with no further consequences) and the other for the administration of stage I and II intravenous analgesics, classified as grade I according to Clavien's Dindo classification. No cases of serious complications have been reported. One patient reported an increase of her urinary incontinence. Of the 55 patients, 4 (7.3%) had a slight increase in their post PAFG pain compared to their previous pains. At 3 months, a significant improvement in pain was observed, with a mean decrease of 4.34 points [3.38; 5.30] ($p<0.01$). Pain levels dropped from 7.38 (95% CI [6.76; 7.96]) to 3.03 (95% CI [2; 4]) in a sample of 32 patients (58%). This reduction is both statistically significant ($p<0.001$) and clinically relevant. At 6 months, improvement in dyspareunia becomes noticeable, with a decrease of 4.3 points [3.17; 5.34], from 7.3 (95% CI [6.8; 7.8]) to 3 (95% CI [2.02; 4.03]) ($p<0.001$). However, a limitation of this analysis is the lack of data, with only 31 patients (56% of the initial cohort) available (Figure 3).

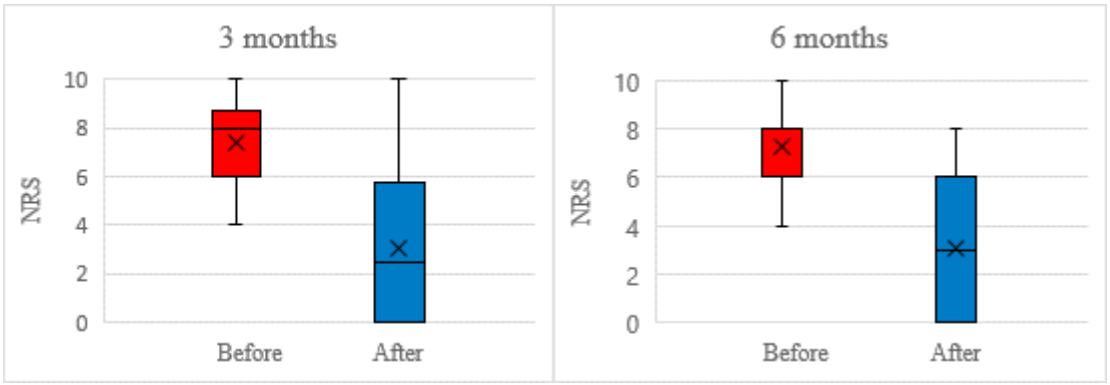

Figure 3: Evolution of NRS in the population at 3 and 6 months.

Euro Qol shows a significant increase of 35.2 points at 3 months, though on a reduced sample ($n=26$, $p<0.001$). The mean score increased from 46.3 (95% CI [36.5; 56.2]) pre-operatively to 81 (95% CI [76.3; 86.7]). At 6 months, despite a limited sample size ($n=26$), an improvement of 32.3 points was observed, from 45.8 (95% CI [35; 56]) to 78 (95% CI [70.7; 85.4]) ($p<0.001$). At 1 year, among 38 patients (69%), the improvement was sustained with a 35-point increase, from 45 (95% CI [37; 53]) to 80 (95% CI [75; 85.2]) ($p<0.001$) (Figure 4).

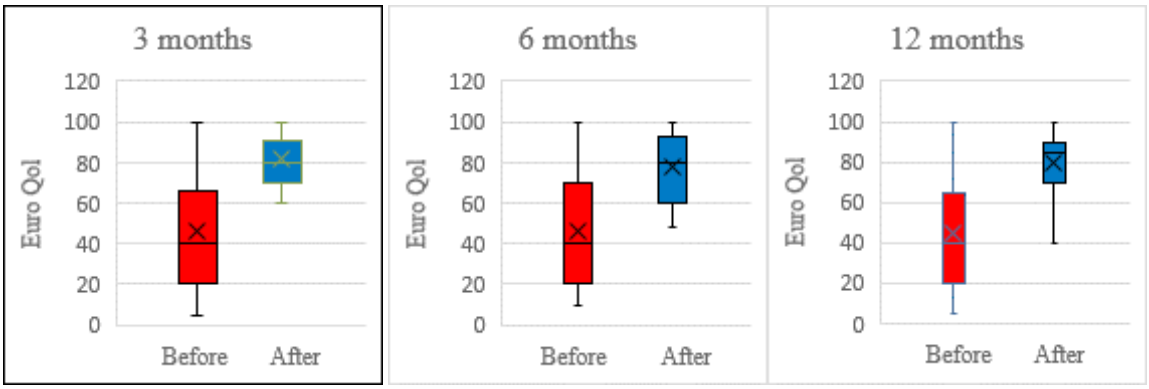

Figure 4: Evolution of Euro Qol in the population at 3, 6 and 12 months.

Regarding the PISQ-12, at 3 months, 13 patients were analyzed, showing a significant reduction of 8.5 points, from 20.2 (95% CI [16.1; 24.3]) to 11.7 (95% CI [9.8; 13.6]) ($p<0.01$). At 6 months, an analysis of 11 patients also showed a reduction of 9.1 points, from 21.4 (95% CI [17; 25.4]) to 12.3 (95% CI [10; 14.4]) ($p<0.01$). At 1 year, among 19 patients, the PISQ-12 score decreased from 16.6 (95% CI [14.8; 18.5]) to 12.7 (95% CI [10.8; 14.7]), a reduction of 3.9 points ($p<0.01$) (Figure 5).

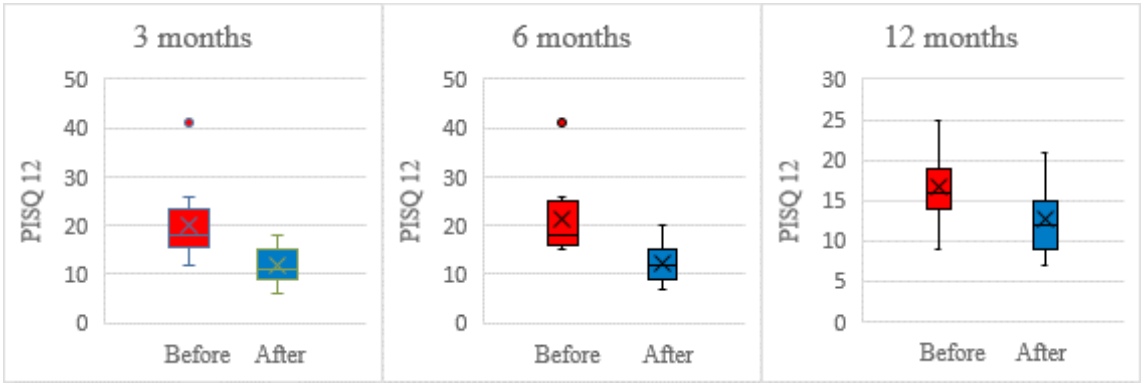

Figure 5: Evolution of PISQ 12 in the population at 3, 6 and 12 months.

MacGill Pain, analyzed in small cohorts, showed a reduction of 17 points at 3 months, from 28 (95% CI [21; 35.6]) to 11.2 (95% CI [6.8; 15.5]) ($p<0.01$) among 12 patients. At 6 months, in a sample of 10 patients, pain decreased from 31.1 (95% CI [21.7; 40.5]) to 15 (95% CI [8.3; 21.7]), but this difference was not significant ($p=0.051$). At 1 year, in 20 patients, a significant reduction in pain was observed, from 28.6 (95% CI [22.5; 34.8]) to 14.6 (95% CI [9; 20.2]) ($p<0.01$) (Figure 6).

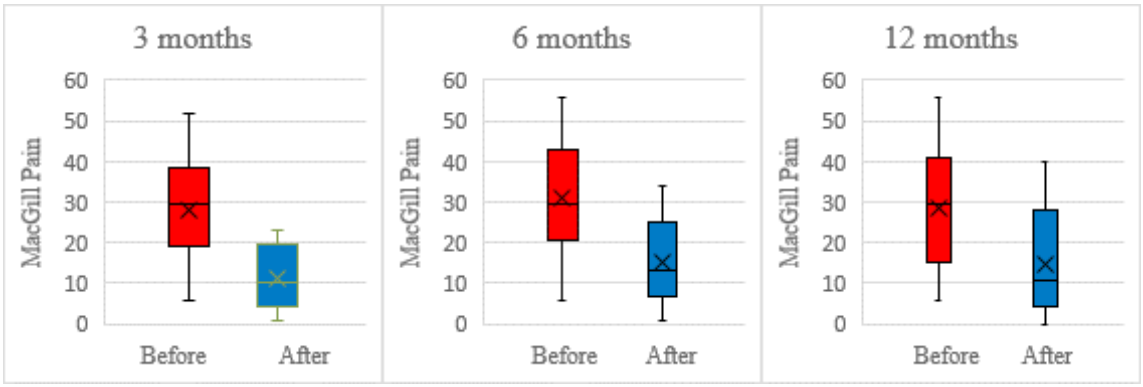

Figure 6: Evolution of MacGill Pain in the population at 3, 6 and 12 months.

As for the Saint Mark's score, an analysis of 15 patients one year after PAFG showed a significant decrease of 8 points, from 12.3 (95% CI [10.6; 14]) to 4.3 (95% CI [2; 6.5]) ($p<0.01$) (Figure 7).

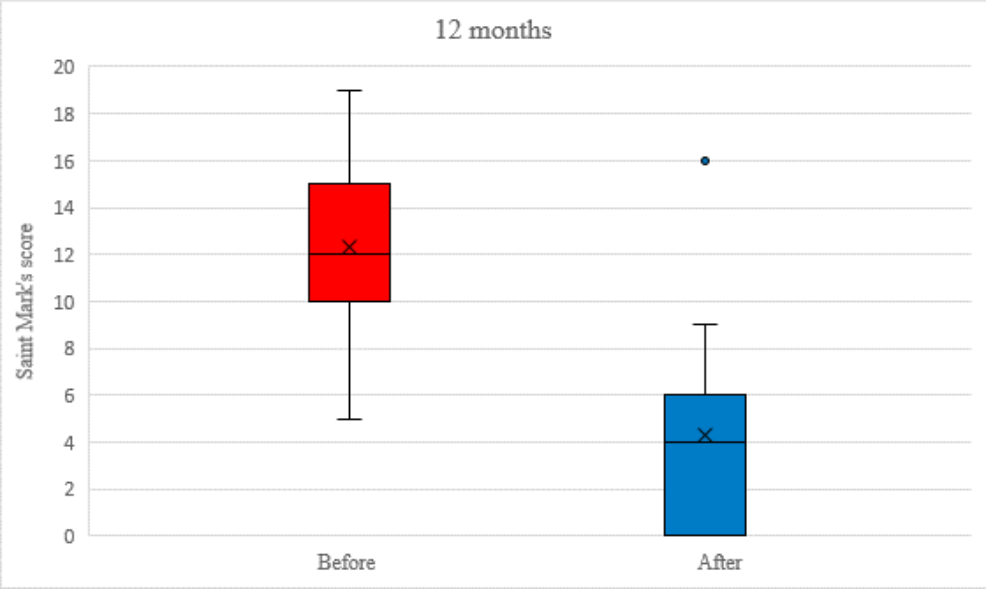

Figure 7: Evolution of Saint Mark's score in the population.

We also conducted a logistical analysis on certain parameters such as age, BMI, the time between delivery and intervention and the volume re-injected fat. The only significant difference was a greater risk of failure that increases with the amount of reinjected fat OR=0.95 (95% CI [0.89-0.99]), (p=0.044).

Discussion

At one year, our study has showed an improvement in dyspareunia of 3 points in 76% of cases. This difference was statistically significant. Indeed, 31% of patients reported zero NRS; 67.3% of cases reported less than 3/10 pain and 75% of patients reported a 50% pain reduction. These results are clinically interesting. By analyzing PISQ-12, Euro Qol, the MacGill Pain Questionnaire and the Saint Mark's score, there was also an improvement in sexual activity, every day's life, women's pains, and anal incontinence. The main complications were postoperative pain. We did not observe any serious adverse events. A moderate increase in dyspareunia was observed in 4 patients. Ten women had more than one PAFG session. Our results were in line with to those reported in literature. In 2012, Ulrich et al. published a prospective study assessing perineal pain after a PAFG, involving 20 patients. Their results were in favor of a significant improvement in pain according to the MacGill Pain test. This improvement appeared in the first month and persisted 6 months later [15]. In 2013, Zetlitz published the care of a patient with post-partum gynecological functional signs treated by PAFG with favorable results [16]. In 2016 Aguilar et al. coupled this technique with the injection of plasma enriched with platelets and hyaluronic acid in a woman suffering from pain on an episiotomy scar: first they injected hyaluronic acid and platelet at the level of the episiotomy scarring and then the PAFG to the vaginal wall. This reduced pain, incontinence and improved sexual activity [17]. Recently in August 2020 and more broadly, a meta-analysis of 3033 patients with various indications of PAFG (burns, dyspareunias, fracture, radiotherapy,..) showed interest in this method with a significant decrease in pain of 3.7 points, with a low risk of non-serious complications (pain, edema, haematomas) 4.8% (95% CI [3.2-7]) [18]. Regarding safety, PAFG was used in aesthetic surgery at the vaginal level. Studies show that the risk of complications was rare [18,19]. However, these studies are few and have a low level of evidence.

The strengths of our study were the use of validated questionnaires including the PISQ-12 specific to sexual activity. The NRS was an easy-to-use one-dimensional scale of interest for intra-individual tracking. The MacGill Pain Questionnaire is a multidimensional scale to assess the dimension of physical, psychological, social, and behavioral pain. As far as we know, our study presents the largest population in the literature with the most tests used. The informations were collected during consultation and were recorded in the patient's medical record. Concerning the unsatisfactory results, they are more likely linked to bias of confusion and not to a failure of the technique: in fact, these patients were diagnosed of endometriosis or adenomyosis on MRI and these pathologies can cause deep dyspareunia.

Concerning the four patients who observed a worsening of their symptoms, one case was related to the presence of adenomyosis

and pelvic varicose veins. Two were related to the absence of fat in the painful areas, either due to failure of injection at the site level (difficulty to create a space between the adhesions leading to a challenging PAFG's distribution around the fibrosis) or due to necrosis of the transplant. Nevertheless, these two patients had a new PAFG session with favorable results. One case remained unexplained to date. On the other hand, six patients had no improvement in their pain: two of them had adenomyosis and one patient had a failure of engraftment. We also had a case of transitory improvement followed by degradation of NRS with loss of the transplant that may be due to excessive weight loss even though neoangiogenesis should theoretically persist. Two patients did not improve although the transplant was present on the ultrasound. Moreover, three other patients did not have a significant reduction in their pain (loss < 3 points on NRS). One case was explained by neurological lesions secondary to childbirth, one patient suffered from adenomyosis and the last patient had only partial engraftment of her transplant. We observed a statistically significant and clinically relevant improvement. This improvement lasts over time where other treatments have failed. Its application for pain after a traumatic vaginal birth was recent. We did not find any more serious complication potentially. The analysis of the values of Euro Qol, PISQ-12, MacGill Pain Questionnaire and Saint Mark's score did not concern the analysis of the total population. We did not have sufficient data to do this analysis, not all women received these questionnaires at 3, 6 and 12 months. We relied on the average of the responses found before PAFG that were compared to the values obtained at 3, 6 and 12 months for the same patients. The psychological impact of women has not been studied through specific tests since many women were unable to answer all of our questions because they had not resumed their sexual activity due to fear of pain during intercourse. Among our questionnaires, the Euro Qol and the MacGill Bread Questionnaire are general and non-specific scales of sexual activity. The Female Sexual Function Index (FSFI) [20] and the Brief Index of Sexual Functioning for Women [21,22] questionnaires could have been used; these were both validated and frequently used tests in sexual dysfunction in women.

Conclusion

Our experience has shown a decreased perineal pain following a vaginal delivery after PAFG et 3, 6, and 12 months with few low grade adverse events. This new alternative surgical therapy seemed promising. This technique remained currently underused, and only few studies with low power were available. Our results could only invite to prospective powerful studies.

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