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Original Research

Fixation free femoral hernia repair with a 3D dynamic responsive implant. A case series report

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ABSTRACT

Background: To date, no gold standard for the surgical treatment of femoral hernia exists. Pure tissue repair as well as mesh/plug implantation, open or laparoscopic, are the most performed methods. Nevertheless, all these techniques need sutures or mesh fixation. This implies the risk of damaging sensitive structures of the femoral area, along with complications related to tissue tear and postoperative discomfort consequent to poor quality mesh incorporation. The present retrospective multicenter case series highlights the results of femoral hernia repair procedures performed with a 3D dynamic responsive implant in a cohort of 32 patients during a mean follow up of 27 months.
Materials and methods: Aiming to simplify the surgical procedure and reduce complications, a 3D dynamic responsive implant was delivered for femoral hernia repair, in a patient cohort. After returning the hernia sack to the abdominal cavity, the implant was simply delivered into the hernia defect where it remained, thanks to its inherent centrifugal expansion, obliterating the hernia opening without need of fixation. Postoperative pain assessment was determined using the VAS score system.
Results: The use of the 3D prosthetic device allowed for easier and faster surgical repair in a fixation free fashion. None of the typical fixation related complications occurred in the examined patients. Postoperative pain assessment with VAS score showed a very low level of pain, allowing the return of patients to normal activities in extremely reduced times. In the late postoperative period, no discomfort or chronic pain was reported.
Conclusions: Femoral hernia repair with the 3D dynamic revealed a quick and safe placement procedure. The reduced pain intensity, as well as the absence of adverse events consequent to sutures or mesh fixation, seems to be a significant benefit of the motile compliance of the device. Furthermore, this 3D prosthesis has already proven to induce an enhanced probiotic response showing ingrowth in the implant of the typical tissue components of the abdominal wall, instead of the low quality tissue ingrowth typical in conventional meshes and plugs. The highlighted features seem to represent a more physiologic and updated repair concept of femoral protrusions.

1. Background

Femoral hernia, accounting for approximately 5% of all abdominal wall hernias, is the second most frequent abdominal protrusion after inguinal hernias [1–4]. Historically, as for inguinal hernia repair, after a long period of pure tissue repair, prosthetic reinforcement of the herniated femoral canal was increasingly proposed as a method of choice. In the last few decades, also the option of laparoscopic repair has been taken into account, especially in the frame of posterior inguinal hernia repair when a femoral protrusion is occasionally detected [3]. Several prosthetic solutions have been highlighted in literature [5–9]. Nevertheless, for the treatment of this protrusion type, to date, there is no gold standard. However, independently of the adopted technique, suturing of the aponeurotic planes and/or fixation of the implanted mesh is considered mandatory. Sutures and point fixation in this delicate area are unanimously indicated as sources of tension and pain, causing complications and delaying the return to normal activity for patients [10]. In light of these considerations, a surgical approach for repairing femoral hernias has been developed by using a 3D dynamic responsive implant, which is delivered into the femoral ring to obliterate the defect fixation free. The results of this newly developed surgical technique are analysed and discussed in this study.

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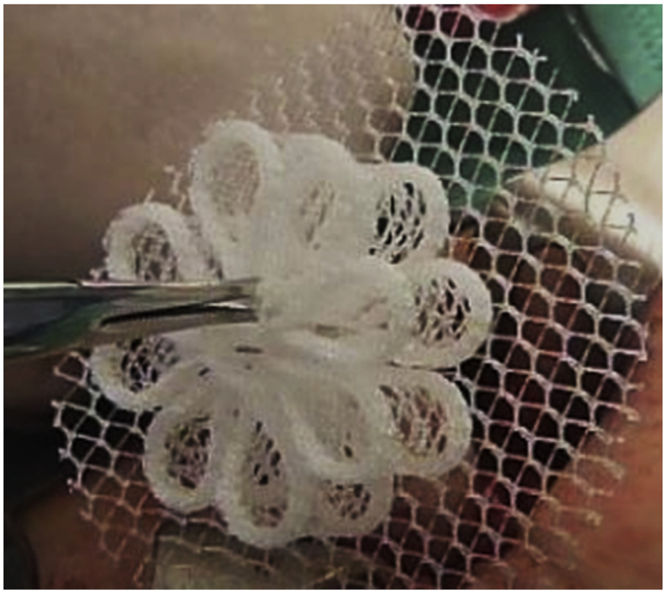

Fig. 1. The multilamellar shape of the 3D dynamic implant with its preperitoneal disc. The diameter of this prosthesis is 40 mm.

2. Materials and methods

The research has been designed as a retrospective multi-centre case series, while the article has been reported in line with the PROCESS criteria [11]. From January 2013 to December 2106, 32 individuals underwent femoral hernia repair with defect obliteration through the 3D dynamic implant, ProFlor (produced under license by Insightra Medical Inc.- USA). A single operator performed the surgeries in academic setting. The 3D implant has a circular, multilamellar shape with reinforced edges, and is available in two sizes: 25 and 40 mm in diameter, both types 15 mm in thickness, with a firmly connected preperitoneal flat disk (Fig. 1). In the patient cohort, 26 were female and 6 male. Mean age was 64 (range 53–78) and mean BMI 29 (range 26–32). 21 protrusions were located on the right side and 11 on the left side. None of the femoral hernias was recurrent, but 3 of the male patients were operated some months previously for inguinal herniorrhaphy at the same groin. Therefore, the repaired femoral protrusion could probably be listed as a forgotten or mistaken hernia. Only one female patient presented with obstructed femoral hernia, which was operated and resolved in emergency without need of bowel resection. The remaining 31 patients were free of hernia related complications, preoperatively. All demographic data of the patients are included in Table 1. In all individuals, the procedure was carried out with an open infrainguinal approach. 28 subjects were operated under local anaesthesia, and in four (one with obstructed hernia and the three male patients already operated for inguinal repair) general anaesthesia was administered. After opening the femoral area with an incision in the lower inguinal aspect and recognising the protrusion, adhesiolysis of sac followed until the hernia defect was fully identified. Then, the hernia sack with its content was returned to the abdominal cavity. In some cases, where the hernia opening was too narrow to return the sack back into the abdomen, the enlargement of the defect with a small retractor allowed for an uncomplicated repositioning of the sac and its content. At this stage, using a forceps for delivery, the ProFlor implant was introduced to fill the defect. After deployment, a forceps guided adjustment allowed for properly placement of the implant within the hernia gap (Fig. 2A and B). In all subjects, except those operated in general anaesthesia, a stress test carried out by inviting the patient to cough served as demonstration of the permanence in situ of the prosthesis even under load (Fig. 3). No suture or other kind of fixation was used to hold the implant in place. After suturing the subcutaneous fat, the skin was closed using a running intradermal suture. The patients were discharged the same day with a prescription of an analgesic prophylaxis based on oral administration of 100 mg paracetamol 3 times per day until third postoperative day. Visual analogue scale (VAS) was used to assess postoperative pain at operation day, after one week, four weeks, three and six months post-operation.

3. Results

The 3D prosthesis was employed to obliterate femoral hernia defects also in the case of large femoral protrusions (Figs. 4–6). In the majority of cases, the operative procedure lasted around 30 min, but in general did not exceed 40 min. All patients were discharged the same day of operation. No bleeding, hematoma, or infections were reported in patient cohort, only superficial bruising that faded within a few days. The return to normal activity occurred from 4 to 6 days post-operation. In a mean follow up of 27 months (range 48 to 12 months), no recurrences were reported. Postoperative pain, measured with the VAS scale, progressively decreased and within the one week post-operation all patients were free of pain (Table 2). Analgesic drug assumption was suspended 3 days after the operation. No sense of foreign body, discomfort, chronic pain or vascular impairment was reported among the operated patients.

4. Discussion

Femoral hernias are less frequent than inguinal protrusions but diagnosis is often challenging. Incarceration, strangulation and intestinal obstruction are not rare in femoral hernia. If they occur, they require emergency surgery, which is associated to a higher rate of morbidity and, sometimes, death [12–14].

Femoral protrusions can be managed with open or laparoscopic approach. Open techniques include: Lockwood's infra-inguinal approach [15], Lotheissen's *trans*-inguinal approach [16] and, if strangulation is suspected, McEvedy's high approach which allows better visualization and facilitates an intestinal resection, if needed [17]. Prosthetic repair of femoral hernia has become increasingly popular since the adoption of alloplastic material for the repair of abdominal

Table 1
Patient's demographic.

Femoral hernia repair with 3D dynamic implant - Patients total 32 (100%)								
		Female	Male	Range	Right	Left	Local	General
Gender		26	6					
Age (mean)	64			53/78				
BMI (mean)	29			26/32				
Primary repair	32	26	6		21	11		
Previous inguinal surgery	3	0	3		2	1		
Anaesthesia							28	4
Hernia related complications		1 obstruction						
Emergency	1							

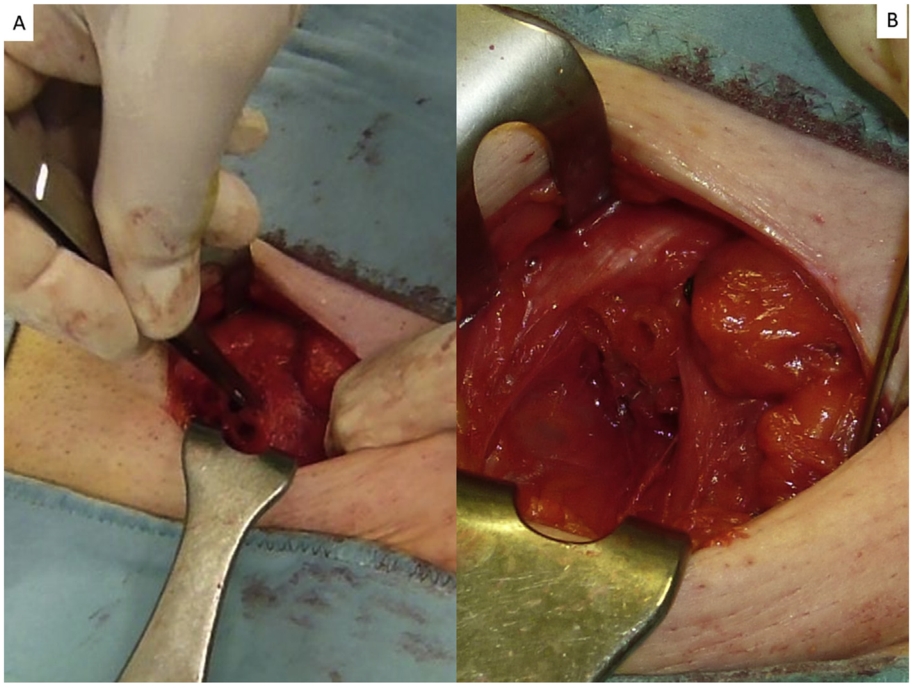

Fig. 2. A: The 25 mm sized 3D implant is already delivered to obliterate the hernia defect in a female patient. Forceps guided adjustment allows the right positioning of the implant into the hernia defect. – B: the 3D implant is properly lodged into the femoral defect.

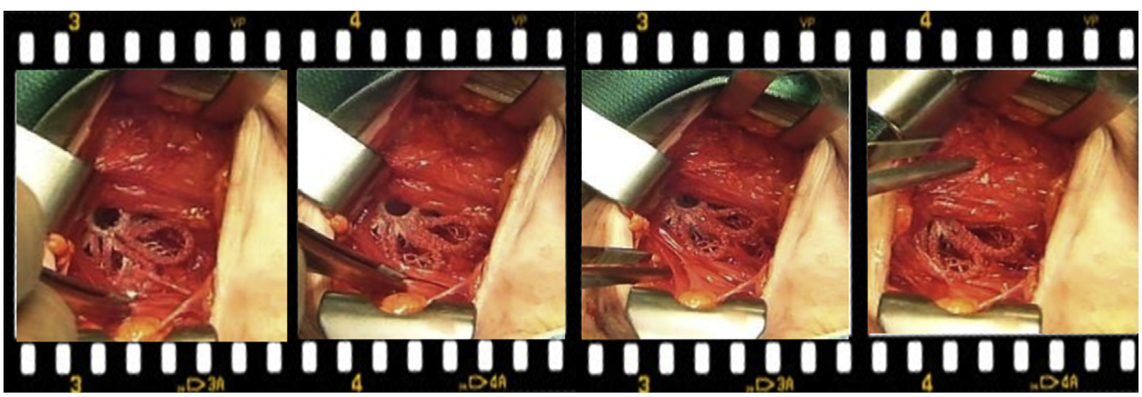

Fig. 3. Filmed sequence of a stress test carried out by inviting the patient to cough after implant deployment. The 40 mm sized 3D prosthesis clearly squeezes and relaxes in synchrony with the myotendineal structures of the femoral area. No signs of implant dislocation are evident. Despite the forceful movements, the hernia defect remains fully obliterated.

protrusions. Lichtenstein first introduced a cylindrical shaped polypropylene mesh into the femoral ring to repair femoral hernias [18]. Gilbert, intraoperatively, rolled out a conic shaped piece of polypropylene with the intent to obliterate the femoral defect [19]. In the late 90s, Rutkow and Robbins developed a pre-shaped mesh plug to repair inguinal and femoral hernias [20].

Concerning laparoscopic repairs, extra-peritoneal (TEPP) or transabdominal preperitoneal (TAPP) techniques are those of choice [21,22]. Nevertheless, in daily practice, the infra-inguinal approach is preferred to the laparoscopic approach as it can be carried out under local anaesthesia and allows for an effective mini-invasive procedure, also in high-risk patients. With the infra-inguinal approach, the hernia protrusion is easy to recognize and can be visualized and managed well. It is less invasive, being deemed the most appropriate for avoiding nerve and vascular damage [23]. This has extremely positive results: noteworthy postoperative pain reduction as well as low incidence of chronic postoperative pain [24].

Nevertheless, all described techniques have a significant limitation: the mandatory need to suture the myotendineal structure of the inguino-femoral area in the case of pure tissue repair, as well as mesh fixation with sutures or tacks in the case of prosthetic repair. Implant/plug fixation causes the most frequent complications, such as bleeding (due to tissue tear caused by stitches), hematoma, infection and a high rate of discomfort. Therefore, it appears obvious that implant fixation is not in line with the kinetics of the highly motile surrounding of the femoral area and, consequently, should be avoided. In the case of prosthetic repair, another concern derives from implant shrinkage consequent to poor quality of tissue ingrowth. This, together with mesh fixation, is considered a source of the frequently reported discomfort and occasionally chronic pain due to injuries of peripheral nerves [8].

These considerations have encouraged the use of a 3D dynamic responsive implant, already used for inguinal hernia repair, also for surgical treatment of femoral hernias [25]. This implant, introduced into the femoral defect, thanks its intrinsic centrifugal force expands until the complete obliteration of the hernia opening is achieved. No fixation of the prosthesis is needed since the natural centrifugal expansion of the implant is sufficient to firmly hold the device in place even under load. This device has another advantage if compared with

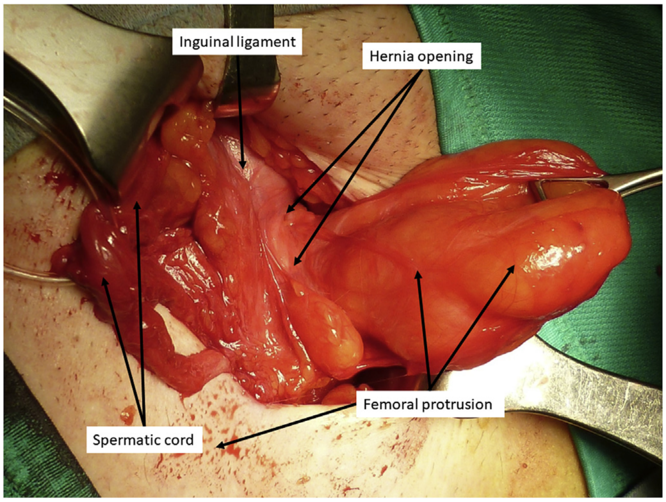

Fig. 4. In a male patient who underwent inguinal hernia repair three months before arises a 6 × 3 cm large hernia sack from the femoral ring.

conventional meshes and plugs: thanks to its inherent motile compliance, instead of a shrunken and disordered fibrotic ingrowth, characteristic of flat meshes, it promotes the incorporation of viable connective tissue with the development of the typical tissue elements of the abdominal wall. The ingrowth of newly formed elastic fibers, arteries, veins and nerves in the implant structure has already been scientifically demonstrated, both in the animal model as well as in humans [26,27]. Ultimately, a fleshy barrier made of viable, well vascularized tissue should impede the reappraisal of the protrusion (Fig. 7A and B). In addition, the deep placement associated with the already proven motile compliance, means it is not perceived by patients [25,28]. This effect is deemed crucial to avoid discomfort for the patients, also in the short term.

5. Conclusions

By analysing the outcomes of the patient cohort described herewith, the extremely low pain score, starting from the early postoperative phase, stands out. Pain assessment shows a rapid reduction within one week post-operation, when the VAS score is almost nullified. This would appear to be an effect of the extremely simple surgical procedure that, after replacing the hernia sac in the abdomen, allows delivery of the implant in an easy, uncomplicated way, eliminating the need of further manipulation or suture placement in a delicate area where nerves and vascular structures can be easily damaged. This dynamic repair technique incorporates updated concepts leading to a more physiologic treatment of femoral protrusions.

Ethical approval

The investigation is a retrospective study and do not need approval by Ethics Committee. All procedures involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This article does not contain any studies with animals performed by any of the authors.

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Author contribution

Amato G. Study design.
Romano G. Data analysis.
Agrusa A. Data collection.
Gordini L. Language editing.
Gulotta E. Data collection.
Erdas E. Data interpretration.
Calò P.G. Final approval.

Conflicts of interest

AG. Is the developer of the implant and technique. All authors have no conflict of interest.

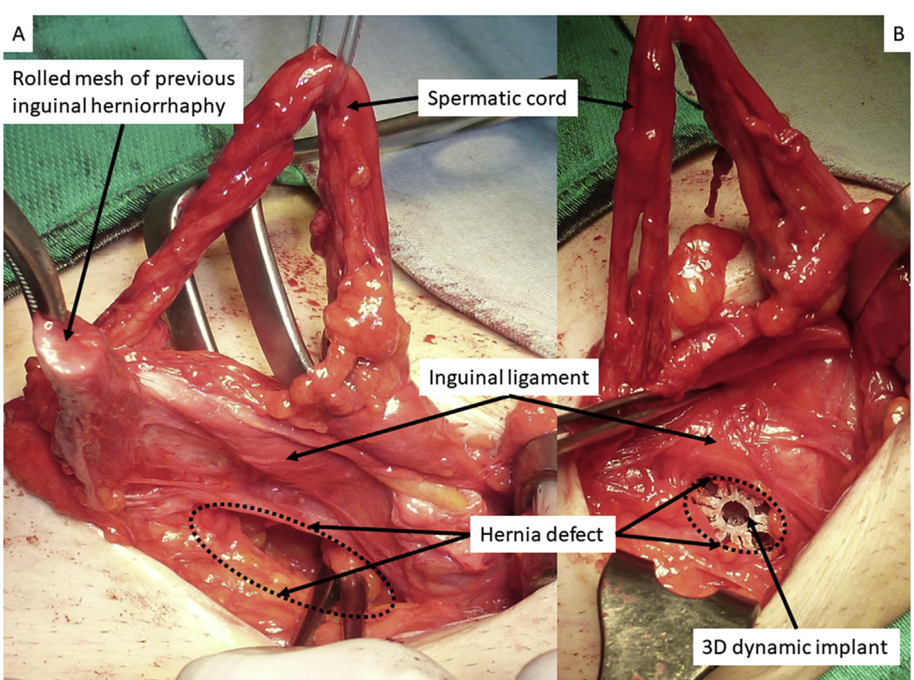


Fig. 5. Same patient of Fig. 3 – A: a forceps inserted through the hernia defect returns the hernia sac back to the abdominal cavity. Medially and cranially of the defect the rolled contour of the distal portion of the flat mesh positioned during the previous inguinal hernia repair is clearly detectable. – B: the femoral hernia defect already obliterated with a 25 mm large 3D dynamic implant.

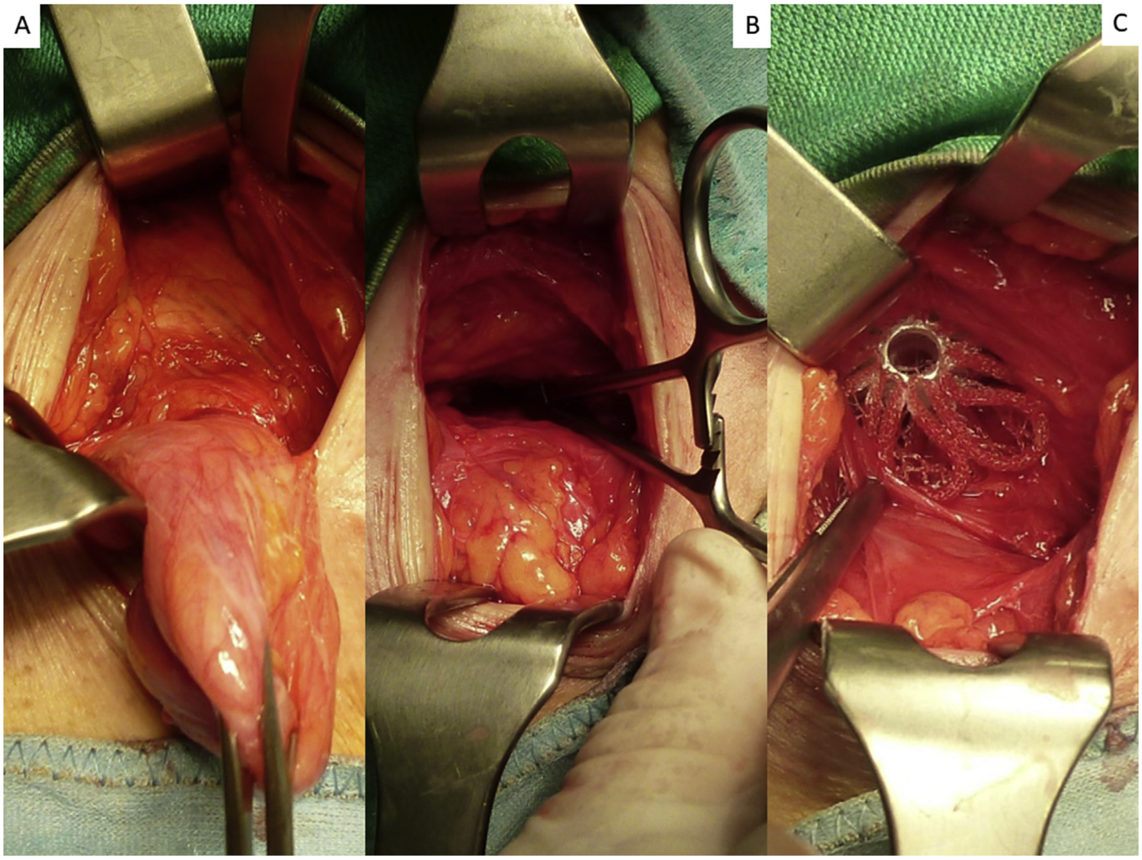
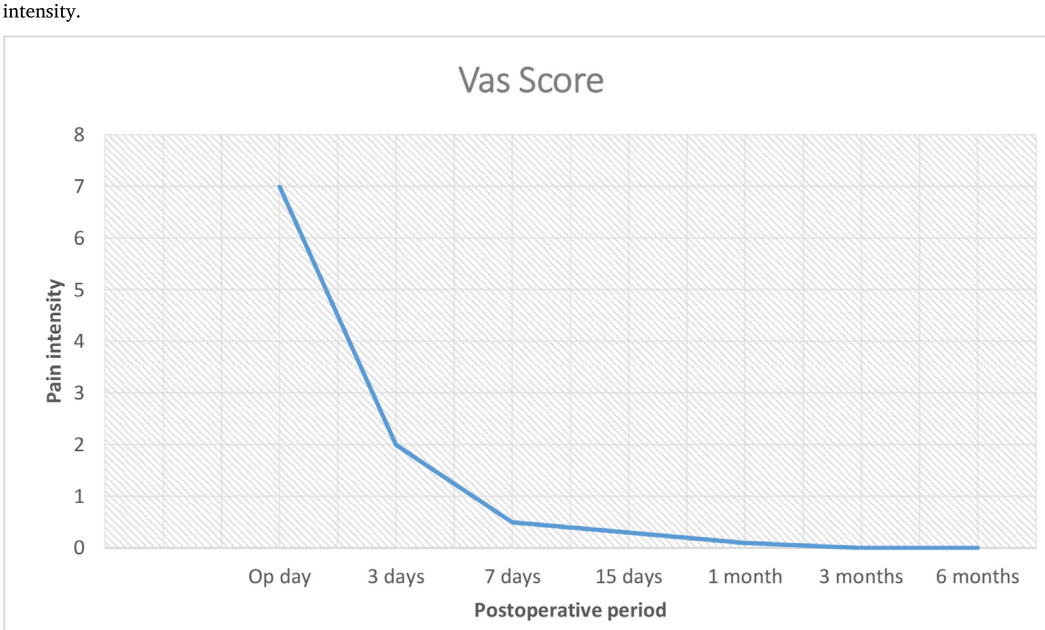


Fig. 6. A: large femoral hernia in a female patient. – B: the hernia sac with its content is returned into the abdominal cavity. – C: the large femoral defect has been fully obliterated by a 40 mm dimensioned 3D dynamic prosthesis.

Table 2
Postoperative pain intensity.



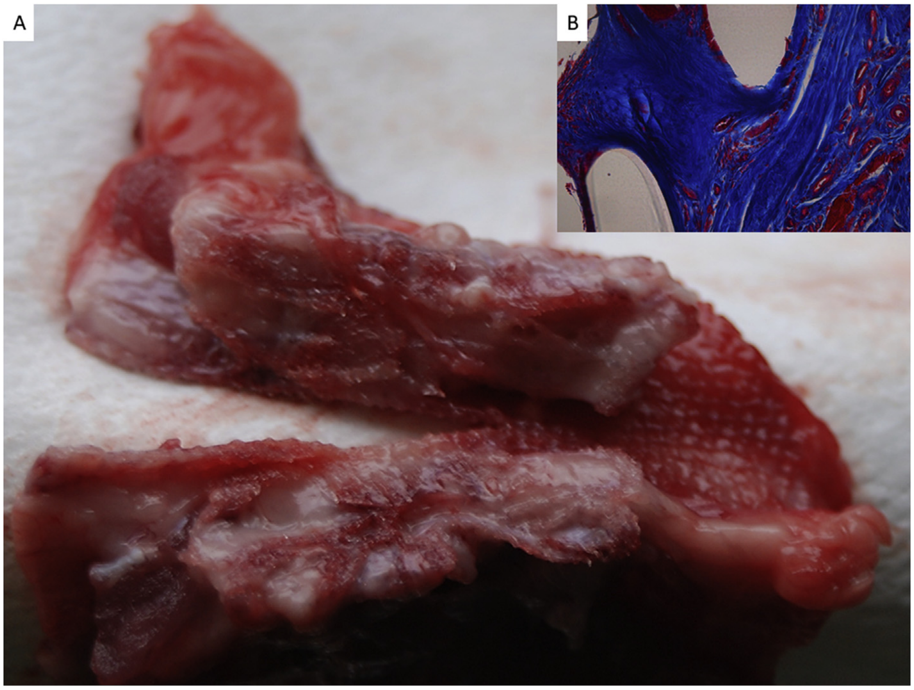


Fig. 7. A: 3D dynamic implant excided from the groin of a pig 8 months after implantation in the frame of an experimental attempt. The implant is split in the middle, within its arrangement the ingrowth of viable tissue is clearly evident. Being the prosthetic tissue no manifestly detectable, its structure resembles a fleshy barrier. (Reference article #26) – B Microphotograph of a biopsy specimen excised from a patient 7 months after implantation: plenty of newly formed mature vascular structures (stained in red) in a surrounding of viable and well hydrated connective tissue (stained in blue) among the implant fibers (withe spots). AM 20x (Reference article #25). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Research registration Unique Identifying Number (UIN)

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Guarantor

Prof. Giuseppe Amato.

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The study has been registered in the Research Registry. Being the investigation a retrospective study do not need approval by Ethics Committee. Sources of funding: this research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ijsu.2018.04.031.

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