

## Original Research Article

# Effectivity of the PGA rapid Atramat® and PGA Atramat® sutures for the closure of minimal invasion and abdominal-inguinal wounds in surgery

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## ABSTRACT

**Background:** The use of suture materials for the closure of wounds is a practice described in Egyptian parchments since 3500 b.C. through the use of linen, animal hair, vegetable fiber, silk, leather and others. The election of the ideal suture material has to be based in the appropriate resistance to traction, tissue biocompatibility and resorption rates..

**Methods:** An open longitudinal clinical trial was performed with data recollection in a prospective way, in which was calculated the incidence of complications; dehiscence, wound seroma, surgical site infection hemorrhage and abscess when PGA Atramat® and PGA rapid Atramat® was employed in laparoscopic and open surgery for treatment of inguinal and umbilical plasties.

**Results:** During the period from January 2016 to August 2016, the procedures included: 31 laparoscopic cholecystectomies, 18 laparoscopic funduplications, 45 laparoscopic appendicectomies, 12 abdominal plasties and 16 inguinal plasties. This series shows the null incidence of complications in 31 cholecystectomies, 18 funduplications, 16 inguinal plasties and 12 abdominal plasties.

**Conclusions:** The employment of the PGA Atramat® and PGA rapid Atramat® sutures maintains the features of a braided, absorbable suture, and it also results a feasible and secure resource for its use in minimal invasion surgery, abdominal and inguinal plasties, showing low incidence of surgical site infection.

**Keywords:** Polyglycolic acid, Sutures, Surgical site infection

## INTRODUCTION

One of the most common causes of abdominal pain with surgical implications is the acute appendicular pain, which represents the most frequent cause of acute abdomen, with a risk of 8.6% for men and 6.7% for women.<sup>1-2</sup> Open appendicectomy was the usual treatment

for appendicitis, since the description of the technique by McBurney in 1894.<sup>1,3</sup> The first experimental laparoscopy was performed in 1901 by Dr. George Kelling in a dog, who maintained a prolonged experimental phase so this could posteriorly be performed for first time in humans in 1983 by Semm and in children in 1994; since then, the efficiency and superiority of the laparoscopic

management in comparison with the open technique has been a debate topic.<sup>1,4-6</sup> 30 years have passed over the introduction of laparoscopic management for appendicitis however there is no still an absolute consensus about its advantages and disadvantages in comparison with the conventional technique, making them both valid procedures for the surgical management of the disease.<sup>7</sup>

In recent years, minimal invasion surgery has increased as an ideal therapeutic option, the motivations to choose this method are stables even the great variability in anatomical sites and procedure indications, progressing in all surgical branches.<sup>8</sup> Laparoscopy, in general permits an exhaustive and complete assessment, especially in women, where the rate of appendicectomies with normal histology is high; the laparoscopic management is accepted as the gold standard for the treatment for gallbladder conditions.<sup>4,7</sup>

The decision to perform a minimal invasion surgery has sanitary policies implications, where the evidence shows better health outcomes when making small incisions such as aesthetic, lower incidence of post-surgical pain, ambulatory management, brief recovery and hospitalization periods, as well as the decrease of costs in health care, due mainly to the possible comorbidities and complications that can be develop.<sup>8-9</sup> All this, make laparoscopic management an effective alternative for the surgical procedures with predominance in developed countries such as the USA.<sup>11</sup>

### **Complications**

The development of post-surgical infections and the presence of dehiscence are worldwide modern challenges to overcome; estimating as the 40-60% of surgical site infections as preventable; defining them as infections that develop within the 30 days after a surgery procedure.<sup>12,13</sup> Despite the decrease in morbimortality related to laparoscopic procedures, due to advances in perioperative cares, it still exist a register of a low rate of surgical site infections, representing by this a significant morbidity and consuming an important part of the health budget in an institutional level.<sup>14</sup>

Theoreon Fullum et al demonstrated that the laparoscopic approach in cholecystectomy, appendicectomy and hysterectomy reduces in more than 50% the acquisition of nosocomial infections from all sources. It also reduces in two thirds of the cases the readmission to hospital due to infection. Theoreon Fullum et al mention in a study that the patients who went under open procedures presented more frequency of hemorrhages and infections.<sup>10</sup> Corroborated by Sauereland et al results, they also refer that the patients who went under minimal invasion procedure were discharged a day earlier than those who went under an open surgery.<sup>15</sup> Schwenk et al in their meta-analysis concluded that patients treated with minimal invasive techniques were less prone to experiment a paralytic ileus or a surgical site infection.<sup>16</sup>

A multi-centric study performed by Xiao et al showed in a 30 day follow up in patients who had experienced a cholecystectomy, an infection incidence consistently lower in laparoscopic managements (0-6.3%) in comparison to the open technique (5-23%), they referred that the minor size of the laparoscopic incisions may reduce the probability to develop an infection.<sup>17</sup>

In the use of antibiotics area, a clinical trial performed in the Netherlands by Rossem et al established that a 3 day intravenous antibiotic therapy is equally effectively as a 5 day therapy after an appendicectomy secondary to a complicated appendicitis.<sup>18</sup> Despite the use of antibiotics and the peri and post-surgical care, the infection of surgical sites remains the most common complication, delaying by this the primary closure of the wound especially in complicated cases.<sup>19</sup> Reports made in hospitals where the infections are related with suture usage and knot performance are frequently observed.<sup>20</sup> The relevance of suture materials related to the development of surgical site infections make sense regarding the fact that sutures provide a local surface for the adherence of microorganisms, creating a biofilm that promotes bacterial resistance, and predisposing the wound to develop an infection. The bacterial adhesion to the suture material is variable, based in inner material characteristics such as structure, chemical compounds and the immunological state of the patient at the moment of the intervention, as well as diverse factors that prone to establish an immunological inflammatory answer, excessive or deficient.

### **Sutures in wound closure**

The use of suture materials for the closure of wounds is a practice described in Egyptian parchments since 3500 b.C. through the use of linen, animal hair, vegetable fiber, silk, leather and others. Suture is a device of natural or synthetic material, used to bind tissues, with the objective of achieving the obliteration of the death space, a uniform distribution of tension trough out the stitches and the maintenance of resistance to traction in the wound, until this resistance turns the ideal one.<sup>21</sup> The election of the ideal suture material has to be based in the appropriate resistance to traction, tissue biocompatibility and resorption rates.

The Polyglycolic Acid (PGA) is a Glycolic Acid polymer, being for its origin a synthetic absorbable and braided suture.

The surgical absorbable suture PGA Atramat® may cause a minimal inflammatory response in tissues, the one that is followed by a gradual encapsulation of the suture by fibrous connective tissue. Its absorbable mechanism is through hydrolysis where the polymer is degrades producing glycolic Acid the one that is absorbed and metabolized by the organism. Implantations studies shows that the absorbable surgical suture PGA Atramat® mantain 70% pf its original tensil strength to the second

week and 50% during the third week. Its absorption is completed between 60 and 90 days before the placement. Absorption of the suture is initiated by the loss of resistance to the tension, followed by the loss of mass. The PGA Atramat® suture has superior properties than other materials, for instance, the decrease of reaction to synthetic material, providing in comparison with other similar materials major resistance to traction, employment ease, without producing stitching marks like silk or catgut.<sup>21</sup>

The PGA rapid Atramat® surgical suture is made of low molecular weight filaments of glycolic acid homopolymers it is also braided, sterile and absorbable by a hydrolysis process. The strand contains a covering of Polycaprolactone and Calcium Stearate, the substances contained in the strand and the covering are no collagen, non-allergens, non-antigens, non pyrogens and non toxics, its use is for soft tissues, where it is only required the support for the wound in short term and where its rapid absorption (42 days) would be beneficial.

PGA rapid Atramat® absorption properties are similar to the PGA Atramat® suture for the fact that both are produced with the same coated Polyglycolic Acid. Records show 5 days posterior to their placement a traction resistance of 50% regard to the initial one. The median pH level is an important factor in suture reabsorption, finding that the alkaline conditions speed up its degradation.<sup>23</sup>

The absorbable surgical suture PGA rapid Atramat® counts with all the requirements established by the United States Pharmacy (USP) and the European Pharmacy (EP).

**METHODS**

An open longitudinal clinical trial was performed with data recollection in a prospective way, in which was calculated the incidence of complications; dehiscence, wound seroma, surgical site infection hemorrhage and abscess when PGA Atramat® and PGA rapid Atramat® was employed in laparoscopic and open surgery for treatment of inguinal and umbilical plasties.

**Surgical team and randomization**

Prior authorization and informed consent of a research protocol, all patients who arrived to the Emergency room with acute abdomen condition were included.

All the patients were operated by the same surgeon with an overcome learning curve.

**Ethical aspects**

This research protocol was assessed and approved by the ethical committee by the research department of the Angeles Hospital London Clinic. The informant consent was created and detailed, which was delivered as a copy

to the patients. Personal data was preserved with total privacy.

**Surgical team**

All the surgeries were performed by the same surgeon with an overcome curve. Three port laparoscopic techniques was used in which the gallbladder or the caecal appendix was collected via an endobag. General Anaesthetic was used for abdominal plasties. Local and epidural block anesthetic was employed for inguinal and umbilical plasties when open surgery was indicated.

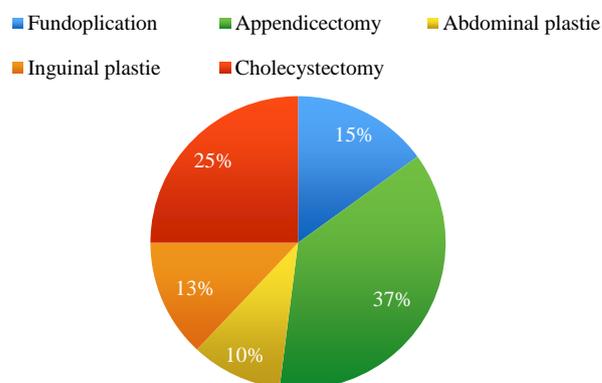
For the surgical wound closure, it was employed PGA rapid Atramat® in fascia an aponeurosis, and PGA Atramat® in muscle and subcutaneous tissue.

**Statistical analysis**

Central trending measures and percentages were calculated, the recollection data was performed in Excel 2012 using the program formulas.

**RESULTS**

During the period from January 2016 to August 2016, 122 patients went under a surgical intervention in different private hospitals, the procedures included: 31 laparoscopic cholecystectomies, 18 laparoscopic funduplications, 45 laparoscopic appendicectomies, 12 abdominal plasties and 16 inguinal plasties Figure 1.



**Figure 1: Percentage surgery distribution.**

There was no report of dehiscence of the wound, surgical site infections, or significant hemorrhage in any of the 122 patients. In laparoscopic appendicectomies, one patient developed a wound seroma, while other two patients developed subcutaneous abscesses with surgical site infection Table 1. This serie shows the null incidence of complications in 31 cholecystectomies, 18 funduplications, 16 inguinal plasties and 12 abdominal plasties. The presence of 5 complications in 45 patients with appendicitis is considered high, however those were patients with advanced appendicular conditions (Phase

IV). In two of them surgical site infection with a subcutaneous abscess was developed. In another patient a

wound seroma in the umbilical area (where the port of the camera was introduced) was developed.

**Table 1: Type of Surgery and observed complications.**

Complications	Cholecystectomy	Fundoplication	Appendicectomy	Inguinal plastic	Abdominal plastic
Dehiscence	0	0	0	0	0
Wound seroma	0	0	1	0	0
Surgical site infections	0	0	2	0	0
Significant hemorrhage	0	0	0	0	0
Abscesses	0	0	2	0	0

## DISCUSSION

With the improvements of the equipment and the increase of clinic expertise it is now possible to perform almost any type of intervention through laparoscopic technique, presenting surgical site infections with low incidence but still significant. Richard et al, in their review of 720 acute appendicitis cases, demonstrated that the time of hospital stay in patients who presented a rupture of the appendix and went under a laparoscopic procedure was of 3.52 days in comparison to those who went under open surgery, where was of 6.03 days; this results are reaffirmed by Guller et al, in a study with 43, 757 appendicitis cases.<sup>24,25</sup>

In United Kingdom it has been recorded that the surgical site infections represents up to 20% of all the infections related to health care services, representing this issue an extra cost, about 1,47-19,1 billions of euros. Identification of risk factors is the first step in the execution of preventive measures that can help the satisfaction in the outcomes.

The healing of a surgical wound implicates the development of a matrix that can unite the edges of the wound, being compatible with the vascular regeneration and the anatomic-functional restitution of the structure in trouble.

Deficiency in resistance in the suture material may result in the preterm rupture of the suture leading this to a poor adaptation of the surgical edges and the induction of the healing tissue by second closure. Synthetic absorbable sutures are used as a temporary mechanical support till the tissues in trouble recover its strength and resistance.

When the recovery of the tissue progress, the suture tends to get weakened progressively until resistance is transferred to the tissue. That is the reason why the adjustment in the speed of degradation of the absorbable suture is an important challenge to take into account in the moment of suture design.<sup>26,27</sup> The development of intra-abdominal abscesses posterior to an

appendicectomy procedure is infrequently, but it's associated with a high mortality. The employment of an adequate surgical technique and antibiotic election is crucial to reduce the incidence of post-surgical intra-abdominal abscess.

Advances in surgical devices and techniques, as well as improvements in peri surgical cares have achieved a significant decrease in worldwide mortality related to surgery. Unfortunately the post-surgical morbidity in some cases is inevitable.

## CONCLUSION

Through this protocol we can demonstrate the utility of the PGA rapid Atramat® and PGA Atramat® in abdominal and inguinal laparoscopic surgery, reporting a low or null incidence in complications with a decrease in costs and an early reincorporation to daily activities.

With the development of materials like the one employed in this protocol, the rates of recurrence have decrease considerably in comparison with other suture materials, being chemical structure one of the most important factors to the development of surgical infections, dehiscence and inflammatory response. PGA rapid Atramat® and PGA Atramat® sutures were well tolerated in our intervened patients according to the data recollected in this study and confirming low complications related to suture material.

The employment of the PGA Atramat® and PGA rapid Atramat® sutures maintains the features of a braided, absorbable suture, and it also results a feasible and secure resource for its use in minimal invasion surgery, abdominal and inguinal plasties, showing low incidence of surgical site infection, moreover it could be recommended the use of suture with antibacterial covering in advanced appendicular phases.

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