

Clinical Evidence

For MonoPlus® – a violet long-term absorbable monofilament suture



Sutures

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Rationale

Median laparotomy is a standard technique of gaining access to the abdominal cavity and requires an adequate closure of the abdominal wall. A great number of different suture materials and techniques are used for the reconstruction of the abdominal wall integrity, but the ideal suture material and the best technique for closing the abdominal fascia has yet not been determined. This lack of a widely accepted surgical standard for abdominal wall closure (AWC) leads to an incidence of abdominal wall hernia up to 20 % (range 9 to 20 %) (1 - 3). Whereby incisional hernias often require repair, with postoperative recurrence rates as high as 45 % (4), further contributing to additional complications. Furthermore burst abdomen is observed in 1 - 3 % of the patients within the first days after laparotomy (5 - 8).

There are several potential risk factors which may have an influence on the occurrence of incisional hernias, like wound healing disorders, wound infections, obesity, chronic bronchitis or diabetes mellitus (9 - 11). However, wound infections remain the most significant early postoperative complication because they develop in 3 - 21 % of patients undergoing median laparotomy, within the first 30 days postoperative depending on the type of surgery performed (12 - 19). Therefore prevention of wound healing complications would reduce the incidence of dehiscence and herniation in abdominal wounds substantially.

At present most surgeons favour a monofilament non-absorbable or a slowly absorbable suture as the most suitable suture material for closing abdominal wounds after midline laparotomy. There are several studies which showed that slowly absorbable monofilament sutures consisting of poly-p-dioxanone are the best choice for fascial closure in a running suture technique.

Additionally, polydioxanone absorbable monofilament sutures are favoured for orthopaedic surgery (20 - 23), because of their easy passage through the tissue, flexibility, excellent knot security and overall good handling. These properties along with the low likelihood of suture-related adverse effects and the favourable influence on wound healing makes them a good option for most surgical procedures. The long-term outcome of vascular anastomoses in children can be compromised by stenosis when the growth of the vessels does not match that of the anastomosis. This can be influenced by the suture material. There are several publications which could show, that polydioxanone absorbable monofilament suture is a suitable suture material for vascular anastomosis as far as vascular growth is concerned (24 - 26).

There are also two publications demonstrating that polydioxanone suture material is also efficient for sternal closure in high risk patient (27) and safe for sternotomy closure of pediatric open cardiac surgery (28).

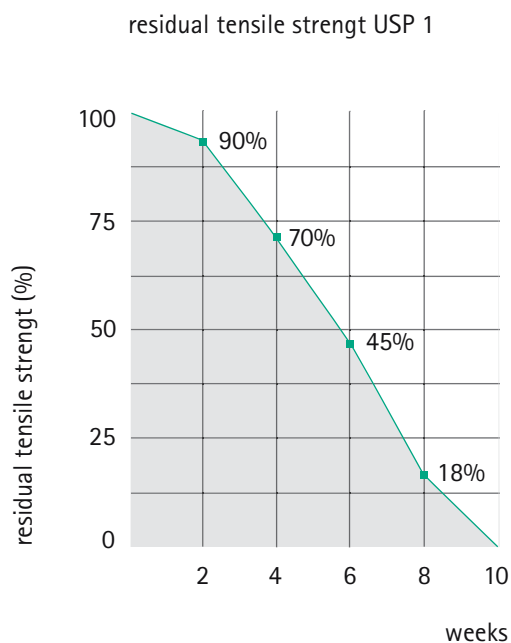
MonoPlus® is a violet synthetic long-term absorbable monofilament suture made of poly-p-dioxanone and sterilized by ethylenoxyd. MonoPlus® offers good handling combined with great strength. Because of its slow degradation profile, MonoPlus® is ideal for all the indications where an extended wound support for up to 10 weeks is requested.

After implantation MonoPlus® reduces its tensile strength



Rationale

via continuous hydrolysis. MonoPlus® loses 50 % of its knot tensile strength after 35 days and is completely degraded via hydrolysis within 180 – 210 days. The degradation profile leads to a very continuous release of 2-hydroxy-ethoxyacetic acid which is completely metabolized in the body.



MonoPlus® causes a very slight inflammation reaction after implantation into the tissue which typically happened to a foreign material.

MonoPlus® is well suited for abdominal wall closure, for paediatric cardiovascular surgery and it is also used in orthopaedic surgery.

MonoPlus® is a very flexible monofilament with high tensile strength which is pliable and easy to knot. It exhibits a smooth passage through the tissue and a high knot tensile strength. MonoPlus® shows optimal tissue compatibility but no capillarity. MonoPlus® is indicated for intervention where extended wound support is required.

Clinical Evidence

1) Abdominal wall closure (AWC)

The current surgical literature has yet not clearly demonstrated an optimal technique and ideal suture material for abdominal closure. Various randomized studies have evaluated techniques and suture materials for abdominal fascia closure but controversy remains, leaving surgeons uncertain about the ideal method to close abdominal wounds and therefore optimally preventing incisional hernias. Selecting an appropriate suture material may lessen postoperative complications such as incisional hernia or burst abdomen, after median laparotomy.

Systematic Review & Meta-Analysis (SR & MA)

The meta-analysis of Van't Riet et al. 2003 (29) showed that slowly absorbable continuous sutures appear to be the optimal method of fascia closure to reduce the incidence of incisional hernias without increasing wound pain or suture sinus frequency. All trials with a follow-up of at least one year that randomized patients with midline laparotomy to close the abdominal fascia by different suture techniques and suture materials were subjected to meta-analysis. Primary objective was the formation of incisional hernias, secondary objectives were wound dehiscence, wound infections, wound pain and suture sinus formation. Abdominal wall closure by using continuous rapidly absorbable suture was followed by a significant higher incidence of incisional hernias than closure by continuous slowly absorbable sutures or non-absorbable suture material. No difference in incisional hernia incidence was found between slowly absorbable and non-absorbable sutures, but more wound pain and more suture sinuses occurred after the use of non-absorbable suture material. The authors suggest, that the ideal suture technique to reduce the incisional hernia rate appears to be mass closure using a continuous suture, with an adequate suture length to wound length ratio of at least 4:1. The suture material should be slowly absorbable.

Rucinski et al. (30) reported no significant difference in relation to the outcome features of dehiscence and infection when absorbable suture material was compared with non-absorbable material. Furthermore, in regard to the probability of hernia formation no difference was seen when monofilament absorbable material was compared with non-absorbable material. However, a higher incidence was demonstrated when braided absorbable suture was used.

They also reported a higher incidence for incision pain and suture sinus formation when non-absorbable suture was used.

In accordance to the meta-analysis of Van't Riet (29), this meta-analysis published by Rucinski (30) also concludes that an absorbable monofilament suture material is superior to non absorbable suture for abdominal closure and that a mass closure is the optimal technique for fascial closure after laparotomy.

In contrast to Van't Riet (29) and Rucinski (30), Hodgson et al. (31) showed in their meta-analysis a significant lower occurrence of incisional hernias when non-absorbable suture materials were used. In agreement with the other two meta-analysis, Hodgson et al. also point out that suture sinuses and wound pain was lower when absorbable sutures were used. They also could not find any difference in the incidence of wound dehiscence and wound infections with respect to the suture material. Subgroup analysis indicated no difference in-relation to incisional hernia between polydioxanone and polypropylene, but polyglactin showed an increased wound failure rate. The authors postulate that the ideal suture is non absorbable and the ideal technique is continuous for reducing the rate of incisional hernias.

The meta-analysis of Weiland et al. (32) was done to choose the best abdominal closure. In this review different suture techniques continuous versus interrupted and non absorbable suture versus absorbable suture material were compared in relation to infection, incisional hernia formation and dehiscence. They conclude that continuous closure with non-absorbable suture should be used to close abdominal wounds. However, if infection is expected interrupted suture are preferred. Mass closure was superior to layered closure. This meta-analysis by Weiland is controversially discussed, because it failed to comply with most of the methodologic requirements supported by a recent consensus. The search strategy was less than explicit, non-randomised trials and poor-quality studies were included in this study, decreasing the validity of their results. The quality of the randomised controlled trials included in this analysis was not assessed. Interpretation of the results was difficult because individual study characteristics were not described.

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Randomized Clinical Trials (RCT)

The three armed, multi-centre, intra-operatively randomised, controlled patient blinded trial (INSECT) evaluates different techniques to close the abdominal wall (Knaebel et al. 33, 34). 625 patients were enrolled in this study who were planned for an elective primary median laparotomy. The aim of the INSECT trial is to compare the frequency of incisional hernias at one year postoperative, between two continuous suture techniques with different, slowly absorbable monofilaments (MonoPlus® and PDS®) and an interrupted suture technique using an absorbable braided suture material (Vicryl®). This trial will answer the question if the continuous abdominal wall closure with a slowly absorbable material with longitudinal elasticity (MonoPlus®) is superior to the continuous suture material lacking elasticity and to interrupted suture material with a braided thread. All surgeon were trained. Primary endpoint was the frequency of incisional hernias within 1 year after surgery diagnosed by clinical examination and confirmed by ultrasound. For the INSECT trial an incisional hernia rate of 13 % was expected for the interrupted group and 4 % for the continuous groups. Complications and safety were used as secondary parameter.

The abdominal wall of 210 patients was closed with interrupted Vicryl, 205 patients received continuous PDS and in 210 patients the closure of the abdominal cavity was performed using continuous MonoPlus suture material (Seiler et al. 40). The primary analysis showed an incidence of incisional hernias of 15.9 % in the Vicryl group, 8.4 % in the PDS group and 12.5 % in the MonoPlus group. Furthermore no significant difference was seen in the three groups in respect to burst abdomen (2 % Vicryl, 3 % PDS, 4 % MonoPlus), wound infection (12.7 % Vicryl, 19.4 % PDS, 16.3 % MonoPlus), pulmonary infections 4.4 % Vicryl, 2.5 % PDS, 2.5 % MonoPlus) and 1 year-mortality (7.9 % Vicryl, 5.5 % PDS, 7.9 % MonoPlus). The length of the incision did not differ within the three groups, but the time for abdominal wall closure was significantly shorter in the continuous groups compared to the interrupted group. There was no correlation between the woundinfection rate and the rate of incisional hernias. Burst abdomen did not occur more frequently in center with more than 12 % incidence of incisional hernias compared to those with less or equal than 12 %.

Insect trial failed to demonstrate any significant reduction of incisional hernia within one year when the abdominal wall was closed with a continuous slowly absorbable monofilament compared to an interrupted rapidly absorbable braided suture material. The incidence of incisional hernias was higher then expected. In addition a high frequency of wound infection was observed.

Hsiao et al. (35) compared in their randomized study early-absorbable polyglactin 910 versus late-absorbable polydioxanone loop suture for fascial closure after abdominal surgery in patients with malignant and non-malignant diseases. A 2-year follow-up revealed an overall mortality of 6.8 %. 10 patients in the polyglactin 910 group and 3 patients in the polydioxanone group developed incisional hernias. Therefore fascial closure was associated with more incisional hernias when polyglactin was used, with a marginal significance for patients in the malignant group. Wound infection developed in 4.1 % of patients. The two suture groups did not differ significantly regarding the incidence of wound infection in either the malignant or the non-malignant patients. This trial suggests that late-absorbable polydioxanone loop suture may be beneficial to patient with malignant disease for preventing incisional hernias.

Bresler et al. (36) compared three different absorbable sutures (polyglactine 910, polydioxanone I and polydioxanone II) for closing the abdominal wall after midline laparotomy by using the continuous technique. Primary outcome was wound infection and wound dehiscence early postoperative, secondary outcome was the development of incisional hernias and suture sinuses 1 year postoperative. No wound infection and no wound dehiscence occurred early postoperative in a total of 235 patients. The total rate of incisional hernia one year postoperatively was 11 %, whereby no significant difference was seen between the three suture groups. The results of the trial indicate that absorbable sutures have a very low incidence of suture sinuses, and that polydioxanone seems to be a good choice for closing laparotomies.

Israelsson et al. (37) investigated the healing of midline laparotomy incisions closed with a continuous suture of nylon or polydioxanone II. Wound dehiscence developed in 0.6 % of 813 patients underwent abdominal surgery, wound infection occurred in 9.0 %. The rates were similar in both suture materials. Incisional hernia were detected in 15.1 % of patients sutured with nylon and in 15.7 % of patients closed with polydioxanone. The authors postulated that the closure of the abdominal wall is safe with polydioxanone as it is with nylon, but the incidence of incisional hernias is more associated with the suture technique than with the suture material.

Wissing et al. (18) compared in their prospective randomized multicentre trial four different suture and technique combinations (interrupted polyglactin, continuous polyglactin, continuous polydioxanone, continuous nylon) to close the fascia after midline laparotomy. The criteria used to assess the results were the occurrence of wound infection and wound dehiscence in the early postoperative period, and the occurrence of wound pain, suture sinuses and incisional hernia 1 year after operation. 1491 patients were analysed in this trial. No statistically significant difference was seen in the occurrence of wound infection (8.6 %) and wound dehiscence (2.3 %) between the four different suture techniques. 1156 patients were analysed one year postoperative, wound pain was present in 9.7 % of patients and suture sinuses developed in 3.5 % of patients, statistically significantly more frequently in the nylon group (16.7 % and 7.7 %). There was also a clear correlation between the development of suture sinuses and earlier wound infection. The frequency of incisional hernias was 10.3 % in the nylon group, 16.9 % in interrupted polyglactin group, 20.6 % in the continuous polyglactin group and 13.2 % in the polydioxanone group. A clear correlation between a postoperative wound infection and the development of an incisional hernia was noted. The results showed that although nylon has the lowest incidence of incisional hernias, it causes significant more wound pain and suture sinuses. The trial also implicates, that the prevention of wound infection is more important in the avoidance of incisional hernias than the kind of suture material or the type of closure used.

Cameron et al. (19) addressed the question which suture material is more suitable for closing the abdominal wall after laparotomy. In this randomized trial 284 patients undergoing laparotomy were randomly allocated to closure with interrupted mass suture of polydioxanone or polypropylene. Ten patients suffered a burst abdomen. One occurred in the polydioxanone group (0.7 %) and nine in the polypropylene group (6.4 %). This difference was significant. Wound infection was found in 8.6 % of patients closed with polydioxanone and in 15.5 % of patients closed with polypropylene. The polydioxanone group had a lower incidence of wound pain and a lower incidence of wound pain and palpable knots. The frequency of incisional hernias was equal in both groups (11 %). We found that wounds closed with polydioxanone were more comfortable-many fewer knots were palpable and fewer patients experienced wound pain. Therefore in long term, polydioxanone may have advantages over polypropylene, although the true incidence of incisional herniation will require longer follow-up.

Krukowski et al. (38) reported the results of a large prospective trial comparing polydioxanone and polypropylene for abdominal wall closure. A total of 757 patients were entered into the trial. Wound infection was seen in 3.5 % of patients in the polydioxanone group and in 7 % of patients in the polypropylene group; the difference was significant. The incidence of late wound failure was four times as high after wound infection compared with non-infected wounds and this difference was significant. No significant difference was shown in terms of dehiscence or incisional hernias one year postoperative in both groups. After 12 months 3.2 % of patients closed with polydioxanone had wound pain which was severe in 0.4 % of these patients. In contrast 6.1 % of the polypropylene patients develop wound pain which was severe in 2.4 % of these patients. In agreement to Cameron et al.(19), Krukowski et al. preferred also suture material consisting out of polydioxanone for closure of midline abdominal incisions, because when compared polydioxanone and polypropylene suture material they found more wound infections and wound pain in the polypropylene group than in the polydioxanone group.

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Table 1: Randomized comparative studies

Reference	Year	No. of patients	Follow-up	Suture technique	Material
Hsiao et al.	2000	340	2 year	continuous single layer	Polyglactin 910 (F) Polydioxanone (S)
Bresler et al.	1995	235	1 year	continuous	Polydioxanone I (S) Polydioxanone II (S) Polyglactin 910 (F)
Israelsson et al.	1994	813	1 year	continuous mass	Nylon (N) PDS (S)
Krukowski et al.	1987	757	1 year	continuous mass	Polydioxanone (S) Polypropylene (N)
Wissing et al.	1987	1486	1 year	Interrupted Continuous Continuous Continuous	Polyglactin (F) Polyglactin (F) Polydioxanone (S) Nylon (N)
Cameron et al.	1987	284	1 year	interrupted mass	Polydioxanone (S) Polypropylene (N)

Incidence of incisional hernia was comparable (=), less (<), or more (>). F, rapidly absorbable; S, slowly absorbable; N, non-absorbable; Int, Interrupted suture technique; Cont, Continuous suture technique.

Wound dehiscence (%)	Incisional hernia (%)	Wound infection (%)	Suture sinus (%)	Conclusion on incidence of incisional hernia	Preference
	2.0 0.8	4.8 3.2		malignant F > S non-malignant F = S	Polydioxanone for patient with malignant diseases
0 0 0	11.2 8.4 14.2	0 0 0	2.8 2.8 0	F = S	No preference
0.7 0.5	15.7 15.1	8.6 9.4		S = N	No preference
0.3 0.3	3.5 4.7	3.2 8.0	0 0.3	S = N	Polydioxanone (Polypropylene more wound infection)
2.2 1.6 3.5 2.1	16.9 20.6 13.2 10.3	6.6 9.0 11.6 7.2	3 1.4 3.9 7.7	F > S F > S S = N Int F = Cont F Int F = Cont S	Polydioxanone (Nylon more suture sinus and wound pain)
0.7 6.4	11.0 11.0	8.6 15.4		S = N	Polydioxanone (Polypropylene more wound infection, wound pain, wound dehiscence)

The purpose of the review of O'Dwyer et al. (39) was to examine the surgical related factors which contribute to incisional hernia and other chronic wound problems after laparotomy in order to provide an evidence-based approach to abdominal wall closure. They summarized in their literature analysis that there is a good clinical evidence from randomized trials and meta-analysis which indicate that

continuous running non-absorbable or slowly absorbable suture such as polydioxanone is the method of choice for abdominal wall closure. The analysis also showed that continuous polydioxanone has a similar incisional hernia rate as its non absorbable counterparts but causes less chronic pain and wound sinuses.

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2) Orthopaedic surgery

Polydioxanone absorbable monofilament sutures are also indicated for orthopaedic surgery.

Randomized Clinical Trial (RCT)

Boehm and colleagues (23) carried out a prospective, randomized study to determine whether a modified Mason-Allen suture with non-absorbable braided Ethibond® provided better result than a modified Kessler suture with absorbable braided polydioxanone cord for the repair of the rotator cuff. They focussed particularly on the rate of further tears, revisions, infections and the clinical results. 100 patients were randomized into two groups. Group one had transosseous repair with Ethibond using a modified Madson Allen sutures and group two had transosseous repair with polydioxanone cord using a modified Kessler sutures. After 24 to 30 months patients were clinically investigated using constant score and by ultrasonography. 83 % patients with polydioxanone reconstruction rated their result as excellent or good and 82 % of patients with Ethibond reconstruction rated their result as excellent or good. 12 % in both groups rated their results as satisfactory, and 4 % of the polydioxanone group and 6 % of the Ethibond group as poor. No statistical difference was seen between the two groups in respect to constant score (91 % vs 92 %), rate of further tears (18 % vs 22 %) and revision (4 % vs 4 %). In case of further tear the outcome in group two did not differ from that for the intact repairs (91 % vs 91 %), but in group one it was significantly worse (94 % vs 77 %). Two infections were present in group one and one in the polydioxanone group which required revision within three weeks of the initial surgery. In each of the two groups, two patients (4 %) required revision surgery because of persistent pain. This study showed, that the repair of tears of the rotator cuff is more or less independent from the used suture material. The authors conclude that although basic science studies support the use of special suture techniques and non-absorbable materials, their advantages are unproven in the clinical setting in terms of both clinical outcome and the rate of recurrence. Absorbable suture material may have advantages in repair of the rotator cuff when the quality of the tendon is poor.

Prospective Non-Randomized Clinical Trials

Hosseini et al. (20) reported the repair of quadriceps tendon ruptures which are unusual injuries caused by direct or indirect trauma. Since complete ruptures lead to loss of active extension of the knee joint, operative treatment is usually indicated. The authors presented a new technique using polydioxanone cord passed through a transverse drill hole in the proximal pole of the patella. 10 patients with a complete quadriceps tendon rupture were operated and analysed after a follow up of 38 months. Physical examination, IKDC Subjective score, Lysholm- and Tegner score and isokinetic test of the quadriceps strength were analyzed in these patients. All patients rated their result as satisfactory. No complications were recognized in this period of time. The average postoperative score were 87 (IKDC), 98 (Lysholm), and 4.5 (Tegner). Isokinetic testing showed an average of 25 % quadriceps strength deficit. The investigators conclude, that the operative treatment of complete quadriceps tendon rupture using polydioxanone cord through a drill hole in the patella is safe and effective, permitting a functional postoperative treatment. Most patients can count on a good result.

Hehl et al. (21) published in 1999 the results of prospective anterior cruciate ligament (ACL) refixation in 33 patients with high proximal rupture. Conservative therapy or only arthroscopic resection of the ACL combined with muscular rehabilitation is no longer acceptable for patients active in sports. Long term results have shown an increased rate of meniscal and cartilage damage due to the instability. Therefore the orthopaedic researchers used a new surgical technique which was specially developed for the refixation of the ACL using a multiple suture loop augmented with intra-articular polydioxanone suture material to avoid derangement of the blood circulation and to guarantee early functional rehabilitation. After a follow up of 28 months 22 patients showed an excellent knee function and 10 patients a good function. Twenty patients regained their pre-injury activity level while 11 patients and two patients had slight and severe limitations of activity respectively. Examination of the range of motion yielded free extension for 32 patients and free flexion for 30 patients. The function of the operated knee joint was expressed as the percentage difference between the injured and non-injured knee joint in the one leg hop test for distance. In 25 patients the operated knee's

function was 90 – 100 % and in 4 patients 76 – 90 %. Postoperative complications were seen in 7 patients. Inflammatory reactions due the polydioxanone cord occurred in 4 patients. In 3 cases of suspected infection arthroscopic re-intervention was done, but the bacterial cultures were negative. Postoperative haematomas, found in 4 patients, resolved with conservative therapy. There was no vascular or nerve injuries. The authors conclude, that primary ACL repair with intra articular resorbable polydioxanone suture augmentation yields good functional and satisfactory anatomical results based on a 2-years experience. Polydioxanone augmentation using improved surgical technique allows immediate rehabilitation thus enhancing healing. This procedure offers an alternative in the treatment of acute ACL rupture in the recreational athlete.

In 1986 Miles (22) investigated the clinical safety and efficacy of polydioxanone absorbable monofilament sutures for tissue closure in orthopaedic surgery in an open-label study with a follow-up of at least 42 days in 55 patients. A total of 150 sutures and six ligatures were used in the 55 completed patients in whom sutures were evaluated. The most common tissue type sutured was subcutaneous tissue, followed by skin, fascia, joint capsule, periosteum, muscle, tendon, synovium and subcuticular tissue. The evaluation of the effectiveness of the polydioxanone suture was based on the ability of the affected organ or structure to gain return of function, the lack of herniation or dehiscence at the suture site, and the appearance of wound, when visible. The occurrence of postoperative adverse effects was monitored for an evaluation of safety. Suture performance was rated on the basis of the following performance characteristics: pliability, strength, ease passage through tissue, ease of tying, fraying characteristics, knot security, needle performance and overall handling. The outcome was rated excellent in all completed study subjects. No operative or postoperative complication or suture-related adverse events were reported. None of the affected organs or vessels failed to return to normal functioning. No evidence for herniation, dehiscence or wound infection was apparent. The suture material was superior to surgical gut with respect to pliability, strength, ease passage, ease of tying, fraying, knot security, wound healing and overall handling. Both the overall handling of the polydioxanone monofilament sutures and performance as it affected wound healing were significant superior to those of surgical gut.

3) Cardiovascular surgery

Randomized Clinical Trial

Luciani and colleagues (27) reported the use of polydioxanone suture material for sternal closure. Median sternotomy remains the most common approach in cardiac surgery. Sternal dehiscence and wound instability are troublesome complications following median sternotomy. Classic sternal approximation with stainless steel wires may not be the ideal approach in patients predisposed to these complications. Therefore, Luciani et al. evaluated the efficacy of polydioxanone suture material in sternal closure and in prevention of complications in comparison to steel wires in high risk patients. A total of 366 patients undergoing elective cardiac surgery with full median sternotomy were randomized to receive polydioxanone suture or stainless steel. Primary outcome was bone dehiscence and superficial wound instability during the intensive care unit course, the hospital course and during the follow-up and the need for surgical revision for sternal dehiscence. In-hospital mortality was 1.6 % and 2.2 % in the polydioxanone group and the stainless steel group. Six months mortality was 2.2 % and 2.7 %. In the general population they observed a 0.29 % incidence rate of bone dehiscence. The incidence of this complication was 1.4 % in the high-risk-cohort. Rates of revision for dehiscence were 0.23 % and 0.5 % in the global population and in the high-risk cohort, respectively. Both bone dehiscence and superficial wound instability was less frequent in the polydioxanone group, although the difference reached no statistical significance. Female sex, chronic renal insufficiency, diabetes, advanced age, lower sternal thickness, osteoporosis, corticosteroid therapy were identified as potential risk factors in both groups to develop sternal complications. The data suggest that polydioxanone suture material can protect against the development of aseptic sternal complications following median sternotomy in high risk patients. The authors conclude that polydioxanone suture material can be recommended for sternal approximation in patients with lower BSA. This suture seems to be protective against development of bone dehiscence even if one or more risk factors for this complication coexist. In properly selected patients, polydioxanone suture material should be considered a further tool available to minimize sternal morbidity and therefore to optimize the final results.

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Prospective Non-Randomized Clinical Trials

Vascular anastomoses in adults are traditionally performed with non-absorbable sutures, under the assumption that vessel-to-vessel healing will not occur. However, permanent non-absorbable suture materials may provoke an intra-luminal foreign-body reaction and resultant granuloma formation, which may in turn lead to graft failure because of development of intimal hyperplasia and anastomotic narrowing. In paediatric patients, non-absorbable suture material may lead to stenosis of the anastomotic site in a growing vessel. The use of polydioxanone suture material for vascular anastomoses and cardiac repairs in paediatric surgery has become accepted (25).

In adults polydioxanone suture material has been used in cardiovascular operations in a few small series. Wang et al. (26) evaluated the potential value of polydioxanone suture material for vascular anastomoses in a preliminary clinical study in adult patients undergoing various vascular procedures. Fifty-three patients undergoing autogenous arterial or venous reconstructive procedures, arteriotomies, venotomies, or major portal depression shunt procedures using prosthetic grafts materials were recruited for this trial. They performed 35 venous and 21 arterial reconstructive procedures using a polydioxanone suture material in 53 patients. A continuous everting running technique was used. Postoperative evaluations of all patients included clinical assessment of vessel patency, non-invasive vascular laboratory tests, and ultrasonographic studies performed 1, 6, 12 months after surgery and each year after. Duplex scanning was used to determine whether any anastomotic pseudoaneurysms or thrombi had formed. Ultrasonography assessed the patency of a prosthetic graft after a portal or inferior vena cava-to-systemic shunt procedure. Postoperative follow-up ranged from 3 to 5 years. Polydioxanone suture material performed well in all procedures. There was no operative death or haemorrhage from the suture line in the early postoperative period. None of the patients had a suture-related complications such as anastomotic thrombosis or formation of pseudoaneurysm during the follow-up period. All patients survived except one who had undergone a mesoatrial shunt and died from hepatic and renal failure resulting from compressed graft occlusion 2.5 years after surgery.

The results indicated that polydioxanone suture maintain an adequate tensile strength in anastomosis until suture line healing occurs, suggesting that this material may be safely used for venous or small arterial anastomosis. Because of its absorbability it results in decreased foreign body reaction, decreased incidence of late stenosis and aneurysmal formation, good healing and minimal inflammatory changes in the vessel wall. The authors recommend, that the use of polydioxanone suture material is advantageous in the management of graft infection or vascular trauma as well as in paediatric patients.

Infants with congenital heart disease frequently require surgical intervention early in life. The present study from Myers et al. (25) was undertaken to evaluate polydioxanone in the repair of congenital cardiovascular anomalies in children. Forty-one patients aged from 2 days to 8 years underwent a total of 46 operations. The patients were divided into those with systemic arterial anastomoses, those with primarily atrial anastomoses and a miscellaneous category. Patients were followed up by both the surgeon and the pediatric cardiologists. Complete repairs for anomalous pulmonary veins and transposition of the great arteries, as well as Fontan procedures and systemic-pulmonary shunts were performed.

Systemic arterial operations:

A total of 23 patients underwent repair of coarctation of the aorta. Nineteen patients from 3 days to 2.1 years of age underwent subclavia flap angioplasty with polydioxanone applied in a continuous running suture technique. Most of these patients had congestive heart failure and were treated initially with digoxin, diuretics and prostaglandin E1 to improve their hemodynamic and metabolic parameters. Ten of the patients have undergone cardiac catheterization since the operation and no impressive gradients across the repair have been found. Two older patients had repair of the coarctation by resection and end-to-end anastomosis. In both cases, the posterior row was completed with 5 - 0 polydioxanone suture in a continuous running horizontal mattress technique. The anterior half of the anastomosis was completed with interrupted sutures. Two patients with interrupted aortic arch had a double flap repair with both the left carotid and left subclavia arteries used

for angioplasty. One patient in this series was recatheterized twice after the initial operation, so that anastomosis growth could be determined. There was no operative deaths. Five of these patients died late, two after repair of Taussig-Bing anomaly by arterial switch operation and two after repair of their complex congenital cardiac lesions. One died 6 months postoperatively of mitral stenosis. Autopsy showed a well-healed anastomosis and microscopy showed healing of the suture line.

Atrial operations:

Five patients underwent repair of anomalous pulmonary venous return. One patient had severe lung disease and died of respiratory failure 9 months postoperatively. There was no obstruction at the suture line in this patient at autopsy and the other four patients were doing well clinically.

Seven patients with transposition of the great arteries with or without VSD underwent Senning operations. Two patients died during the early postoperative period (<30 days) and post-mortem examination revealed excellent healing of all suture lines in which polydioxanone suture was used. The other five patients have been followed up for 10 to 29 months and were doing well without clinical evidence of baffle leak or obstruction.

Two patients underwent direct anastomosis of the right atrium to the pulmonary artery (Kreutzer-Fontan procedure). Both patients were doing well 9 and 30 months postoperatively.

Miscellaneous operations:

One patient underwent repair of a pulmonary artery sling at 2.3 years of age by division of the left pulmonary artery at its origin and reanastomosis to the main pulmonary artery with polydioxanone. This patient was doing well 7 months postoperatively. Three patients had Blalock-Taussig subclavia-pulmonary artery anastomoses performed with 6-0 polydioxanone. All three patients were doing well.

No evidence of aneurysmal dilatation has been found on aortography in the present study. Autopsies were performed in four of eight patients who died during the study and gross and microscopic examinations revealed good healing of the anastomoses and no anastomotic failure. This study showed that polydioxanone is safe and reliable in clinical pediatric cardiovascular operations. There was no complication

attributable to this suture material and the short-term results (up to 30 months) were excellent.



Clinical Evidence

Others

In 1995 Hawkins et al. (24) pointed out the advantage of absorbable polydioxanone in growing vascular anastomosis over non-absorbable suture material to prevent late anastomotic stenosis in total anomalous pulmonary vessels. They compared non-absorbable polypropylene suture material (1982 - 1988) versus absorbable polydioxanone suture material (1989 - 1994) for pulmonary venous-left arterial anastomosis in supracardiac, infracardiac and mixed types of total anomalous pulmonary venous connection (TAPVC). A total of 77 children underwent repair of TAPVC during a 13 year period (1982 - 1994), 65 children with isolated forms of TAPVC and 12 children with more complex associated anomalies. Age of the patients ranged from 1 day to 31 months. All patients underwent repair utilizing cardiopulmonary bypass with profound hyperthermia to 18°C and circulatory arrest. Myocardial protection was achieved with multidose cold cardioplegia administration at 20 minute intervals. A continuous running suture technique for supracardiac, infracardiac, and mixed types of TAPVC was used throughout the experience for the anastomosis between the pulmonary venous confluence and the left atrium. Cardiac catheterization and echocardiography were used to evaluate late pulmonary obstruction. The operative mortality rate for the 65 patients with isolated TAPVC was 12.3 %, decreasing from 19.4 % during 1982 - 1988 period to 5.9 % in the 1989 - 1994 period. Throughout the 13 year study the mortality rate for the complex forms of TAPVC remained higher 33 %. Again, a reduction in the early mortality was seen going from 43 % in 1982 through 1988 to 20 % in 1989 to 1994. Late pulmonary venous obstruction occurred in 17 % of patients from the polypropylene group and in 3.2 % of patient from the polydioxanone group. The 3-year and 5-year freedom from late pulmonary venous obstruction was 96 % for the polydioxanone group and 81 % for the polypropylene group. The authors implicate that continuous absorbable polydioxanone suture for the repair of TAPVC results in a lower incidence of late pulmonary venous obstruction and death and appears to offer advantages over a continuous non absorbable suture. A continuous non-absorbable suture may limit growth of a vascular anastomosis. A more complete understanding of the mechanism of late pulmonary venous obstruction will be necessary to determine the exact role of anastomotic growth in the reduction of long-term morbidity and mortality.

Keceligil and colleagues (28) evaluated the use of polydioxanone suture material for sternal closure after midline sternotomy in children. Traditionally, sternal closure is obtained with nonabsorbable sutures as stainless steel wire or braided polyester. Problems could occur with conventional stainless steel wire, especially in pediatric surgery. This material is difficult for surgeon to handle and may cause pain and discomfort for children. Therefore the investigators closed 264 sternotomies in pediatric patients aged 6 days to 17 years using continuous polydioxanone suture. No sutures were broken during the sternal closure. Sternal wound infections, sternal dehiscence and mediastinitis occurred in 4 patients (1.5 %). The overall hospital mortality rate related to the mediastinitis was 1.1 % in an early postoperative period. Follow-up periods of the whole series were established between 1 to 132 months. In 264 children they could show that the use of polydioxanone suture material allows good sternal stability and wound healing as well as perfect compatibility. They conclude that the absorbable suture material is a safe alternative to standard sternotomy closure after pediatric open cardiac surgery with good clinical results.

Key Messages

■ MonoPlus® is a synthetic long-term absorbable monofilament suture consisting out of polydioxanone and therefore has the advantages of other monofilament sutures.

■ MonoPlus® offers a good handling because of its high flexibility.

■ Because of its slow degradation profile, MonoPlus® is ideal for all indications where an extended wound support for up to 4 acc. to IFU, stur weeks is requested.

■ MonoPlus® is conveniently elongable, pliable and easy to knot.

■ MonoPlus® provides a smooth passage through the tissue and has no capillary effect.

■ In comparison to non absorbable sutures it causes less wound pain and suture sinuses (18, 29, 30, 31, 39).

■ The polydioxanone monofilament absorbable suture material exhibits low foreign body reactions and wound infections are rarely seen (19, 31, 36, 38).

■ Polydioxanone suture material is superior to non-absorbable suture material for abdominal wall closure. (29, 30, 39)

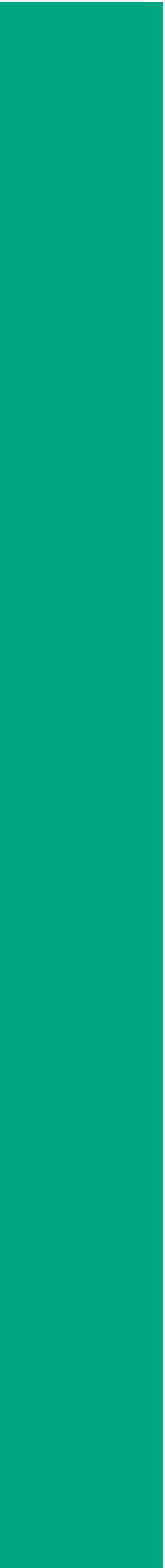
■ A mass closure using a continuous running suture technique is the optimal technique for fascial closure after laparotomy (16, 29, 30, 31), because this technique offers advantages by distributing the tension on the wound across the whole suture line rather than on individual stitches.

■ For safe closure of laparotomy wounds a suture length to wound length ratio of 4:1 should be used to reduce the rate of incisional hernia. (16, 39).

■ The continuous running suture technique causes less tissue necrosis, is easier to perform, is less time-, cost- and material-consuming than the interrupted technique. (18, 29).

■ MonoPlus® is indicated for:

- Abdominal wall closure
- Orthopaedics
- Paediatric cardiovascular surgery



Abstracts

Br J Surg. 2002 Nov; 89 (11): 1350-6.
Comment in: Br J Surg. 2003 Mar; 90 (3): 370.

Meta-analysis of techniques for closure of midline abdominal incisions.

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BACKGROUND: Various randomized studies have evaluated techniques of abdominal fascia closure but controversy remains, leaving surgeons uncertain about the optimal method of preventing incisional hernia.

METHOD: Medline and Embase databases were searched. All trials with a follow-up of at least 1 year that randomized patients with midline laparotomies to closure of the fascia by different suture techniques and/or suture materials were subjected to meta-analysis. Primary outcome was incisional hernia; secondary outcomes were wound dehiscence, wound infection, wound pain and suture sinus formation.

RESULTS: Fifteen studies were identified with a total of 6566 patients. Closure by continuous rapidly absorbable suture was followed by significantly more incisional hernias than closure by continuous slowly absorbable suture ($P < 0.009$) or non-absorbable suture ($P = 0.001$). No difference in incisional hernia incidence was found between slowly absorbable and non-absorbable sutures ($P = 0.75$), but more wound pain ($P < 0.005$) and more suture sinuses ($P = 0.02$) occurred after the use of non-absorbable suture. Similar outcomes were observed with continuous and interrupted sutures, but continuous sutures took less time to insert.

CONCLUSION: To reduce the incidence of incisional hernia without increasing wound pain or suture sinus frequency, slowly absorbable continuous sutures appear to be the optimal method of fascial closure.

Am Surg. 2001 May; 67 (5): 421-6.

Closure of the abdominal midline fascia: meta-analysis delineates the optimal technique.

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The current surgical literature has not clearly demonstrated an optimal technique for abdominal closure. Prospective randomized studies published between 1980 and 1998 were analyzed and the relevant data derived from those studies were pooled for statistical evaluation. The outcome variables of dehiscence, infection, hernia formation, suture sinus formation, and pain were studied and the probability of their occurrence in association with different techniques was calculated. In relation to the outcome features of dehiscence and infection no statistically significant difference was seen when absorbable suture material was compared with nonabsorbable material. In regard to the probability of hernia formation no statistically significant difference was seen when monofilament absorbable material was compared with nonabsorbable material. There was, however, a higher incidence of hernia formation when braided absorbable suture material was used. In addition there was a higher incidence of incision pain and suture sinus formation when nonabsorbable suture material was used. Absorbable monofilament suture material is superior to both absorbable braided and nonabsorbable suture for abdominal fascial closure. A continuous mass (all-layer) closure with absorbable monofilament suture material is the optimal technique for fascial closure after laparotomy.

Abstracts

Ann Surg. 2000 Mar; 231 (3): 436-42.

The search for an ideal method of abdominal fascial closure: a meta-analysis.

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BACKGROUND AND OBJECTIVE: The ideal suture for abdominal fascial closure has yet to be determined. Surgical practice continues to rely largely on tradition rather than high-quality level I evidence. The authors conducted a systematic review and meta-analysis of randomized controlled trials to determine which suture material and technique reduces the odds of incisional hernia.

METHODS: MEDLINE and Cochrane Library databases were searched for articles in English published from 1966 to 1998 using the keywords "suture", "abdomen/surgery", and "randomized controlled trials". Randomized controlled trials, trials of adult patients, and trials with a Jadad Quality Score of more than 3, comparing suture materials, technique, or both, were included. Two independent reviewers critically appraised study quality and extracted data. The reviewers were masked to the study site, authors, journal, and date to minimize bias. The primary outcome was postoperative incisional hernia. Secondary outcomes included wound dehiscence, infection, wound pain, and suture sinus formation.

RESULTS: The occurrence of incisional hernia was significantly lower when nonabsorbable sutures were used. Suture technique favored nonabsorbable continuous closure. Suture sinuses and wound pain were significantly lower when absorbable sutures were used. There were no differences in the incidence of wound dehiscence or wound infection with respect to suture material or method of closure. Subgroup analyses of individual sutures showed no significant difference in incisional hernia rates between

polydioxanone and polypropylene. Polyglactin showed an increased wound failure rate.

CONCLUSIONS: Abdominal fascial closure with a continuous nonabsorbable suture had a significantly lower rate of incisional hernia. The ideal suture is nonabsorbable, and the ideal technique is continuous.

Am J Surg. 1998. Dec; 176 (6): 666-70.

Choosing the best abdominal closure by meta-analysis.

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BACKGROUND: Local custom, rather than evidence-based medicine, dictates how a surgeon closes abdominal wounds. Closures might be more secure if grounded on statistical data.

MATERIALS AND METHODS: A meta-analysis of 12,249 patients with abdominal wound closures was made. Infections, hernias, and dehiscences were compared examining continuous versus interrupted closures, continuous (absorbable versus nonabsorbable), interrupted (absorbable versus nonabsorbable), and mass versus layered.

RESULTS: Continuous absorbable closures showed more hernias ($P = 0.0007$). Dehiscences were significantly more with continuous nonabsorbable suture ($P = 0.01$). Interrupted nonabsorbable closures showed a higher incidence of hernias and dehiscences ($P = 0.0002$, $P = 0.04$). Mass closures produced significantly less hernias and dehiscences when compared with layered closures ($P = 0.02$, $P = 0.0002$).

CONCLUSIONS: Continuous closures with nonabsorbable suture should be used to close most abdominal wounds. However, if infection or distention is anticipated, interrupted absorbable sutures are preferred. Mass closures are superior to layered closures.

Chirurg. 2006 Mar; 77 (3): 267-72.

Operative standardization in randomized controlled surgical trials. Meeting of the INSECT trial.

Knaebel HP, Kirschner MH, Reidel MA, Büchler MW, Seiler CM.

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BACKGROUND: INSECT is an internationally registered, three-armed, multicentre, intraoperatively randomised model trial of the Study Centre of the German Surgical Society. The interventions being compared are running suture technique with slowly absorbable monofilament suture material (PDS vs MonoPlus) and interrupted technique with a braided, rapidly absorbable suture material (Vicryl). The primary endpoint is the rate of incisional hernias 1 year post-operatively.

MATERIAL AND METHODS: A total of 25 surgeons from 24 different institutions at all levels of care evaluated the theoretical and practical sessions of the surgical investigator meeting using 25 criteria, including course organisation, content, and speaker evaluation, and a categorical grading system from 1 (very good) to 6 (insufficient).

RESULTS: Distribution of the 625 grades was: very good (1) $n = 367$, good (2) $n = 207$, satisfactory (3) $n = 39$, adequate (4) $n = 2$, and "No statement" $n = 10$. The average score for the investigator meeting was 1.5.

CONCLUSION: The participants felt they were successfully prepared theoretically and practically for trial interventions and conduct by attending the meeting. Clear explanation of the measures for treatment equivalence before and during trials is mandatory in randomised controlled surgical trials.

Abstracts

BMC Surg. 2005 Mar 8; 5:3.

Interrupted or continuous slowly absorbable sutures—design of a multi-centre randomised trial to evaluate abdominal closure techniques INSECT-trial [ISRCTN24023541].

Knaebel HP, Koch M, Sauerland S, Diener MK, Büchler MW, Seiler CM; INSECT Study

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BACKGROUND: The closure of the abdomen after median laparotomy is still a matter of debate among surgeons. Further well designed and performed randomised controlled trials determining the optimal method of abdominal fascial closure are needed.

DESIGN: This is a three armed, multi-centre, intra-operatively randomised, controlled, patient blinded trial. Over 20 surgical departments will enrol 600 patients who are planned for an elective primary abdominal operation. The objective of this study is to compare the frequency of abdominal incisional hernias between two continuous suture techniques with different, slowly absorbable monofilament materials and an interrupted suture using an absorbable braided suture material at one year postoperatively.

CONCLUSION: This trial will answer the question whether the continuous abdominal wall closure with a slowly absorbable material with longitudinal elasticity is superior to the continuous suture with a material lacking elasticity and to interrupted sutures with braided thread.

Ann Surg. 2009 Apr; 249 (4): 576-82.

Interrupted or continuous slowly absorbable sutures for closure of primary elective midline abdominal incisions: a multicenter randomized trial (INSECT: ISRCTN24023541).

Seiler CM, Bruckner T, Diener MK, Pappan A, Golcher H, Seidlmayer C, Franck A, Kieser M, Büchler MW, Knaebel HP.

Study Center of the German Surgical Society, University of Heidelberg, Im Neuenheimer Feld 110, 69120 Heidelberg, Germany.

OBJECTIVE: In patients undergoing midline incisions, the abdominal fascia can be closed with a continuous or interrupted suture using various materials. The aim of this study is to compare: (1) interrupted technique with rapidly absorbable sutures and (2) continuous techniques with different slowly absorbable sutures, focusing on the incidence of incisional hernias within 1 year.

SUMMARY OF BACKGROUND DATA: A meta-analysis suggested that the incidence of incisional hernias can be more effectively reduced with slowly absorbable continuous sutures.

METHODS: Multicenter randomized surgical trial with 3 parallel groups. Patients were scheduled for primary elective midline incisions. All surgeons were trained (4:1 suture wound length in continuous groups) and monitored. Primary end point, measured within 1 year after surgery, was the frequency of incisional hernias diagnosed by clinical examination and confirmed by ultrasound. Complications and safety were used as secondary end points. This study has been registered with the ISRCTN Register (INSECT: ISRCTN24023541).

RESULTS: Conducted on 625 randomized patients (210 interrupted Vicryl, 205 continuous polydioxanone suture (PDS), 210 continuous Monoplus), the primary analysis showed an incidence of 28 incisional hernias (15.9 %) versus 15 (8.4 %) versus 22 (12.5 %) for the 3 closure techniques, respectively ($P = 0.09$). No significant difference was observed between the 3 groups with regard to burst abdomen (4 [2.0 %] vs. 6 [3.0 %] vs. 8 [4.0 %], $P = 0.46$), wound infection (26 [12.7 %] vs. 39 [19.4 %] vs. 33 [16.3 %], $P = 0.19$), pulmonary infections (9 [4.4 %] vs. 5 [2.5 %] vs. 5 [2.5 %], $P = 0.46$), serious adverse events (63 [30.0 %] vs. 57 [27.8 %] vs. 61 [29.1 %], $P = 0.89$), and 1-year mortality (16 [7.9 %] vs. 11 [5.5 %] vs. 16 [7.9 %], $P = 0.54$).

CONCLUSIONS: The incidence of incisional hernias and the frequency of wound infection was higher than expected in all groups. New concepts need to be developed and studied to substantially reduce the frequency of incisional hernias.

PMID: 19300233 [PubMed – indexed for MEDLINE]

World J Surg. 2000 Jun; 24 (6): 747–51; discussion 752.

Incisional hernia after laparotomy: prospective randomized comparison between early-absorbable and late-absorbable suture materials.

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Incisional hernia is a serious postoperative complication of laparotomy. Selecting an appropriate suture material may lessen such morbidity. This study undertook a prospective, randomized comparison of early-absorbable polyglactin 910 suture versus late-absorbable polydioxanone loop suture for fascial closure after abdominal surgery. A series of 340 consecutive patients undergoing elective laparotomy were randomized to have fascial closure with either polyglactin 910 suture or polydioxanone loop suture between October 1993 and August 1996. A 2-year follow-up revealed that 23 patients had died, and the overall mortality rate was 6.8 % (23/340). Ten (10/340, 2.9 %) patients, including seven with polyglactin 910 suture and three with polydioxanone loop suture, developed incisional hernias. The early postoperative evaluation revealed an incidence of wound infection of 4.1 % (14/340). The development of incisional hernia was not secondary to postoperative wound infection in this study. Among these 340 patients, 192 had malignant diseases and 148 had nonmalignant ones. Fascial closure with polyglactin 910 suture was associated with more incisional hernias than that with polydioxanone loop suture, with marginal significance for patients in the malignant group (4.7 % versus 0 %, $p = 0.07$) but not in the non-malignant group (2.6 % versus 4.2 %, $p = 0.67$). In conclusion, abdominal closure with a late-absorbable polydioxanone loop suture may be beneficial to patients with a malignant disease for preventing incisional hernia.

Abstracts

Ann Chir. 1995; 49 (6): 544-8.

[Results of a controlled trial comparing 3 suture threads at slow resorption for the closure of supra-umbilical midline laparotomies]

[Article in French]

Bresler L, Courbey PJ, Feldman L, Bilweiss J, Tortuyaux JM, Rauch P, Boissel P, Grosdidier J.

Clinique Chirurgicale C, CHRU de Nancy, Hôpitaux de Brabois, Vandoeuvre-les-Nancy.

A randomized prospective trial was carried out between September 1987 and February 1989 to compare 3 different absorbable sutures (polyglactine 910, polydioxanone I, polydioxanone II) for closure of the abdominal wall after upper midline laparotomy for elective operations. The technique used to close the fascia was always a continuous suture. The criteria used to assess the results were the development of wound infection and wound dehiscence in the early post-operative period, and the development of suture sinuses and incisional hernia 1 year after operation. The early post-operative results in 235 patients revealed no wound infection and no wound dehiscence. Suture sinuses developed in 4 patients (2 %) 2 months after operation, but resolved spontaneously. We reviewed 203 patients after one year. The total number of incisional hernias detected 1 year post-operatively was 22 cases (11 %), (polyglactine 910, 14.2 %; polydioxanone I, 11.2 %; polydioxanone II, 8.4 %). The difference between the 3 groups was not statistically significant. The results of the trial indicate that absorbable sutures have a very low incidence of suture sinuses, and that polydioxanone II seems to be a good choice for closing laparotomies.

Br J Surg. 1994 Nov; 81 (11): 1606-8.

Closure of midline laparotomy incisions with polydioxanone and nylon: the importance of suture technique.

Israelsson LA, Jonsson T.

Department of Surgery, Sundsvall County Hospital, Sweden.

The healing of midline laparotomy incisions closed with a continuous suture of nylon or second-generation polydioxanone was evaluated in a randomized clinical trial. The effect of suture technique, reflected in the suture length to wound length ratio, was also assessed. All patients who underwent abdominal surgery through a midline incision were included except those with incisional hernia after previous midline operation. Wound dehiscence occurred in five (0.6 per cent) of 813 patients and wound infection in 73 (9.0 per cent). These rates were similar for both suture materials, as were those for the development of suture sinus and prolonged postoperative wound pain. Incisional hernia 12 months after surgery was found in 49 (15.1 per cent) of 325 wounds sutured with polydioxanone and in 50 (15.7 per cent) of 318 closed with nylon ($P = 0.91$). There was a significant correlation between the hernia rate and the suture to wound length ratio for both materials ($P < 0.001$). These results indicate that suture of midline laparotomy wounds is as safe with polydioxanone as it is with nylon. Incisional hernia is associated more with suture technique than with the material used.

Br J Surg. 1987 Aug; 74 (8): 738-41.

Fascia closure after midline laparotomy: results of a randomized trial.

Wissing J, van Vroonhoven TJ, Schattenkerk ME, Veen HF, Ponsen RJ, Jeekel J.

Department of Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands.

Four techniques to close the fascia after midline laparotomy were compared in a prospective randomized multicentre trial. The four techniques were: interrupted closure with polyglactin; continuous closure with polyglactin; continuous closure with polydioxanone-s, and continuous closure with nylon. The early postoperative results in 1491 patients revealed an incidence of wound infection of 8.6 per cent and of wound dehiscence of 2.3 per cent with no statistically significant differences between the four techniques. We reviewed 1156 patients after 1 year. Wound pain was present in 9.7 per cent of the patients, statistically significantly more in the group closed with nylon (16.7 per cent). Suture sinuses developed in 3.5 per cent of the patients, statistically significantly more frequently in the nylon group (7.7 per cent). The total number of incisional hernias detected 1 year postoperatively was high (15.2 per cent) (interrupted polyglactin 16.9 per cent, continuous polyglactin 20.6 per cent, continuous polydioxanone 13.2 per cent and continuous nylon 10.3 per cent). The difference between nylon and continuous polyglactin is statistically significant. The results of this trial indicate that although nylon has the lowest incidence of incisional hernia it also is associated with more wound pain and suture sinuses.

Ann R Coll Surg Engl. 1987 May; 69 (3): 113-5.

A randomised comparison of polydioxanone (PDS) and polypropylene (Prolene) for abdominal wound closure.

Cameron AE, Parker CJ, Field ES, Gray RC, Wyatt AP.

Two hundred and eighty four patients undergoing laparotomy by vertical incision were randomly allocated to closure with interrupted mass sutures of No. 1 polydioxanone (PDS) or No. 1 polypropylene (Prolene). Dehiscence occurred in 0.7 % of the PDS group but in 6.4 % of the Prolene group ($P = 0.018$). Wound infection occurred in 8.6 % of the PDS group and 15.4 % of the Prolene group ($P = 0.1$). One hundred and ninety patients attended for review at a minimum of one year. Incisional herniation, usually asymptomatic, was present in 11 % of each group. Knots were palpable in 2 % of the PDS patients but in 12 % of the Prolene: wound pain occurred in 12 % of the PDS group but in 23 % of the Prolene group ($P = 0.06$). These results suggest that PDS may be useful for abdominal closure.

Abstracts

Br J Surg. 1987 Sep; 74 (9): 828-30.

Polydioxanone or polypropylene for closure of midline abdominal incisions: a prospective comparative clinical trial.

Krukowski ZH, Cusick EL, Engeset J, Matheson NA.

Department of Surgery, Medical School, University of Aberdeen, Foresterhill, UK.

Seven hundred and fifty-seven consecutive patients undergoing a midline abdominal incision were stratified according to age, sex, type of operation and degree of operative contamination and were randomly allocated to mass closure of the abdominal wall with continuous 4 metric polydioxanone (PDX; 374 patients) or continuous 4 metric polypropylene (PPL; 383 patients). Wound infection was less common with PDX (PDX 3.5 per cent; PPL 7.0 per cent; P less than 0.05) and there was one dehiscence in each group. The incidence of defective wounds in patients surviving 1 year was similar (7.7 per cent PDX; 9.7 per cent PPL) but the PPL suture had to be removed because of persisting wound pain or sinus formation in five patients. PDX is the preferred suture material for closure of midline abdominal incisions.

Surgeon. 2003 Feb; 1 (1): 17-22.

Factors involved in abdominal wall closure and subsequent incisional hernia.

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Incisional hernia is a frequent complication of abdominal wall closure with a reported incidence of between 5 % and 15 % following vertical midline incisions at one-year follow-up. Evidence from randomised clinical trials and meta-analysis indicate that a continuous running non-absorbable or slowly absorbed suture such as polydioxanone is the method of choice for abdominal wall closure. Continuous polydioxanone has a similar incisional hernia rate to its non-absorbable counterparts but causes less chronic pain and wound sinuses. Evidence from randomised clinical trials indicates that a lateral paramedian incision is associated with a lower incidence of incisional hernia when compared with other abdominal incisions. Transverse abdominal incisions have no advantage over midline incisions in reducing incisional hernia rate. Although experimental and clinical evidence indicate that a greater number of stitches with a suture length to wound ratio of at least 4:1 is associated with a lower incidence of incisional hernia, there is no evidence from randomised clinical trials to support this. Intuitively one may think that putting as little tension as possible on the closure is important, but there is no evidence for this. Clinical trials evaluating these factors would be difficult to undertake making it important that surgeons continue to audit incisional hernia rates following abdominal closure.

J Bone Joint Surg Br. 2005 Jun; 87 (6): 819-23.

The effect of suture materials and techniques on the outcome of repair of the rotator cuff: a prospective, randomised study.

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In a prospective, randomised study on the repair of tears of the rotator cuff we compared the clinical results of two suture techniques for which different suture materials were used. We prospectively randomised 100 patients with tears of the rotator cuff into two groups. Group 1 had transosseous repair with No. 3 Ethibond using modified Mason-Allen sutures and group 2 had transosseous repair with 1.0 mm polydioxanone cord using modified Kessler sutures. After 24 to 30 months the patients were evaluated clinically using the Constant score and by ultrasonography. Of the 100 patients, 92 completed the study. No significant statistical difference was seen between the two groups: Constant score, 91 % vs 92 %; rate of further tear, 18 % vs 22 %; and revision, 4 % vs 4 %. In cases of further tear the outcome in group 2 did not differ from that for the intact repairs (91 % vs 91 %), but in group 1 it was significantly worse (94 % vs 77 %, $p = 0.005$). Overall, seven patients had complications which required revision surgery, in four for pain (two in each group) and in three for infection (two in group 1 and one in group 2).

Orthopäde. 2005 Jun; 34 (6): 550-5.

A simplified technique for repair of quadriceps tendon rupture by transpatellar PDS-cord

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Quadriceps tendon ruptures are relatively unusual injuries caused by direct or more frequently indirect trauma. Since complete ruptures lead to loss of active extension of the knee joint, operative treatment is usually indicated. Several techniques are described in the literature. However, relatively little is known about the functional outcome after operative treatment of acute quadriceps tendon ruptures. We present a new operative technique using a 1.3 mm PDS cord passed through a transverse drill hole in the proximal pole of the patella. We operated ten consecutive cases of complete quadriceps tendon ruptures with the technique described between January 2000 and June 2003. Eight of ten patients were evaluated after a mean follow-up time of 38 months by physical examination, IKDC Subjective score, Lysholm and Tegner score as well as an isokinetic test of the quadriceps strength. No complications were noted in this period. The average postoperative scores were 87 (IKDC), 98 (Lysholm), and 4.5 (Tegner). Isokinetic testing showed an average of 25 % quadriceps strength deficit. The operative treatment of complete quadriceps tendon ruptures using a PDS cord through a drill hole in the patella is a safe and effective technique permitting functional postoperative treatment.

Abstracts

Knee Surg Sports Traumatol Arthrosc. 1999; 7 (2): 102-6.

Clinical experience with PDS II augmentation for operative treatment of acute proximal ACL ruptures-2-year follow-up.

Hehl G, Strecker W, Richter M, Kiefer H, Wissmeyer T.

Traumatologic Department of Surgery, University of Ulm, Germany.

The results of prospective anterior cruciate ligament (ACL) refixation in 33 patients with high proximal rupture is reported at 20 - 28 months' follow-up: mean age was 31.1 +/- 12.5 years. The surgical technique was a specially developed refixation of the ACL using a multiple suture loop (modified Marshall technique) augmented with intra-articular PDS II (polydioxanone, resorbable, Ethicon, Hamburg, Germany) to avoid derangement of blood circulation and to guarantee early functional rehabilitation. All patients were operated on within 7.3 +/- 4.5 days after injury. According to the IKDC evaluation score, 22 patients showed excellent and 10 patients good subjective function. Twenty regained their pre-injury level of activity. Anterior stability was tested manually and by KT-1000 max (Medmetric, San Diego). Twenty-eight patients had a firm end-point, although there was a positive Lachman test in 16 patients. Maximal joint laxity as measured by KT-1000 showed a 1 - 2 mm, 3 - 5 mm, 6 - 10 mm and > 10 mm anterior drawer for 16, 14, 2 and 1 patients, respectively. Twenty-five of the evaluated knee joints had a negative pivot shift test. Three patients had a limited range of motion. The potential advantages of PDS II-augmented refixation of acute proximal ACL ruptures are anatomic reconstruction without destruction of other anatomic structures used as grafts, early functional rehabilitation and possibly better proprioception.

Orthopedics. 1986 Nov; 9 (11): 1533-6.

Use of polydioxanone absorbable monofilament sutures in orthopedic surgery.

Miles JS.

The safety and efficacy of polydioxanone absorbable monofilament sutures was documented in 57 orthopedic surgery patients (32, dyed sutures; 25, undyed sutures), 55 of whom were followed for at least 42 days postoperatively. The other two patients were lost to follow up prior to 42 days. The final clinical outcome was excellent in all completed study subjects. No suture-related adverse effects were reported. Both dyed and undyed sutures were consistently better than surgical gut with respect to pliability, strength, ease of passage, ease of tying, fraying, knot security, and overall handling. Intraoperative visibility of dyed polydioxanone sutures was consistently superior to that of surgical gut. The visibility of undyed sutures was rated better than surgical gut in 16 cases, equal in 8, and worse in 1. Both the overall handling of the polydioxanone monofilament sutures and performance as it affected wound healing were significantly superior to those of surgical gut.

J Card Surg. 2006 Nov-Dec; 21 (6): 580-4.

Polydioxanone sternal sutures for prevention of sternal dehiscence.

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BACKGROUND: Sternal dehiscence and wound instability are troublesome complications following median sternotomy. Classic sternal approximation with stainless steel wires may not be the ideal approach in patients predisposed to these complications. We tested the efficacy of polydioxanone (PDS) suture in sternal closure and in prevention of complications in comparison to steel wires in high-risk individuals.

METHODS: Three hundred sixty-six patients undergoing elective cardiac surgery with full median sternotomy and having body surface area (BSA) less than 1.5 m² were randomly assigned to receive PDS (n = 181) or stainless steel (SS, n = 185) sternal approximation. The study was focused on aseptic sternal complications, namely bone dehiscence and superficial wound instability.

RESULTS: Both bone dehiscence and superficial wound instability were less frequent in the PDS Group (4 and 3 cases in the SS Group, respectively, vs. no cases in the PDS Group). Cox proportional hazards regression model in the whole study population identified female sex, chronic renal insufficiency, diabetes, advanced age, lower sternal thickness, osteoporosis, corticosteroid therapy, and prolonged CPB or ventilation times as predisposing factors to any of the two studied sternal complications.

DISCUSSION: Data suggest that PDS suture can protect against development of aseptic sternal complications following median sternotomy in high-risk patients with little body mass. The adoption of PDS in other subsets of patients, i.e., obese individuals, is to be questioned.

Abstracts

Cardiovasc Surg. 1994 Aug; 2 (4): 508-13.

Polydioxanone absorbable sutures in vascular anastomoses: experimental and preliminary clinical studies.

Wang ZG, Pu LQ, Li GD, Du W, Symes JF.

Vascular Institute, Beijing Post and Telecom Hospital, China.

To assess the safety and efficacy of polydioxanone suture (PDS) for vascular anastomoses, bilateral carotid end-to-end anastomoses using PDSs on the left and Dacron sutures on the right in 18 dogs were performed. The anastomoses were assessed at 4, 6 and 8 weeks after surgery. A breaking-strength test (300 mmHg) did not show a significant difference between PDS and Dacron anastomoses, but partial absorption was grossly evident in the PDS group. Some 35 venous and 21 arterial reconstructive procedures were also carried out using PDS in 53 patients. At follow-up of 3 - 5 (mean 3.5) years, none of the patients had experienced any suture-related complications. The results indicate that PDS maintains an adequate tensile strength in anastomoses until suture-line healing occurs, suggesting that this material may be safely used in venous or small arterial anastomoses. In addition, because it is absorbable, resulting in decreased foreign-body reactions, PDS may have the potential to improve the long-term patency of venous or small arterial reconstructions.

J Thorac Cardiovasc Surg. 1986 Oct; 92 (4): 771-5.

The use of absorbable monofilament polydioxanone suture in pediatric cardiovascular operations.

Myers JL, Campbell DB, Waldhausen JA.

Growth of suture lines and anastomoses is required for long-term success after the repair of congenital cardiovascular anomalies. Polydioxanone, an absorbable monofilament suture material, has been used in a variety of operations since April, 1983. Twenty-two of the 46 procedures were coarctation repairs. Complete repairs for anomalous pulmonary veins and transposition of the great arteries, as well as Fontan procedures and systemic-pulmonary shunts, have been performed. Angiographic, gross, and microscopic examination showed good healing. There was no anastomotic disruption or aneurysm formation. The results with this absorbable vascular suture have been uniformly encouraging in a follow-up of up to 30 months.

Ann Thorac Surg. 1995 Jul; 60 (1): 55-9.

Absorbable polydioxanone suture and results in total anomalous pulmonary venous connection.

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BACKGROUND: Despite theoretical advantages of absorbable suture in the growing vascular anastomosis, there has not been a documented advantage over nonabsorbable suture in preventing late anastomotic stenosis in total anomalous pulmonary venous connection (TAPVC).

METHODS: We reviewed our experience from 1982 to 1994 with 65 hospital survivors of total TAPVC repair to examine the influence of suture type on survival and incidence of late pulmonary venous obstruction. From 1982 until 1988, we used continuous nonabsorbable polypropylene suture for the pulmonary venous-left atrial anastomosis in supracardiac, infracardiac, and mixed types of TAPVC. In 1989, we adopted a running absorbable polydioxanone suture technique. Cardiac catheterization and echocardiography were used to evaluate late pulmonary venous obstruction.

RESULTS: Late pulmonary venous obstruction occurred in 17 % (4/23) of survivors after repair with polypropylene suture compared with 3.2 % (1/32) after repair with polydioxanone suture ($p < 0.05$). There were no instances of late pulmonary venous obstruction in the intracardiac TAPVC group (0/10). All late pulmonary venous obstructions occurred within 16 months after operation. The actuarial 3-year and 5-year freedom from late pulmonary venous obstruction was 100 % for intracardiac TAPVC, 96 % for the polydioxanone group, and 81 % for the polypropylene group. Five patients died late (5/65, 7.7 %), 3 in the polypropylene suture group (3/23, 13 %) and 2 in the polydioxanone group (2/32, 6 %).

CONCLUSIONS: Continuous absorbable polydioxanone suture for the repair of TAPVC results in a low incidence of late pulmonary venous obstruction and death and appears to offer advantages over a continuous nonabsorbable suture. A continuous nonabsorbable suture may limit growth of a vascular anastomosis, particularly one involving a "low-pressure" anastomosis such as in the repair of TAPVC.

Abstracts

J Pediatr Surg. 2000 Sep; 35 (9): 1309-11.

Sternal closure with resorbable synthetic loop suture material in children.

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PURPOSE: The reliability of poly-p-dioxanone (PDS) suture for sternal closure was tested on 264 consecutive sternotomies in the authors' department from April 1987 to May 1998.

METHODS: The reason for sternotomy was tetralogy of Fallot in 65 cases (24.6 %), ventricular septal defect (VSD) in 38 cases (14.4 %), atrial septal defect (ASD) in 77 cases (29.2 %), ASD + VSD in 23 (8.7 %), mitral valve replacement in 22 cases (8.3 %), aortic valve replacement in 10 cases (3.8 %), and other cardiac disorders in 29 cases (11.0 %).

RESULTS: Sternal wound infection, sternal dehiscence, and mediastinitis occurred in 1.5 % of patients (4 of 264). The overall hospital mortality rate related to the mediastinitis was 1.1 % (3 of 264) in the early postoperative period.

CONCLUSION: This absorbable suture and our different technique are a safe alternative to standard sternotomy closure after pediatric open cardiac surgery.

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