Static solutions for highly motile structures such as the groin seem to represent a procedural incongruence. Another important issue in prosthetic hernia repair is related to the poor quality of tissue ingrowth within conventional flat meshes and plugs. These are all static, passive devices, and thus do not move in synchrony with the natural movements of the groin. In the literature there is a clear understanding of how conventional prostheses used for inguinal hernia repair are incorporated by rigid fibrotic tissue. The term “scar plate” well emphasizes this occurrence. The ingrowth of this kind of stiff fibrotic scar leads to mesh shrinkage and to the reduction of the mesh surface area. This is considered a significant cause of recurrence and discomfort. With this in mind, the need for a more physiologic procedure to further decrease complications and recurrences in inguinal hernia repair due to implant design seems obvious.

This report shows how, by eliminating invasive fixation and improving the quality of tissue ingrowth within the implant, it is possible to reduce complications. To achieve these results, a new type of 3D dynamic
Dynamic Inguinal Hernia Repair with a 3D Fixation-free and Motion-compliant Implant: A Clinical Study

AMATO/ROMANO/AGRUSA/COCORILLO/GUILLOTA/GOETZE

The study demonstrates that by using a purposefully designed 3D geometric implant expulsion forces can be switched into gripping forces, avoiding the need for traumatic fixation. This eliminates the typical complications related to mesh fixation such as bleeding, hematoma, chronic pain, and tissue tearing, often resulting in mesh dislodgement and recurrence. This new 3D implant results in open hernia repair procedures being safer, faster, and easier.

**INTRODUCTION**

Prosthetic repair nowadays represents the treatment of choice for inguinal hernia disease. Nevertheless, despite undeniable improvements achieved by using synthetic materials for repairing inguinal protrusions, many unresolved issues are the subject of continuous discussions among herniologists. Mesh fixation, implant shrinkage, poor quality of tissue ingrowth, patient discomfort, and chronic pain are the main concerns in hernia repair. The mentioned postoperative complications seem to be consequent to the discrepancy between the static design of conventional prostheses and the dynamic arrangement of the inguinal region. In addition, taking into account that implant/plug fixation causes the most frequent complications following inguinal hernia repair, such as bleeding, hematoma, and infection (due to tissue tear caused by stitches), it appears obvious that implant fixation is not in line with the kinetics of the groin and, consequently, should be avoided.

These considerations have encouraged further reflections concerning the physiology and physiopathology of the inguinal region. A wide series of studies focused on the detection of the histological changes in the herniated groin supported the concept that an appropriate repair of inguinal hernia should respect the physiology of this area. The evidence of degenerative tissue damages facilitating or even causing hernia protrusion leads to the conviction that the target for the treatment of the disease should be the regeneration of the affected area. Therefore, by considering techniques and prostheses currently used in hernia repair, an evident contradiction arises. Both techniques and devices used for hernia repair seem to be inappropriate if related to the etiology and physiopathology of the inguinal protrusion.

These thoughts motivated the search for new therapeutic strategies, leading to a new generation of prosthetic devices respectful of the physiology of the groin and the pathogenesis of the disease. Actually, in opposition to the regressive stiff fibrotic mesh incorporation typical of conventional implants, tissue regeneration seems effectively to be in line with the pathogenesis of the hernia disease. Following these considerations, a new type of 3D dynamic responsive implant has been developed. This innovative prosthetic device is delivered in constrained mode into the hernia defect and, after deployment, thanks to its intrinsic centrifugal expansion obliterates fixation free of the hernia opening. In this article, we discuss the results of a single operator case series of 91 patients who underwent hernia repair procedure based upon this newly designed 3D dynamic compliant implant.

**MATERIALS AND METHODS**

**Study Design and Endpoints**

This investigation was designed to collect perioperative and postoperative data to evaluate a new hernia repair system. Endpoints included the ability of the device to be safely delivered and to follow up immediate postoperative and long-term complications including recurrence. Follow-up on all patients was conducted by a combination of office visits and telephone calls at 1 week, 2 weeks, 1 month, 3 months, 6 months, 12 months, and 3 years (36 months).

Data were collected and analyzed on patients who consented to the use of a new 3D prosthesis. The investigators identified appropriate candidates based on the inclusion and exclusion criteria identified in the protocol described next.
Confidentiality
All clinical information obtained in the study was considered confidential and used only for research purposes. The identity of individual subjects was kept confidential to the extent permitted by the applicable laws and regulations and safe medical practice. Each subject was identified by a code composed of a sequential number in order of surgery.

Patient Eligibility
Inclusion criteria:
- Scheduled to undergo routine inguinal hernia repair
- Competent to give consent
- Clinically relevant inguinal hernia (classification: NYHIS I, II, IIIa, IIIb, IV)
- Male or female
- Over 18 years old to 85 years old
- Life expectancy of at least 12 months
- Diagnosed with primary direct, indirect, or mixed inguinal hernia, unilateral or bilateral

Exclusion criteria:
- Signs of obvious local or systemic infection
- Hernia was not in the inguinal area
- Presenting with unstable angina or NYHA class of IV
- Pregnant
- Active drug user
- Immunosuppression, prednisone >15 mg/day, active chemotherapy
- End stage renal disease
- Abdominal ascites
- Skin infection in area of surgical field
- BMI >35

Patients who met all of the inclusion criteria and none of the exclusion criteria were eligible for the study.
Patient enrollment was from August 2009 to August 2012.

Prosthetic Devices and Delivery Tool
A newly designed 3D implant made of a specially manufactured lightweight and large porous polypropylene (manufactured under license by Insightra Medical Inc, Irvine, CA) was used in the described patient cohort. The prosthesis was designed with a multilamellar, flower-like structure, having “petals” connected at the center with a small polypropylene ring (Fig. 1). The edges of the petals were made of reinforced polypropylene in order to ensure springiness. The implant is manufactured in two sizes: a small one measuring 25 mm in diameter and 15 mm in height, having a flat disc of 60 mm in diameter and 6 petals; a large one 40 mm in diameter and 15 mm in height, with a flat disc of 70 mm in diameter and 8 petals.

Two different sizes of this implant were used:
1. A small implant with a pre-peritoneal disc 60 mm in diameter (weight 0.77 grams, core diameter 25 mm and 15 mm height, having 6 petals)
2. A large implant with a pre-peritoneal disc 70 mm in diameter (weight 1.51 grams, 3D core diameter 40 mm and 15 mm in height, with 8 petals).

The delivery tool was a tubular insertion device designed to radially compress the implant into a constrained position (Fig. 2A). After lodgment into the delivery device (Figs. 2B & 2C), the prosthesis is ready for the deployment. In combination the device has an oversized tip to gently dilate the hernia opening to allow easier insertion of the device. The implant is folded and placed into the distal chamber with the pre-peritoneal disk outside of the dilating tip. For this study there were two sizes of delivery device (25 mm and 40 mm) corresponding to the implants.

Primary Efficacy Objectives
Procedural success was defined as the ability to successfully deploy the implant into the inguinal hernia defect without complications.

Pain and discomfort scores were taken at 1 and 2 weeks, and at 1, 3, 6, 12, and 36 months.

Secondary Objectives: Assessment of the Complications (type and rate)
Collection of data on any perioperative/postoperative complications including recurrence occurred at 1 and 2 weeks, and at 1, 3, 6, 12, and 36 months.

Surgical Procedure
Anesthesia was either local, spinal, or general depending upon patient desire and suitability. The procedure was carried out through a 4-cm to 6-cm skin incision in the groin. After opening the external oblique fascia, the hernia sac was identified. Afterward, adhesiolysis and dissection of the hernia sac were performed. In principle, a broad but gentle adhesiolysis of the inguinal floor is also important to eventually identify an ipsilateral occult hernia. Before delivering the implant, a manual dissection of the peritoneum from pos-
terior abdominal wall was carried out (Figs. 3A & 3B). This maneuver was intended to realize a space large enough to accommodate the flat disk of the implant in the preperitoneal space beyond the hernia opening. Specifically, in the case of indirect hernia, the blunt dissection detached the peritoneal sheath from the posterior abdominal wall around the internal ring. In the case of direct hernia, the transversalis fascia was opened, then the implant disk was deployed in the interstitium between the posterior aspect of the fascia and the peritoneal sheath.

To determine size of the implant to deliver, the dimension of the hernia opening was measured. The implant size was selected to be at least 10% to 15% larger than the hernia defect. This was to ensure an adequate compression of the implant when inserted into the defect frame.

The 3D prosthesis was then loaded into the delivery device and gently inserted with a slight rotation to ensure the pre-peritoneal mesh was delivered into the correct space. The delivery device was introduced until its flange, which acted as a depth stop (Fig. 2D). The plunger was then deployed while retracting the delivery device to allow the implant to be delivered into the defect. At the end of this step the delivery tool could be removed.

The 3D implant through its radial expansion filled the defect – self-gripping (Figs. 4A & 4B). No sutures, clips, tacks, or glue were used to hold the device in place. To test the self-retaining behavior of the implant, all patients (except those operated on under general anesthesia) were invited to repeatedly cough. This stress test was used to determine the initial gripping strength of the implant even under expulsive muscle movements (Fig. 5A). If needed, a forceps-guided maneuver was used to adjust the implant within the hernia opening to ensure the correct anatomical placement (Fig. 5B). In the case of indirect hernia repair the spermatic cord was aligned laterally between the petals of the implant. Before closing, a meticulous inspection of the inguinal area was carried out to look for signs of bleeding, tissue damage or other complications. The procedure was completed by suturing the fascia and the subcutaneous layer. The skin was closed with a total intradermal suture. Antimicrobial prophylaxis was administered according to our institutional guidelines.

Data Collection
Data collection was performed pre- and postoperatively. These records were inserted into a master spreadsheet for data aggregation and statistical analysis (Tables I, II, & III).

Evaluation of Implant Shrinkage
An ultrasound control of the delivered implant was performed in all patients at discharge as well as at 1, 2 weeks, and 1, 3, 6, 12, and 36 months postop. This was performed as a control for early dislocation or migration of the implants and for long-term follow-up to demonstrate the integration of the implant into the abdominal wall, and
differences in dimension of the device by time were detectable.

Risk Assessment

The purpose of the study was to evaluate the safety and efficacy of the new 3D implant for inguinal hernia repair and its delivery system. The use of a polypropylene implant is already considered a standard of care in general hernia surgery. As with any medical procedure there are known risks to this surgical procedure, which employs an implantable prosthesis. These risks include: bleeding, infection, pain, mesh shrinkage and/or dislodgement, recurrence, hematoma, testicular injury, and reactions to anesthesia.

RESULTS

Ninety-one patients (88 male, 3 female) were enrolled from August 2009 to August 2012 with a mean age of 50.3 years (SD = 17.23, range 18 to 85).

Two patients were lost to follow-up (one at 19 months due to death from heart failure, one at 24 months due to stroke), both deaths were unrelated to the procedure.

Of the 91 patients, 5 were discovered to have a double inguinal hernia at same groin (direct and indirect) through our detection method. The total number of hernias repaired was 97. Thirty-one with the 25-mm-size implants and 66 with the 40-mm large implants.

Hernia types were classified by the NYHUS classification. Ten patients had a NYHUS type 1 inguinal hernia, 47 type 2, 19 type 3a, 9 type 3b, and 12 type 4.

The anesthesia used was: local 81%, spinal 10%, general 9%. Mean operative time was 28 minutes (range 18 to 47 minutes). Mean length of stay was 0.97 days (SD = 0.651). Mean follow-up was 54.78 months (SD = 25; min 8.5, max 88.7).

Due to the rather uneventful long-term complications, all postoperative complications were consolidated and are displayed in Table IV.

Highlights of the results included:

1. Follow-up using ultrasound of the dimensions of the implants (post-implantation) showed nearly no shrinkage in both the radial and vertical axes. This represented a virtually absent loss of volume and surface of the scaffold (Figs. 6 & 7).

Table I

<table>
<thead>
<tr>
<th>Preoperative screening evaluations (baseline data)</th>
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</thead>
<tbody>
<tr>
<td><strong>EVALUATION</strong></td>
</tr>
<tr>
<td>• Subject demographics (age, gender)</td>
</tr>
<tr>
<td>• Pre-existing medical conditions or risk factors</td>
</tr>
<tr>
<td>• Routine blood work</td>
</tr>
<tr>
<td>• Evaluation for hernia (side, type, reducibility, defect size)</td>
</tr>
<tr>
<td>• Preoperative medications</td>
</tr>
<tr>
<td><strong>PROCEDURE EVALUATION</strong></td>
</tr>
<tr>
<td>• Date of procedure</td>
</tr>
<tr>
<td>• Description of procedure</td>
</tr>
<tr>
<td>• Problems related to anesthesia</td>
</tr>
<tr>
<td>• Hernia identified as direct or indirect (left, right, or bilateral; primary or recurrent)</td>
</tr>
<tr>
<td>• Perioperative complications (hematoma, bleeding, testicular swelling, infection at surgical site, pain not controlled with usual analgesics)</td>
</tr>
<tr>
<td>• Injury to vessel, bleeding</td>
</tr>
<tr>
<td>• Bowel injury</td>
</tr>
<tr>
<td>• Peritoneal defect over implant at closure</td>
</tr>
<tr>
<td>• Fixation required or not</td>
</tr>
<tr>
<td>• Other</td>
</tr>
</tbody>
</table>
2. Pain scores as measured by VAS were very low in the early postoperative phase: nearly all patients were pain free starting from 2 weeks postop (Table V).

3. No patient reported discomfort or chronic pain during all examination periods.

Subjectively, for the operator the procedure was fast and safe, the implant deployment and the delivery of the device were very easy.

**DISCUSSION**

Indisputably, the inguinal region is one of the most motile areas of the body. In fact, the groin is actively involved in the movements of both abdominal wall and thigh. Furthermore, this area is subject to the compression exerted by the impact of the abdominal viscera. If we consider that all prostheses used to repair an inguinal hernia are static and passive, it seems obvious that their use in this dynamic context could be inadequate. Moreover, fixation of a motionless device to highly motile muscular fibers reasonably appears non-physiologic. This does not matter if bleeding and/or hematoma are due to torn muscle fibers during the movements, or caused by suture stitches as well as other fixation methods.

Scientific literature evidences that conventional implants after a few months are incorporated by stiff and dehydrated scar tissue, a poor quality biologic response that in time causes the well-known phenomenon of mesh shrinkage. This occurrence is a potential source of de-coverage of the hernia defect and a prelude to recurrence.

These facts lead to several unanswered questions. Among these the main issue is: Are current hernia repair techniques consistent with the genesis of the disease?

Because the etiology of inguinal hernia has not been addressed to date, we do not know how and why an inguinal hernia develops. Because of this, it is assumed that currently hernia disease is being managed without the effective knowledge of the protrusion development through the abdominal wall. This is probably the main issue. Other questions are generated from this.

Therefore, in modern prosthetic hernia repair several important issues still need to be addressed:

1. Hernia genesis should be definitely clarified.
2. Repair systems must be developed to contrast the pathogenetical factors of hernia disease.
3. Repair techniques should be linked to the physiology and biodynamic of the groin. Therefore, dynamic compliant implants rather than static and passive solutions should be developed.
4. Development of a real fixation-free hernia repair with no impact on recurrence rate is needed.
5. The biologic response induced by the conventional meshes is poor, resulting in stiff and shrunken fibrotic scar. This seems to be the culprit with regard to patients’ dis-
comfort, chronic pain, mesh shrinkage, and recurrences. Consequently, modern implants should promote enhanced biologic response, improving the quality of tissue ingrowth.

Addressing all these questions could probably help to develop improved hernia repair systems that are more respectful of the physiology, biology, and kinetics of the groin.

The authors have considered all these aspects and developed scientific evidence concerning the physiopathology of the inguinal region, and look forward to developing a suitable method that meets the requirements depicted earlier. The results of these efforts were verified in experimental studies in animals. What follows is a point-by-point analysis concerning the issues raised.

To better clarify the physiopathology of the inguinal area, specific studies have been carried out to histologically detect structural damages in the herniated groin. These investigations demonstrated the presence of significant degenerative damage involving the myotendineal structure of this region. These tissue injuries showed the typical characteristic of chronic compressive damage, with the results to be likely consequential to the steady compression exerted by the abdominal viscera upon the inguinal barrier.9–13

1. Once degenerative tissue damage was hypothesized as a culprit of the protrusion, it was clear that a remedy to this should work in opposite fashion: achieving tissue regeneration by activating a process that promotes the regeneration of the typical components of the inguinal structure.

2. To improve the results of the static and passive prostheses currently used, a new kind of implant was developed. This was realized by arranging the most used material for abdominal wall prosthetics, polypropylene, in a different fashion. After a specific manufacturing process, a 3D dynamically responsive implant in a proprietary design was created. This device, experimentally tested in a porcine model, demonstrated an active response to compression and relaxation in compliance with the groin movements.14

These features seem to represent an absolute novelty for a prosthetic device, even more so if compared with the unprocessed static and dynamically passive implants used to date.

3. To resolve the problem of a true fixation-free hernia repair, the intrinsic centrifugal expansion of the 3D implant results is very helpful. The prosthesis could be introduced within the hernia defect in compressed mode via a delivery device. Once released into the hernia opening, the device effectively obliterated the gap thanks to its enlargement. Owing to its centrifugal gripping force and the friction exerted by the lateral surface against the hernia frame, the deployed implant remained stable within the hernia opening.

4. Concerning the biological response, a histological study carried out upon 3D devices removed from the porcine model in a period ranging from 1 week to 8 months post-implantation proved that its biologic response was unquestionably different if compared with that of static meshes and plugs.14 This seems to

<table>
<thead>
<tr>
<th>Table III</th>
<th>Post-procedure evaluations (from discharge to final follow-up at 36 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVALUATION at 1 and 2 weeks; 1, 6, 12, and 36 months</td>
<td></td>
</tr>
<tr>
<td>• Freedom from recurrence</td>
<td></td>
</tr>
<tr>
<td>• Postoperative pain assessment (VAS pain score)</td>
<td></td>
</tr>
<tr>
<td>• Infection/abscess</td>
<td></td>
</tr>
<tr>
<td>• Ultrasound scan</td>
<td></td>
</tr>
<tr>
<td>• Dislodgement of the implant</td>
<td></td>
</tr>
<tr>
<td>• Discomfort from the implant (subjective evaluation)</td>
<td></td>
</tr>
<tr>
<td>• Hematoma</td>
<td></td>
</tr>
<tr>
<td>• Seroma</td>
<td></td>
</tr>
<tr>
<td>• Testicular swelling – atrophy, orchitis</td>
<td></td>
</tr>
<tr>
<td>• Other adverse events</td>
<td></td>
</tr>
</tbody>
</table>
be a consequence of the responsiveness to the cyclical load during the groin movements. In fact, the 3D structure of the prosthesis, which contracts and releases in unison with the muscles of the inguinal area, appears to be the keystone of this different behavior. The detected multistructured tissue ingrowth within the implant not only resembles the regeneration of the normal components of the abdominal wall (elastic fibers, slack and well-hydrated connective mature vessels and nerves), but also serves as the explanation for why the dynamic 3D implant doesn’t shrink. In fact, shrinkage of conventional meshes has been proven to be a consequence of dehydration (therefore, curbing and hardening) of the ingrown tissue within the static prosthesis.\textsuperscript{15–22} The response to cyclical load makes the difference among devices composed of identical material but showing different dynamic behavior.

Another essential discrepancy between conventional mesh and the 3D dynamic compliant implant arises from the thickness of the tissue incorporation. The static meshes and plugs are intended to reinforce the groin by defect coverage, promoting the ingrowth of a thin and stiff scar plate. Conversely, the 3D dynamic compliant prosthesis generated a thick tissue barrier composed of viable and well-hydrated tissue. As a result, starting from the early postoperative period, the hernia defect was effectively obliterated by the 3D implant.

Concerning the mass of the implant, we have compared the weight of the structured 3D implant to available plug and mesh systems. This comparative assessment demonstrated no valuable weight differences between the static systems and the 3D dynamic compliant prosthesis (Table VI).

Starting from these premises, we analyze the results for the 91 patients of the present group of this newly developed hernia repair technique with the 3D implant.

\textbf{Intraoperative Benefits}

The surgical procedure has been demonstrated to be simpler, with fewer
occasions for intraoperative complications. The use of the delivery device for implant placement was very easy and intuitive. After implant placement, occasionally, a forceps-guided adjustment of the implant was necessary. The obliteration of the hernia defect always resulted effective. In procedures under local or regional anesthesia, a cough test could immediately demonstrate the self-retaining effect of the implant. This is due to the intrinsic friction of the edges of the implant against the hernia border and the combined action consequent to visceral impact and the contraction of the groin musculature, which turns the ejection force into gripping force. In general, if compared with the conventional prosthetic repair techniques, a significant shortening of the operative time was achieved. The lack of intraoperative complications further demonstrates the safety and simplicity of the procedure.

In terms of prevention of a potential future direct hernia when repairing an indirect one, the size of the preperitoneal disc of the implant, which radius ranges from 3 cm to 3.5 cm, helps in avoiding this occurrence. The preperitoneal deployment of the implant disk provides a large enough coverage and protection of the fossa inguinalis (Fig. 8).

Spermatic Cord Compliance
Concerning the effects upon the spermatic cord structures, especially in case of indirect hernia repair, we could always visually demonstrate in every procedure that no compression upon the cord vessels is exerted by the implant structure (Fig. 5C). Both in the early and late postoperative follow-up, no sign of spermatic cord compression or testicle sufferance was noted.

Postoperative Outcomes
The reported very low incidence of perioperative and postoperative adverse events seems to be a consequence of the reduced surgical trauma and the fixation-free placement of the prosthesis. This could be achieved thanks to the self-retaining behavior of the 3D implant, which is immediately effective after its placement. Postoperative pain was subjectively low. Starting from the day of the procedure, the pain reduction reported by the VAS pain scale was rapid, after 2 weeks almost all patients were pain free (Table V). Even the

<table>
<thead>
<tr>
<th>Complication*</th>
<th>Number</th>
<th>% (n=91)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence</td>
<td>0</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Infection/abscess</td>
<td>0</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Dislodgement of the implant</td>
<td>0</td>
<td>0%</td>
<td>US detection was used to check the implants</td>
</tr>
<tr>
<td>Nerve pain/chronic pain</td>
<td>0</td>
<td>0%</td>
<td>Subjective assessment by the patients</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1</td>
<td>1.1%</td>
<td>Resolved with needle aspiration without drain</td>
</tr>
<tr>
<td>Seroma</td>
<td>4</td>
<td>4.2%</td>
<td>2 required needle aspiration, the remaining 2 patients received conservative therapy</td>
</tr>
<tr>
<td>Testicular swelling</td>
<td>3</td>
<td>4.4%</td>
<td>All related to large inguinoscrotal hernias spontaneously resolved*</td>
</tr>
<tr>
<td>Scrotal effusion/suffusion</td>
<td>2</td>
<td>2.2%</td>
<td>Resolved without intervention</td>
</tr>
<tr>
<td>Other complications</td>
<td>1</td>
<td>1.1%</td>
<td>Discharge delay for bladder training due to urinary retention caused by hypertrophic prostate</td>
</tr>
<tr>
<td>Adverse events requiring further procedure</td>
<td>0</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

*All patients resolved within 1 month follow-up

Figure 9. Biopsy specimens of 3D dynamic implant excised from patients 8 months postop. A: Lax and well-hydrated connective ingrowth among the implant fibers (X). Noteworthy amount of mature vascular structures. Negligible inflammatory reaction. He 20x. B: Incorporation of lax and well-established connective among the implant fibers (X). Presence of a great number of mature vascular structures (red spots). AM 5x. C: Multifocal evidence of dense area of elastic fiber (colored in black) among the implant structure (X). WvG 5x. D: Detection of numerous, well-formed nervous elements (red circles) close to the polypropylene fibers of the 3D implant (X). NSE 5x.
absence of recurrences certified the effectiveness of the surgical procedure. This could also be connected with the nearly absent shrinkage evidenced by the ultrasound detection of the implant diameter at different postoperative stages (Figs. 6 & 7). This feature undoubtedly contrasts with the reduction of the surface area due to the shrinkage typical in conventional implants, which represents a risky occurrence that can lead to recurrence. These facts demonstrate that the concept of obliteration of the hernia opening seems to be superior if compared with the simple defect coverage achieved by flat meshes. Even the cited histological evidence of the animal experimentation has been confirmed by the examination of biopsy specimen excised from the 3D implant positioned in human patients at different stages post implantation. Actually, the ingrowth of viable and multistructured

<table>
<thead>
<tr>
<th>Device Manufacturer</th>
<th>Device</th>
<th>Size</th>
<th>Implant type</th>
<th>Weight (grams)</th>
<th>Additional flat mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bard</td>
<td>Perfix Plug</td>
<td>Small</td>
<td>Static</td>
<td>0.347</td>
<td>Not integrated (extra mesh needed)</td>
</tr>
<tr>
<td>Bard</td>
<td>Perfix Plug</td>
<td>Medium</td>
<td>Static</td>
<td>0.563</td>
<td>Not integrated (extra mesh needed)</td>
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<tr>
<td>Bard</td>
<td>Perfix Plug</td>
<td>Large</td>
<td>Static</td>
<td>0.920</td>
<td>Not integrated (extra mesh needed)</td>
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<tr>
<td>Bard</td>
<td>Perfix Plug</td>
<td>Extra large</td>
<td>Static</td>
<td>1.159</td>
<td>Not integrated (extra mesh needed)</td>
</tr>
<tr>
<td>Ethicon</td>
<td>Prolene Hernia System</td>
<td>Medium</td>
<td>Static</td>
<td>0.934</td>
<td>Integrated (anterior &amp; preperitoneal)</td>
</tr>
<tr>
<td>Ethicon</td>
<td>Prolene Hernia System</td>
<td>Large</td>
<td>Static</td>
<td>1.227</td>
<td>Integrated (anterior &amp; preperitoneal)</td>
</tr>
<tr>
<td>Ethicon</td>
<td>Prolene Hernia System</td>
<td>Extended</td>
<td>Static</td>
<td>1.437</td>
<td>Integrated (anterior &amp; preperitoneal)</td>
</tr>
<tr>
<td>Insightra</td>
<td>Freedom Dynamic Implant</td>
<td>Small</td>
<td>Dynamic</td>
<td>0.792</td>
<td>Integrated (only preperitoneal)</td>
</tr>
<tr>
<td>Insightra</td>
<td>Freedom Dynamic Implant</td>
<td>Large</td>
<td>Dynamic</td>
<td>1.453</td>
<td>Integrated (only preperitoneal)</td>
</tr>
</tbody>
</table>
tissue within the implant resembles an enhanced biological response exhibiting the proliferation of slack and well-hydrated connective, elastic fibers as well as mature arteries, veins, and nerves (Fig. 9). The proliferation of these typical components of the abdominal wall within the 3D implant seems to effectively contrast the degenerative source of the hernia disease. Because of this regenerative process, a newly formed and thick inguinal barrier is established that should permanently protect the inguinal area from advancing of further protrusions. This evidence clearly differs from the ingrowth of a tiny fibrotic plaque, which is a typical result of the incorporation achieved in conventional flat meshes.

**CONCLUSIONS**

An important endpoint of the present study was certifying the safety of the technique and the low complication rate consequent to the dynamic hernia repair. Among these, more important than the lack of recurrences was the absence of subjective symptoms reported by the patients, such as discomfort, numbness, and chronic pain. Actually, the described 3D implant is unquestionably the first example of a prosthetic characterized by dynamic responsiveness. After more than 5 decades of prosthetic hernia repair carried out with static and passive flat meshes made by heavy and, more recently, lightweight and macro-porous polypropylene, the scientific community imagines the ideal implant to be one that is as thin as possible. Therefore, by considering the structure of the described newly developed 3D implant, at first glance it could be envisioned as a bulky and impairing device. This line of thought does not take into consideration the dynamic attributes of the 3D prosthesis, which cannot be compared to passive and static devices. The stiff scar plate resulting as biologic response in static conventional implants greatly contrasts with the high mobile attribute of the lower abdominal wall. The shrunken static meshes and plugs seem to impair muscle movements, sometimes causing a “sandpaper” effect consequent to the friction between scar plate and muscle bundles. The consequences are: upsetting sense of tissue stretching and a wide range of discomforts or even chronic pain. This is different from the outcome of the new 3D, dynamic, compliant implant, distinguished by a lack of discomfort, numbness, and chronic pain evidenced in the described patient cohort. These outcomes could be explained by the steady responsiveness of the dynamic implant, which, being structurally and biometrically integrated, moves in unison with the groin, and consequently, is not perceived as a foreign body. Because of this dynamic compliance, the 3D implant seems to act as a regenerative scaffold promoting enhanced biologic response that leads to the regeneration of the typical tissue components of the inguinal structure.

**AUTHORS’ DISCLOSURES**

Dr. Amato is the inventor of the prosthesis and developer of the surgical technique described in this article. InSightra Medical Inc. (Irvine, CA) provided initial financial support of the report. The other authors have nothing to disclose.

**REFERENCES**