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ORIGINAL ARTICLE

PerFix™ plug versus 4DDOME® implants for inguinal hernia repair: prospective multicentric randomised controlled trial

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Abstract
Introduction Anterior mesh placement is the standard of care for hernia repair. The use of partially absorbable meshes may limit post-operative pain without altering the durability of the repair. We designed a prospective randomised study, which aims to compare the PerFix™ plug to the 4DDOME®, a partially absorbable mesh.
Materials and methods Inguinal hernia patients were prospectively and randomly included in the study. Hernia repair was performed using either the PerFix™ plug (Davol) or the 4DDOME® implant (Cousin Biotech). Operative evaluation included type and duration of anaesthesia, characteristics of the incision, post-operative hospital stay and pain evaluated through a visual analogue scale (VAS) at day 1, day 8, month 1, month 6, and year 1. Return to personal or professional activity was evaluated. Quality of life was measured by a SF36 questionnaire at 1, 6, and 12 months' follow-up.
Results Ninety-five patients were prospectively enrolled and randomised to one type of prosthetic repair. The two groups of patients did not differ in terms of clinical characteristics, type of hernia, and intra-operative course. When comparing PerFix™ plug to 4DDOME® groups, the post-operative course was similar: pain (VAS 3.42 (SD 1.83) vs. 3.82 (SD 2.0), $p = 0.69$); in-hospital stay (2.12 (SD 1.36) vs. 2.25 (SD 1.62), $p = 0.67$); and return to personal (9.39 days (SD 8.15) vs. 9.48 days (SD 11.68), $p = 0.96$) and professional activity (25.71 days (SD 17.47) vs. 22.82 days (SD 18.10), $p = 0.62$). Post-operative pain and discomfort assessed by the SF36 questionnaire at day 8, months 1, 6, and 12 were similar, but significantly lower after 4DDOME® repair at 3 months for "pain" ($p = 0.021$) and at 6 months for "health" criteria ($p = 0.028$).
Conclusion This clinical study demonstrated similar short-term results. The 4DDOME® was associated with less pain and discomfort after 3 and 6 months. The combination of the dome shape and the double component mesh including an absorbable part meet the conflicting demands of early strength with a long-term low-weight material to minimise shrinkage and fibrosis. This design represents a potential advance in anterior tension-free hernia repair with mesh.

Keywords Hernia · Repair · Mesh · Plug · DOME · Polypropylene · Composite · Bioactive

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Introduction

The use of prosthetic meshes for inguinal hernia repair has become the gold standard and most common approach to herniorrhaphy [1]. It allows to develop the concept of

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tension-free repair. The aim of prosthetic meshes is to achieve the greatest physiological reinforcement of the abdominal wall through the introduction of fibrosis. This is currently achieved through the use of non-absorbable mesh material that has gained global acceptance within the surgical community over the last 15 years [2–4]. As per the surgeon's request, surgical mesh manufacturers have started to market various types of prostheses. These are made of different materials (polyester, polypropylene) and shapes [5]. Whereas many surgeons consider the basic shape as the one that re-assembles the tracing of footprint including a sharp curve and the keyhole to pass around the inguinal elements, other shapes are suggested to fit in the inguinal defects more precisely.

One option is to include a specific part of the mesh that aims at exerting counter-resistance to the intra-operative pressure of the abdomen during the healing process. This can be achieved through a dome-shaped configuration of the mesh [5]. The first mesh designed for this specific application was the PerFix™ plug, consisting of a plug and an anterior mesh (PerFix™ Plug, Davol, a Bard Company, Warwick, RI, USA). This has been promoted by Rutkow and Robbins [6]. This approach has gained large recognition, and it is nowadays claimed that 22 % of all groin hernias in the United States are repaired with the PerFix™ plug [7]. Two questions regarding the use of this type of mesh are currently raised in the literature. The first concerns the risk of complications associated with the mesh plug. This is associated with specific complications among which the migration of the mesh plug into loco-regional anatomical structures [8, 9] is a devastating one. These complications are not specific to this type of approach or mesh, as they are also described for other approaches such as the laparoscopic ones [10]. These complications are partially ascribable to the type but mostly to the amount of implanted biomaterial. This material is also suspected to account for the second type of deleterious post-operative patient outcome, especially including chronic groin pain [11, 12]. In fact, recent prospective clinical studies report that some pain or discomfort might occur in 19–30 % of patients [12, 13].

However, simply reducing the amount of polypropylene in the mesh configuration is not satisfactory as tensile strength may be reduced, whereas the risk of shrinkage increases. Therefore, the development of new meshes that include a low amount of remaining material, but which keep their structural resistance for the implantation and early post-operative period, has been pursued. This association may optimise patients' compatibility and acceptance for the repair of abdominal wall defects. Nevertheless, the place of ultra light weight and large pore materials is still under evaluation: these factors may significantly affect the shrinkage of the new meshes. An original composite prosthesis designed to fulfil the contradictory request of resistance and low amount of remaining prosthesis was designed. It included a dome-shaped element associated with a lightweight polypropylene mesh (the 4DDOME® implant—Cousin Biotech—Wervicq-Sud—France) [14]. It has been achieved by the association of an absorbable poly-L-lactic acid (PLLA) component with a conventional lightweight prosthesis. This association significantly changes the manipulation of the mesh and its placement during the surgical approach. The first clinical studies were encouraging [4]. They demonstrated that the mesh was well tolerated. Its shape was progressively modified as it flattened out at 6 months and became incorporated into the repair. The effectiveness of these new meshes is best evaluated through a comparative study facing the standard of care for the same indication. We have designed a multicentre prospective randomised and controlled trial that aims at comparing the early and one-year results of inguinal hernia repair in patients treated with a PerFix™ plug as compared to patients managed with the new 4DDOME® implant.

Materials and methods

This multicentric study included 3 surgical centres that have a regular practice in the anterior approach for inguinal hernia repair. The study has been submitted and obtained the approval of the French National Ethics Committee ("Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale"—Approval No. 05/03 delivered on January 12, 2005).

Patients' characteristics

Patients over the age of 18 with an uncomplicated unilateral inguinal hernia were selected for the study. All patients were eligible for a local anaesthetic approach. This approach was systematically recommended to all patients, but they were also allowed to request for general anaesthesia. All patients were informed and signed an informed consent. Contra-indications to the inclusion included chronic intake of analgesic treatment, BMI over 40 kg/m^2, long-term treatment by corticosteroids, bilateral hernia, recurrent hernia, and emergency management. All patients were randomly allocated to each group after inclusion in the study. A random generator (R® project for statistical computing) was used to create an inclusion list. Every patient was successively randomised according to the list.

Surgical technique

Prior to the study, the surgical approach was standardised. After the reduction of the hernia sac, the type of defect was classified according to the Nyhus classification (Nyhus II, IIIa, IIIb). The surgical techniques used were those previously described for the 4DDOME® technique [14], and by Rutkow and Robbins [15] for the PerFix™ plug. In the 4DDOME® group, the mesh was sutured in position and covered with an onlay mesh placed over the posterior inguinal wall. The same fixation was used for the heavyweight polypropylene mesh PerFix™ plug. According to the standardised protocol, all patients received a single dose of non-steroidal anti-inflammatory drug after operation, and an outpatient prescription was supplied to each patient for analgesic medication if required (paracetamol, 1–3 g/day).

Data collection and follow-up

Data were collected following a standardised data collection form. This included patients' characteristics (age, medical history, hernia description, and significant clinical history). All intra- and post-operative follow-ups were recorded and monitored by the primary investigator. Pre-operative data included clinical evaluation of the patients, BMI, potential quantification of pre-operative pain, and pre-operative discomfort when existing. The operative evaluation took into account the type of anaesthesia, duration of anaesthesia, duration of the operative procedure, and description of the hernia. The name of the operator was recorded. The post-operative evaluation included the local aspect of the scar (haematoma, infection, potential delay in healing), post-operative hospital stay, post-operative pain evaluated through a visual analogue scale (VAS: scale 0–10) at day 1. Patients were controlled at day 8, month 1, month 6, and year 1. At these periods, the quality of the scar, post-operative pain, post-operative discomfort (evaluated as atypical sensation or numbness without significant pain), medication and return to personal or professional activity were evaluated. Quality of life was assessed by an SF36 questionnaire at 1-month, 6-month, and 1-year follow-up. This questionnaire featured 36 items evaluating 8 dimensions of health on multi-item scales, and a further dimension on a single-item scale measured changes in health over the last year [16]. Finally, ultrasonography evaluated the healing at 1 month and at 6 months, and a clinical evaluation looked for possible clinical inguinal hernia recurrences.

Statistical analysis

The statistical analysis used the Fischer's exact test. SF36 questionnaire used a Student's t test. In both, p was considered as statistically significant when < 0.05.

Results

The study was planned and authorised for 2 years. An extension was given for 6 additional months. Ninety-five patients were prospectively included from 2006 to 2008 and randomly assigned to one type of prosthetic repair. All patients were assigned to a 1-year follow-up. The two groups of patients did not differ in terms of clinical characteristics, type of hernia and operative records (general or local anaesthesia, operative duration) (Table 1). Twelve various operators (all senior operators) were identified. No operator-related difference appeared.

When comparing the results of the PerFix™ plug group to the 4DDOME® groups, the early post-operative course was similar in terms of complications (4 vs. 1, $p = 0.37$) (haematomas, seromas, no infection), pain (VAS 3.42 (1.83) vs. 3.82 (2.0), $p = 0.69$), and in-hospital stay (2.12 (1.36) vs. 2.25 (1.62), $p = 0.67$). The same comparable evolution was observed in the return to personal (9.39 days (SD 8.15, extremes from 2 to 35 days) vs. 9.48 days (SD 11.68, extremes from 1 to 41 days), $p = 0.96$) and

Table 1 Patients' data and operative records

Patients	PerFix™ plug	4DDOME®	p
n	48	47	
Age (extremes)	60.5 (23–92)	61.7 (27–92)	ns (0.36)
Hernia type II	25	27	ns
Hernia type IIIa	16	15	
Hernia type IIIb	7	5	
BMI	25.1 (2.55)	24.8 (3.99)	ns (0.28)
Pre-operative discomfort	2.38 (2.7)	2.58 (2.35)	ns (0.89)
General/local anaesthesia	23/25	16/31	ns
Op duration (mean-SD)	41.11 (18.8)	39.11 (15.2)	ns (0.56)

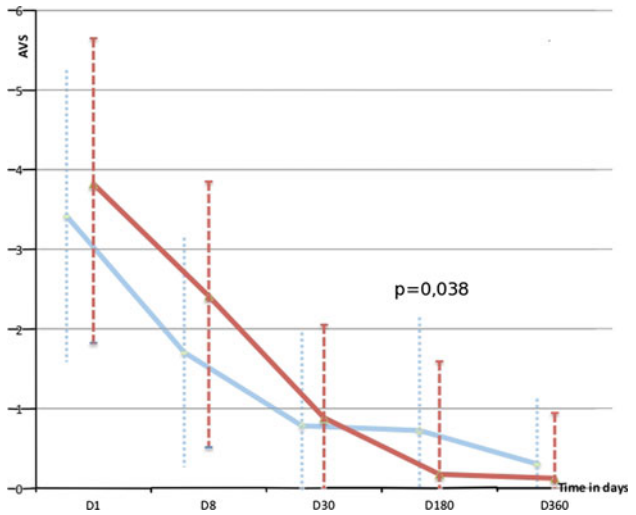

Fig. 1 Pain evaluation: VAS scores $\geq p < 0.05$ statistically significant

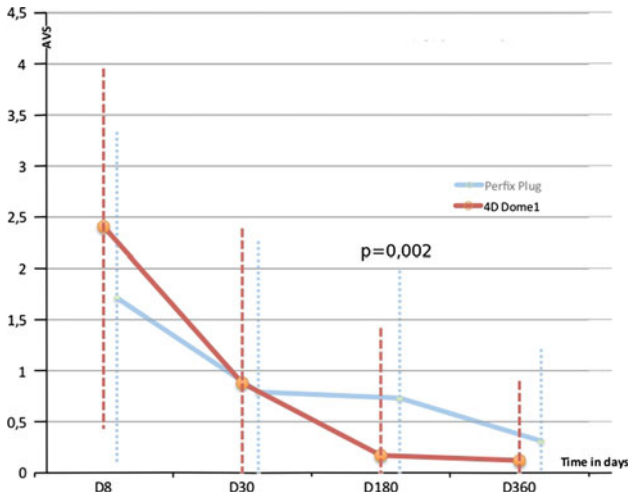

Fig. 2 Discomfort evaluation: VAS scores $\geq p < 0.05$ statistically significant

professional activity (25.71 days (SD 17.47, extremes from 5 to 72 days) vs. 22.82 days (SD 18.10, extremes from 5 to 52 days), $p = 0.62$).

The evolution of post-operative pain and discomfort evaluated at day 8, months 1, 6 and 12 is reported in Figs. 1, 2.

Post-operative data issued from the SF36 questionnaire are reported in Tables 2 and 3. The results obtained from the evaluation of "pain" sensation were significantly lower in the 4DDOME® group at 3 months ($p = 0.021$) and at 6 months for "health" criteria ($p = 0.028$).

Ultrasonography controls did not show any significant data. At 1 month, both types of meshes were unchanged on ultrasound examination. At 6 months, the PerFix™ plug remained unchanged when the 4DDOME® demonstrated a flattening of the dome-shaped prosthesis as interpreted by the radiologist. No recurrence was observed in this series at 1 year.

Table 2 SF36 data collection

	Mean/date	4DDOME®	PerFix™ plug	*p*
Physical function	D 30	83.05	77.07	0.51
	D 180	94.37	90.5	0.26
	D 360	96.4	97.14	0.59
Physical status	D 30	69.44	69.35	0.99
	D 180	93.18	91.67	0.76
	D 360	88	85.72	0.73
Pain	D 30	45.73	34.89	0.021*
	D 180	59.37	52.13	0.12
	D 360	58.6	51.5	0.18
Health	D 30	7.76	7.82	0.89
	D 180	8.13	7.04	0.028*
	D 360	7.65	6.7	0.17
Vitality	D 30	6.94	6.77	0.698
	D 180	7.5	7.15	0.503
	D 360	7.28	7.34	0.88
Social	D 30	87.14	86.15	0.884
	D 180	88.04	85.83	0.798
	D 360	69.5	70.09	0.88
Emotional	D 30	81.61	85.56	0.510
	D 180	97.10	90.48	0.129
	D 360	98.67	97.44	0.582
Mental	D 30	78	76.53	0.706
	D 180	73.13	71.73	0.546
	D 360	71.04	71.86	0.865

Table 3 SF36 physical and mental health summary scale

	Mean/date	4DDOME®	PerFix™ plug	*p*
Physical health	D 30	35.72	32.74	0.53
	D 180	51.88	49.76	0.54
	D 360	47.67	45.33	0.34
Mental health	D 30	44.04	42.92	0.80
	D 180	54.68	54.32	0.88
	D 360	54.76	51.74	0.22

Discussion

The first analysis of the results confirmed that for primary uncomplicated inguinal hernia, a dome-shaped reinforcement of the inguinal hernia completed by onlay mesh

appeared as a high-quality standard for the management of inguinal hernia in young patients. Globally, the early results of inguinal hernia repair did not differ between the two groups and are comparable to those of other types of standard approaches. Some data may appear uncommon to several readers (number of general anaesthesia, hospital stay) but reflect the real practice in France. As they are comparable in both groups, they do not alter the analysis of the results. A likewise remark can be made for the return to personal and professional activity, which is comparable in both groups.

The key points of the study focused on pain, discomfort and on the global feeling of well-being. In the immediate and early post-operative course, the patients presented a comparable day 1, day 8 and 1-month VAS evaluation. This appeared compatible with the surgical practice that performed the same dissection of the inguinal hernia for each technique. At this early stage, pain is certainly related to the procedure. In fact, as no difference was observed in either group at day 1, day 8, and at 1 month, we consider that dissection, positioning of the mesh, fixation of the 4DDOME® or of the plug, is associated with a comparable pain and with the quality of life evaluation no matter which mesh has been used. The difference between meshes appears only after several months. But after several months, the impact of the prosthesis may be increasingly significant, and a benefit appears for the patients treated with the 4DDOME® implant. These results are comparable in both types of evaluation, VAS record and SF36 questionnaire, which is probably the most objective [17]. This significantly improved well-being can be ascribable to the lower amount of biomaterial that remains at this point. These results are in accordance with the literature, promoting the use of lightweight prostheses in order to diminish the final post-operative pain linked to this procedure.

As for the other parameters, no specific complication was associated with each type of prosthesis. Interestingly, 12 operators (all senior operators) were identified, but no operator-related difference appeared.

This type of study presents some limitations. One of them involves the recurrence rate. The number of patients in this study is too small to address the question of post-operative recurrence. Nevertheless, previous data and 1-year follow-up are in accordance with standard results, and no specific adverse events were observed with the new prosthesis as compared to the standard PerFix™ plug. Another limitation was the difficulty to include a high number of patients accepting a long-lasting follow-up, especially in Western countries, such as France, where patients are treated for any type of medical treatment without any charge. This means that the number of patients refusing to be enrolled in the study or refusing repeated or late evaluation was significant. However, the results observed are comparable in both groups without a statistical tendency that would open up further questions.

Many studies have demonstrated that the immune response to foreign body material (along with the subsequent scarring process) is the most important factor in long-term healing and lack of recurrence. However, the same process is also responsible for mesh shrinkage that may underlie hernia recurrence. In parallel, important peri-prosthetic inflammation can induce chronic groin pain and may be associated with adhesion, migration, and erosion of the mesh into adjacent organs, including adjacent sensory nerves, potentially resulting in post-operative pain. It has been largely demonstrated that the inflammation is directly proportional to the amount of non-absorbable prosthetic material inserted [18]. Herein, the PerFix™ plug is known to include an important amount of prosthetic material since a dense amount of polypropylene (1 gramme) was inserted in the hernia defect underneath the onlay mesh. This led some surgeons to remove part of the composition of the mesh to reduce this amount. On the opposite, the conformation of the PerFix™ plug accounts for its resistance and allows a strong counter-pressure to the abdominal wall. The 4DDOME® implant aims at proposing the same resistance by strongly limiting the amount of implanted material (0.1 gramme residual light polypropylene). This was achieved by the association of 2 types of biomaterial. PLLA is a slowly hydrolysed biodegradable polymer of amino-acid-lactate [19]. It is used in various applications (orthopaedic surgery, neurosurgery, plastic surgery, cardiac stenting, tissue engineering). With a very small amount of polypropylene, it allows to offer an early resistant dome-shaped configuration at its early stage of implantation and enables a flattening of the dome-shaped mesh in over 50 % of cases at 6 months [14].

The comparison between pure polypropylene and a composite combination of PLLA and PP demonstrated a significant limitation of mesh shrinkage as well as a lower inflammation for the PLLA composite mesh [20]. This lower foreign body reaction may account for the long-term limitation of potential post-operative pain and discomfort. The clinical results confirm this theoretical reflection. After a 5-year clinical experience using the 4DDOME® implants, no significant adverse reaction has been reported. This new product offers high-quality results in the management of these patients. The lack of significant complications as observed in other meshes may be linked to the low amount of polypropylene left in the inguinal region. This is associated with a lower inflammatory reaction leading to minor adhesions and migration processes.

Groin pain reduction has been cited as a major objective to improve hernia management [21]. Nowadays, it is evident that the remaining lightweight meshes are associated with a lower rate of long-lasting chronic pain as compared to heavyweight meshes [22, 23]. There are few studies comparing long-lasting chronic groin pain and discomfort after all types of inguinal hernia repair in comparative

studies. Our experience confirms the results presented in this study, which demonstrates a low remaining chronic pain and discomfort after using lightweight meshes for inguinal hernia repair.

A recent study demonstrates that the type of mesh composition does not significantly affect the rate of chronic pain; the only mesh associated with an increased early pain is the heavyweight mesh [24].

Conclusion

The management of conventional inguinal hernia by composite dome-shaped multi-layers and partially absorbable meshes is associated with a strong reinforcement in the early stage of healing similar to the PerFix™ plug made of heavyweight meshes without altering early results. Contrarily to the PerFix™ plug, the 4DDOME® implant is partially absorbed. It was associated with a significant prevention of post-operative pain and discomfort when evaluated over a long-term period (3 and 6 months). As expected, all other parameters of this anterior approach are similar to other studies and products, confirming the global quality of both approaches. As a single biomaterial may not be able to provide surgeons with all technical constraints of an ideal mesh, we consider that the association of different biomaterials may provide every advantage of them for an optimal repair of parietal wall defects.

A further evolution in these products will certainly offer more options to select the optimised biomaterial for each patient, thus leading to a tailored proposal for each patient and each defect.

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