Correction of Rectus Abdominis Diastasis: A Prospective Comparative Study Between a New Suturable Polypropylene Mesh vs Polypropylene Standard Suture Plication

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Abstract

Background: Duramesh (Mesh Suture Inc., Chicago, IL) is a new suturing concept, combining the principles of mesh with the precision, flexibility, and versatility of a suture, suitable also for abdominal rectus diastasis (ARD) correction.

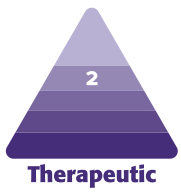
Objectives: This prospective research aimed to compare mesh with the standard polypropylene suture plication for rectus diastasis repair with regard to safety (infection, seroma, hematoma, surgical wound dehiscence, and fistula rates and hospital stay); effectiveness (ARD recurrence by ultrasound sonography, palpability of the muscular suture, surgical time, and postoperative pain evaluation); and satisfaction of the patients based on the BODY-Q, a patient-reported outcome measure.

Methods: Sixty-five of the initial 70 patients who underwent rectus diastasis repair with a 6-month follow-up were randomly divided into 2 groups, comprising 33 patients treated with Duramesh and 32 patients treated with standard 0 polypropylene suture plication. Data regarding infection, seroma, hematoma, surgical wound dehiscence, and fistula rates; hospital stay; ARD recurrence; palpability of the muscular suture; surgical time; postoperative pain evaluation (measured by visual analog scale, or VAS); and the BODY-Q were analyzed by Prism 9 (GraphPad Software Inc., San Diego, CA).

Results: No significant differences were reported between the 2 groups with regard to infection, seroma, hematoma, surgical wound dehiscence, and fistula rates and hospital stay. The mesh decreased the time required to perform plication compared with standard polypropylene detached sutures. No statistically significant differences were found with respect to the VAS and BODY-Q data.

Conclusions: Duramesh 0 application for rectus diastasis repair is safe and effective without compromising aesthetic improvement when compared with standard 0 polypropylene plication.

Level of Evidence: 2



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Abdominal rectus diastasis (ARD) related to pregnancy, massive weight loss, or previous abdominal surgery is a condition that affects the quality of life of patients, including both activities of daily living and physical tasks.[1-4] ARD may be associated with low back pain, abdominal discomfort, urinary incontinence, and other problems.[5,6] There are several techniques and approaches for the correction of ARD.[7] A direct median access or abdominoplasty access (according to Pfannenstiel access prolonged bilaterally toward the anterior superior iliac spines), or a mini-abdominoplasty technique can be utilized.[8,9] Absorbable or nonabsorbable sutures may be placed to perform the muscle plication.[10] Furthermore, mesh or autologous tissues, helpful for the stabilization of the surgical correction, should also be considered.[11,12] Endoscopic surgery, albeit with some limitations, can also be a viable alternative.[13-15] Plication of the linea alba represents the gold standard for treatment of ARD.[16] Sometimes, especially as a result of strain in the immediate postoperative period, the plication may fail before the fibrosis that internally stabilizes the abdominal wall has formed. For this reason, plastic surgeons are searching for new stronger materials and increasingly effective techniques suitable for supporting the forces exerted by the abdominal wall to allow the proper correction of diastasis and avoid the possible recurrence. A new medical device based on polypropylene (Duramesh; Mesh Suture Inc., Chicago, IL) has recently come on the market. It is CE (conforming to European standards) and FDA approved. This is a new suturing concept, combining the principles of meshes with the precision, flexibility, and versatility of a suture, suitable for ARD correction.[17] This nonabsorbable suture is made of 12 polypropylene filaments woven into an open cylindrical crosshatch configuration.[18] The power of this new technology lies in the distribution of forces across the suture-tissue interface and in its significantly greater strength compared to conventional suture materials.[19] Its structural composition is also designed to resist suture pull-through.[18] The filaments provide a suture-tissue interface 5 times larger than that offered by conventional sutures. Also, with its macroporous structure, a larger surface area than standard sutures is ensured. This permits a fibrovascular ingrowth and the encapsulation of individual filaments.[20] It is available in 4 USP sizes; the authors suggest Duramesh 0 for rectus diastasis repair. In the current literature, Duramesh has been reported as a valid ally for the closure of the linea alba in the porcine abdominal wall, especially when performed in small bites (ie, 5 mm between 2 consecutive stitches and a 5-mm distance from the incision).[18] This prospective research aimed to compare this mesh with the standard polypropylene suture plication for rectus diastasis repair as far as safety (infection, seroma, hematoma, surgical wound dehiscence, and fistula rates and hospital stay); effectiveness (ARD recurrence by ultrasound sonography, palpability of the muscular suture, surgical time, and postoperative pain evaluation); and satisfaction of the patient based on a patient-reported outcome measure, the BODY-Q abdomen scale.

METHODS

Seventy consecutive patients who underwent rectus diastasis repair from August 2022 to January 2023 were enrolled in this prospective study. Inclusion criterion were a male or female undergoing rectus diastasis repair with concomitant skin tailoring through conventional abdominoplasty, with a follow-up of 6 months. We excluded patients with: concurrent sizable ventral hernia who required intra-abdominal dissection, rectus diastasis ≤4-cm diameter, psychiatric disorders, immunological disorders, bleeding disorders, diabetes mellitus, uncompensated comorbidities, previous rectus diastasis correction procedure, a BMI higher than 30, concomitant liposuction procedure or concomitant other procedure (eg, breast or thigh tailoring procedures), or follow-up of less than 6 months after surgery. Follow-up included a postoperative examination 4 days after surgery, then 1 visit every week for the first month and at 3 and 6 months postsurgery. Each surgical procedure was performed by the same senior surgeon and the same 2 residents to avoid technique bias. The patients were made aware of this clinical investigation and signed a specific written consent. Assigning each patient a code, a physician who was external to the surgical team and to the statistical analysis process randomly divided the patients into 2 groups. A random number generator software was employed (RANDOM.org). Group 1 comprised patients undergoing diastasis correction with Duramesh, and Group 2 was the control group (standard 0 polypropylene suture plication). Initially, we decided that each group would include 35 patients. Three patients were excluded because of lack of follow-up, and an additional 2 patients were excluded due to an intraabdominal dissection for hernia repair. The final sample was composed of 65 patients: 33 patients in Group 1 and 32 in Group 2. Sociodemographic and medical characteristics were defined for both groups (Tables 1, 2). The patients underwent an ultrasound 6 months postoperatively to ensure that there was no recurrence of diastasis. During each postoperative visit, a physician external to the surgical team compiled a report that included signs of infection or seroma, palpability of the muscular suture, and presence of wound dehiscence, fistula, or hematoma. A visual analog scale (VAS) was administered to each patient at 1 and 2 weeks after surgery to evaluate variations in pain occurrence between the 2 groups.[21] Hospital stay (in days) was also reported. In each surgery we timed the plication procedure, which was performed by the senior surgeon only. The BODY-Q abdomen scale was administered in the preoperative setting and after 6 months.[22] Each BODY-Q abdomen scale total score was converted to a RASCH scale

Table 1. Distribution of Patients Treated With Duramesh Suture Alone (Group 1) and With Standard 0 Polypropylene Suture Plication (Group 2), According to Sociodemographic Characteristics

Sociodemographic characteristics	Group 1		Group 2	
	n	%	*n*	%
Sex				
Female	20	30.77	17	26.15
Male	13	20	15	23.08
Age				
< 45	28	43.08	25	38.46
≥ 45	5	7.69	7	10.77
Marital status				
Single/divorced	6	9.23	8	12.31
Not single	27	41.54	24	36.92
Occupation				
Yes	28	43.08	30	46.15
No	5	7.69	2	3.08
Education				
Primary education	3	4.62	0	0
Higher education degree	30	46.15	32	49.23

Percentages are based on total number of patients (65).

Table 2. Patients' Medical Characteristics and Medical History

	Group 1		Group 2	
	n ± SD	%	*n* ± SD	%
Comorbidities and medical history				
Smoking habit				
Current	0	0	1	1.54
Former	12	18.46	13	20.00
Never	21	32.31	18	27.69
BMI	24.67 ± 2.70		24.88 ± 2.64	
Intraoperative maximum width of rectus diastasis (cm)	5.32 ± 0.65		5.36 ± 0.61	
Intraoperative diastasis and plication length (cm)	24.29 ± 2.002		24.13 ± 2.095	
History of pregnancies	18	27.69	14	21.54
Twin pregnancy	1	1.54	0	0
History of abdominal surgical procedure	22	33.85	27	41.54
History of bariatric surgeries	19	29.23	25	38.46
Concomitant intraoperative hernia diagnosis and treatment without intraabdominal dissection	15	23.08	6	9.23

Percentages are based on total number of patients (65). BMI, body mass index

score, providing evaluation on a scale ranking from 0 to 100, to better compare statistical results.[23] All data (including plication time and plication centimeters) were provided to a physician external to the surgical team after every procedure, and were exported to an Excel worksheet (Microsoft Corporation, Redmond, WA) and then to Prism 9 (GraphPad Software Inc., San Diego, CA) for the descriptive analysis. The study was set up as single-blind. Statistical significance of the BODY-Q abdomen scale score delta (between preoperative and postoperative scores) was investigated by unpaired *t* test with Welch's correction. Statistically significant differences of deltas between the 2 groups were evaluated with the Mann-Whitney test. This study was conducted in accordance with local regulations, international standards of good clinical practice in the European Community, and the principles of the Declaration of Helsinki.

Technique

In each surgical procedure, the skin incision was made with a cold no. 10 blade, with the lowest point of incision 6 to 7 cm from the vaginal fornix or base of the penis. The incision was prolonged bilaterally toward the anterior superior iliac spines. The dissection over the rectus muscle sheath was conducted up to the xiphoid process with the electrocautery cutting function. The umbilicus was isolated with a cold no. 15 blade. Any hernia located was reduced, and its breach was sutured with 2-0 Vicryl (Ethicon, Raritan, NJ). In Group 1, the diastasis of the rectus muscles was corrected with the polypropylene mesh, the first stitch being placed near the xiphoid area, with a knot falling inside so that the suture knot could not be felt from outside. A continuous suture of the fascia of the rectus muscles was performed with Duramesh (soaked in a sterile lubricant, Vaseline [Unilever, London, UK], to improve flow through tissues) to correct the diastasis (Figures 1, 2). At the umbilicus, the continuous suture bypassed the umbilicus, passing only on 1 side, and began again with both rectus muscles below the umbilicus (Video 1, available online at www.aestheticsurgeryjournal.com). The last suture knot was covered with small fat flaps to reduce palpability. In Group 2, diastasis was corrected with standard diastasis correction, utilizing 0 polypropylene single stitches (figure-of-8: in-out on 1 side and then out-in at the same level on the other side of the fascia, and then 0.5 cm lower in-out on the

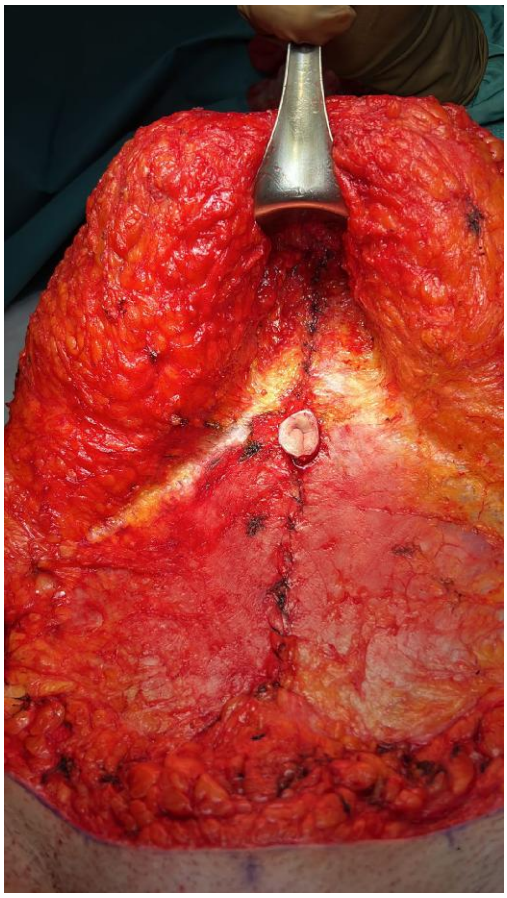


Figure 1. Intraoperative photograph of Duramesh (Mesh Suture Inc., Chicago, IL) for rectus diastasis repair.

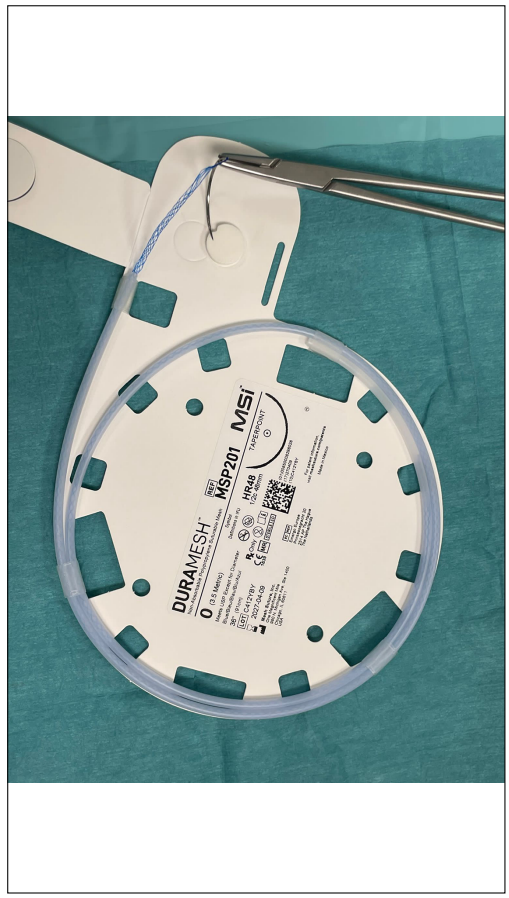
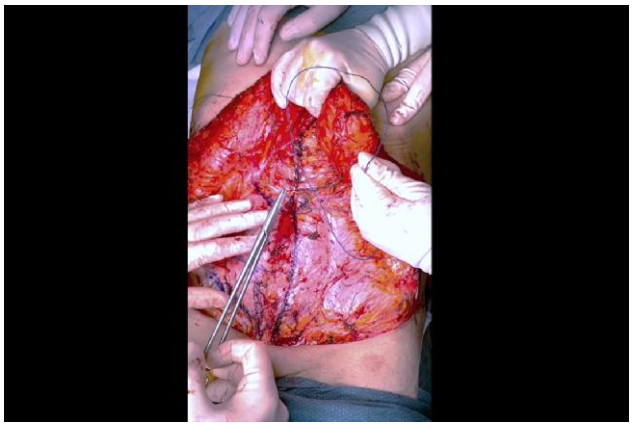


Figure 2. Photograph illustrating Duramesh (Mesh Suture Inc., Chicago, IL) conformation.

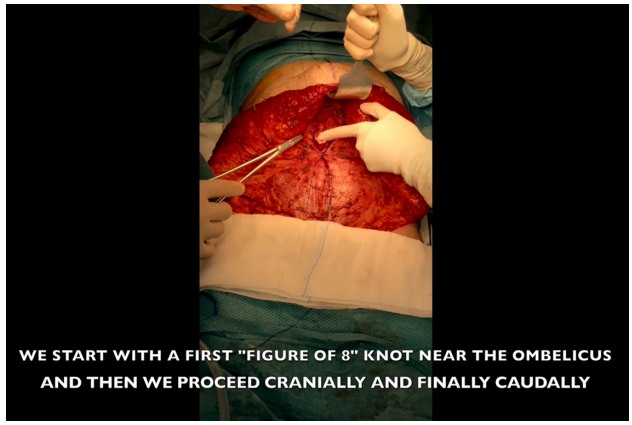
first side and out-in on the second side), with the knot falling on the inside (Video 2, available online at www.aestheticsurgeryjournal.com). No plication other than the median was performed. After skin tailoring, omphaloplasty was performed.[24] Two no. 16 drains, according to Redòn, were placed in situ.[25] These were removed 3 to 5 days after surgery, depending on the quantity of serum. A layered suture was performed with 2-0 Vicryl, 3-0 Vicryl, and 4-0 Vicryl Rapide. An elastic compression dressing was applied immediately after each surgical procedure, and a postoperative abdominal garment was placed in situ for 1-1/2 months.

RESULTS

The Mann-Whitney test and unpaired *t* test with Welch's correction demonstrated comparability of groups 1 and 2 for gender, BMI, age, and intraoperative rectus diastasis maximum width ($P > .05$). The majority of the study sample was composed of female patients, younger than 45 years old and not single. The other sociodemographic characteristics are reported in Table 1. BMI mean values were 24.67 ± 2.70 for Group 1 and 24.88 ± 2.64 for Group 2. Table 2 shows patients' comorbidities and ARD-related medical history events. No infection was detected in Group 1 patients during the follow-up time; only 1 patient (1.54%) in Group 2 had a procedure-related infection. Seroma rate was 1 of 65 (1.54%) in Group 1, and 2 (3.08%) in Group 2. Few hematomas were detected after surgery: 2 (3.08%) in Group 1, and 1 (1.54%) in Group 2. In 4 cases (6.15%) there was a surgical wound dehiscence in Group 1, with 3 cases (4.62%) in Group 2. On average, hospital stay was 2.030 days and 2.063 days for groups 1 and 2, respectively. No rectus diastasis recurrence was detected at 6 months after surgery by ultrasound in either group. In 2 patients (3.08%) of Group 2 there was palpability of the muscular suture over the skin. Each plication was timed (sec) and the greatest length of the plicated area was measured (superior-inferior diameter in centimeters). The mean length for Group 1 was 24.29 ± 2.002 cm, while for Group 2 it was 24.13 ± 2.095 cm. The mean plication time for Group 1 was 420 seconds (7 minutes, 10 seconds), while for Group 2 it was 803 seconds (13 minutes, 39 seconds). The Gaussian distribution of measured lengths for each group



Video 1. Watch now at http://academic.oup.com/asj/articlelookup/doi/10.1093/asj/sjae006



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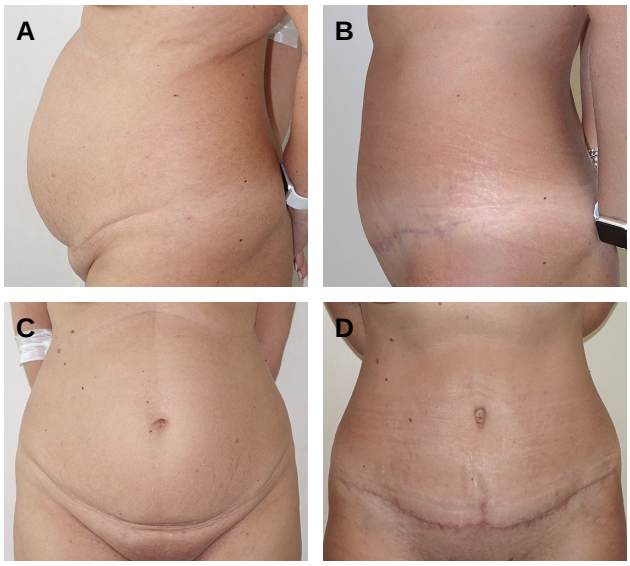

Figure 3. (A, B) Lateral view and (C, D) frontal view preoperative and 6 months postoperative photographs of a 39-year-old female patient who underwent abdominal rectus diastasis repair with utilization of Duramesh.

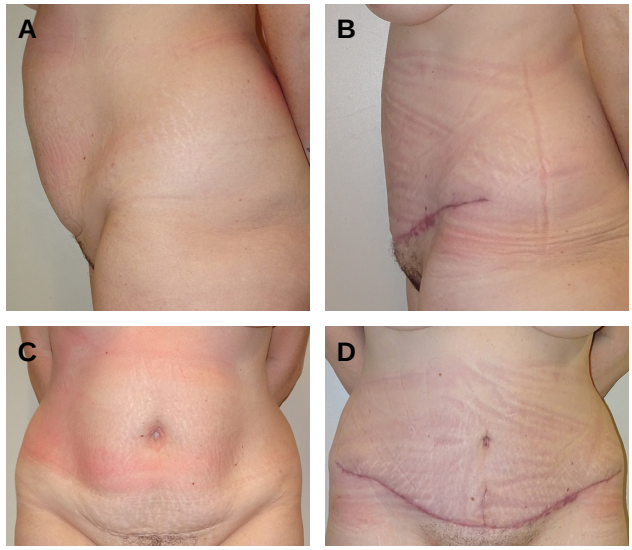

Figure 4. (A, B) Lateral view and (C, D) frontal view preoperative and 6 months postoperative photographs of a 35-year-old female patient who underwent abdominal rectus diastasis repair with standard polypropylene suture plication.

was evaluated with the Shapiro-Wilk test. An unpaired *t* test with Welch's correction was conducted to assess whether there was a statistically significant difference between those values, but this was not demonstrated. The BODY-Q abdomen scale mean value rose from 25.27 ± 4.90 to 71.33 ± 7.59 6 months postoperatively for Group 1. In Group 2, the mean value, converted to the RASCH scale, rose from 26.59 ± 5.19 to 70.41 ± 7.42. The Wilcoxon matched-pairs signed rank test showed statistically significant differences between BODY-Q preoperative and postoperative values in each group. The delta mean values (preoperative and postoperative) were calculated. The Mann-Whitney test did not prove a statistically significant difference of BODY-Q deltas between the 2 groups. Regarding the postoperative pain experienced by patients, VAS mean values reduced from 3.49 ± 0.97 (first week) to 2.15 ± 0.83 (second week) for Group 1, and from 3.38 ± 0.94 to 2.47 ± 0.76 for Group 2. There were no statistically significant differences between groups 1 and 2 values either at 1 or at 2 weeks postoperatively by Wilcoxon matched-pairs signed rank test. The outcome rates and BODY-Q and VAS mean values are provided in Table 3.

Table 3. Outcomes Evaluated Over Follow-up Time

	Group 1		Group 2	
	n	%	*n*	%
Outcome				
Infection	0	0	1	1.54
Seroma	1	1.54	2	3.08
Hematoma	2	3.08	1	1.54
Surgical wound dehiscence	4	6.15	3	4.62
Fistula	0	0	0	0
Hospital stay (days)	2.030		2.063	
Rectus diastasis recurrence by ultrasound evaluation	0	0	0	0
Plication suture palpability	0	0	2	3.08
Plication time (sec)	420		803	
BODY-Q abdomen scale Rasch values				
	Group 1		Group 2	
	Pre	6 months PO	Pre	6 months PO
Mean values converted to Rasch scale (0-100)	25.27 ± 4.90	71.33 ± 7.59	26.59 ± 5.19	70.41 ± 7.42
Delta of mean values (pre, PO)	46.06 ± 9.45		43.81 ± 9.48	
Statistically significant difference between pre and PO values on Wilcoxon matched-pairs signed rank test	[a]		[a]	
Statistically significant difference of deltas between the 2 groups with Mann-Whitney test	No			
Visual analog scale				
	Group 1		Group 2	
1 week PO mean values (0-10)	3.49 ± 0.97		3.38 ± 0.94	
2 weeks PO mean values (0-10)	2.15 ± 0.83		2.47 ± 0.76	
Statistically significant difference between groups 1 and 2 values at 1 week PO with Wilcoxon matched-pairs signed rank test	No			
Statistically significant difference between groups 1 and 2 values at 2 weeks PO with Wilcoxon matched-pairs signed rank test	No			

[a]statistically significant. sec, seconds; pre, preoperative; PO, postoperative.

DISCUSSION

Safety is the foundation of elective plastic surgery procedures, especially if permanent materials or prostheses are placed. Therefore, risk assessments of infection, seroma, hematoma, surgical wound dehiscence, and fistula rates and hospital stay were essential in this study. Prolene (Ethicon) is a permanent material, as is Duramesh, which is integrated by new fibrotic tissue that provides an optimal and secure muscular seal. No significant differences were reported between the 2 groups in infection, seroma, hematoma, surgical wound dehiscence, fistula rates, or hospital stay.

With regard to ARD recurrence, we may assume that in both the short term and the long term the fibrous tissue formed at the mesh allows good continence of the anterior abdominal wall. However, we must remember that recurrence may also be due to other factors that are not dependent on and cannot be controlled by surgery, such as lifestyle and work and sports activity. The lack of palpability

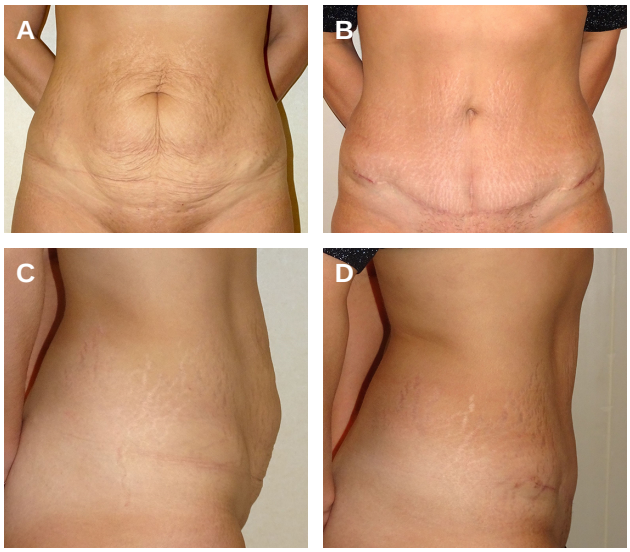

Figure 5. (A, B) Frontal view and (C, D) lateral view preoperative and 6 months postoperative photographs of a 40-year-old patient who underwent abdominal rectus diastasis repair with Duramesh.

of the mesh muscular suture is also justified by the surgical technique covering the first and last knots, as reported previously. Furthermore, Duramesh knots have been shown to be stronger than standard suture knots with the same number of throws.[17,20] Because there was no statistically significant difference between the plication lengths in the 2 groups, and the average plication time was longer in Group 2, we can assert that the Duramesh decreased the time required to perform plication when compared with standard Prolene interrupted sutures. By reducing the operating room time, there was also a reduction in the risk of operative infection and less general anesthesia time.[26] The type of suture (continuous suture) also contributed to the speed of plication. In addition, because the structural composition of Duramesh is designed to resist suture pull-through, there is no risk of it breaking by passing the mesh through the fascia, unlike what can happen with Prolene. Pull-through happens when the suture stitch tears the tissue, fraying it, due to poor force distribution at the suture-tissue interface. Duramesh allows a better distribution of the tension due to the larger mesh surface area, and the internal growth of the fabric around the suture filaments improves its grip. No statistically significant differences were observed in pain as measured by the VAS scale between groups 1 and 2 at 1 and 2 weeks postoperatively, as determined by the Wilcoxon matched-pairs signed rank test. The BODY-Q is a helpful tool for assessing patients' point of view on their own appearance.[27,28] Data from the administration of the BODY-Q abdomen scale showed that there was no statistically significant difference between the BODY-Q deltas of the 2 groups (Figures 3-5). This may also depend on other factors than ARD correction, such as skin tailoring. Regarding the price of these sutures, at the authors' facility a Prolene thread costs about $9, and the type of Duramesh employed costs about $216. On average, during an ARD repair procedure, the authors utilize not less than 4 to 5 Prolene threads, or just 1 Duramesh. With Duramesh, even if operative time is reduced, the material price is higher. The limitations of this prospective study included the number of patients enrolled, the follow-up time, the single-center setting of the trial, and the absence of functional outcomes for core strength evaluation. The authors could not compare continuous mesh suture with Prolene continuous suture plication, because in their clinical practice a Prolene continuous suture may lead to sheath cuts and tears, with increased risk of diastasis recurrence; so this is not the first choice for ARD repair. Further multicenter comparison research studies with other suture types, absorbable or not, may lead to the detection of a new gold standard for ARD repair.

CONCLUSIONS

Duramesh 0 application for rectus diastasis repair is safe (with regard to infection, seroma, hematoma, surgical wound dehiscence and fistula rates and hospital stay) and effective (by ARD recurrence by ultrasound, palpability of the muscular suture, surgical time, and postoperative pain evaluation), without compromising aesthetic improvement, when compared with standard 0 polypropylene suture plication.

Supplemental Material

This article contains supplemental material located online at www.aestheticsurgeryjournal.com.

Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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