

**Appendix 1** to Tomassini F, Brescia A, Berardi G, et al. A new fixation-free 3D multilamellar preperitoneal implant for open inguinal hernia repair. *Can J Surg* 2016.

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## **APPENDIX**

Between September 2014 and December 2015, thirty-two patients with inguinal hernia were treated using the 3D-mesh (Figure 1) in our department. Recurrent or bilateral hernias were excluded from the study, as well as emergency operation. A 1:1 ratio retrospective case-control analysis was performed with a control group (CG) of patients treated with a traditional large-pore polypropylene mesh between the same periods. The two groups were comparable according to age, ASA score, BMI and type of hernia according to the European Hernia Society Classification (Table 1).

Operative time (OT) was recorded for both groups and compared. All patients were treated in a “day surgery” regimen and discharged after 6 to 7 hours after the procedure. The presence of postoperative complications was recorded and classified using the Clavien-Dindo classification.

The pain assessment is routinely performed in our department immediately after the procedure and then at 4 and 8 days from the discharge using the VAS scale. The presence of recurrence was evaluated at 30-days, 3 and 6 months and 1 year after the procedure. Chronic pain was defined as persisting pain beyond 3 months.

Patient’s characteristics are depicted in Table 1. The mean OT of the 3D-mesh group was significantly shorter than in the CG ( $p=0.02$ ) (Table 2). The mean VAS scale recorded immediately after the procedure in the CG was significantly higher than in the 3D-mesh group ( $p=0.02$ ). The trend of mean VAS scale after 4 and 8 post-operative days shown significant better results in the 3D-mesh group (Figure 2).

Only 3 patients in the 3D-mesh group (9.4%) experienced complications represented by subcutaneous edema, all defined as CD Grade 1. These patients were all classified as having a PL3 hernia.

Seven patients in the CG (21.8%) developed postoperative complications with a mean Clavien-Dindo grade of  $1.4\pm 0.5$  ( $p=0.3$ ; Table 2). Three patients (9.4%) presented subcutaneous hematoma not requiring treatment. Four patients (12.5%) experienced subcutaneous edema and in 3 cases an anti-inflammatory therapy was necessary. These patients were all classified as PL3. No recurrence was observed in all the population at 30-days, 3 and 6 months. The 1-year follow up was completed in all the patients of the CG and in the 84.4% of the 3D mesh group (27/32) without observing recurrence. No chronic pain was diagnosed in all the population.

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Parameter	3D Mesh Group n=32	Control Group n=32	p
Sex (M/F)	29/3	28/4	1
Age	56.2±7.9	56.3±7	0.96
EHS Classification			1
1 (<1.5 cm)	9 (28.1%)	9 (28.1%)	
2 (<3 cm)	19 (59.4%)	19 (59.4%)	
3 (>3 cm)	4 (12.5%)	4 (12.5%)	
L	22(68.7%)	23 (71.9%)	
M	10 (31.3%)	9 (28.1%)	
BMI (Kg/m <sup>2</sup> )	25.6 ± 3.2	25.5 ± 2.8	0.87
ASA score II/III	40.6% (13/32)	43.7% (14/32)	1

**Table 1:** Patients characteristics

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Parameter	3D Mesh Group n=32	Control Group n=32	p
OT (mean)	44.1±5.2	48.3±5.3	0.02
Complication n (%)	3 (9.4%)	7 (21.8%)	0.3
Subcutaneous Edema	3	3	
Hematoma	-	4	
Clavien Dindo grade (mean)	1	1.4±0.5	0.3

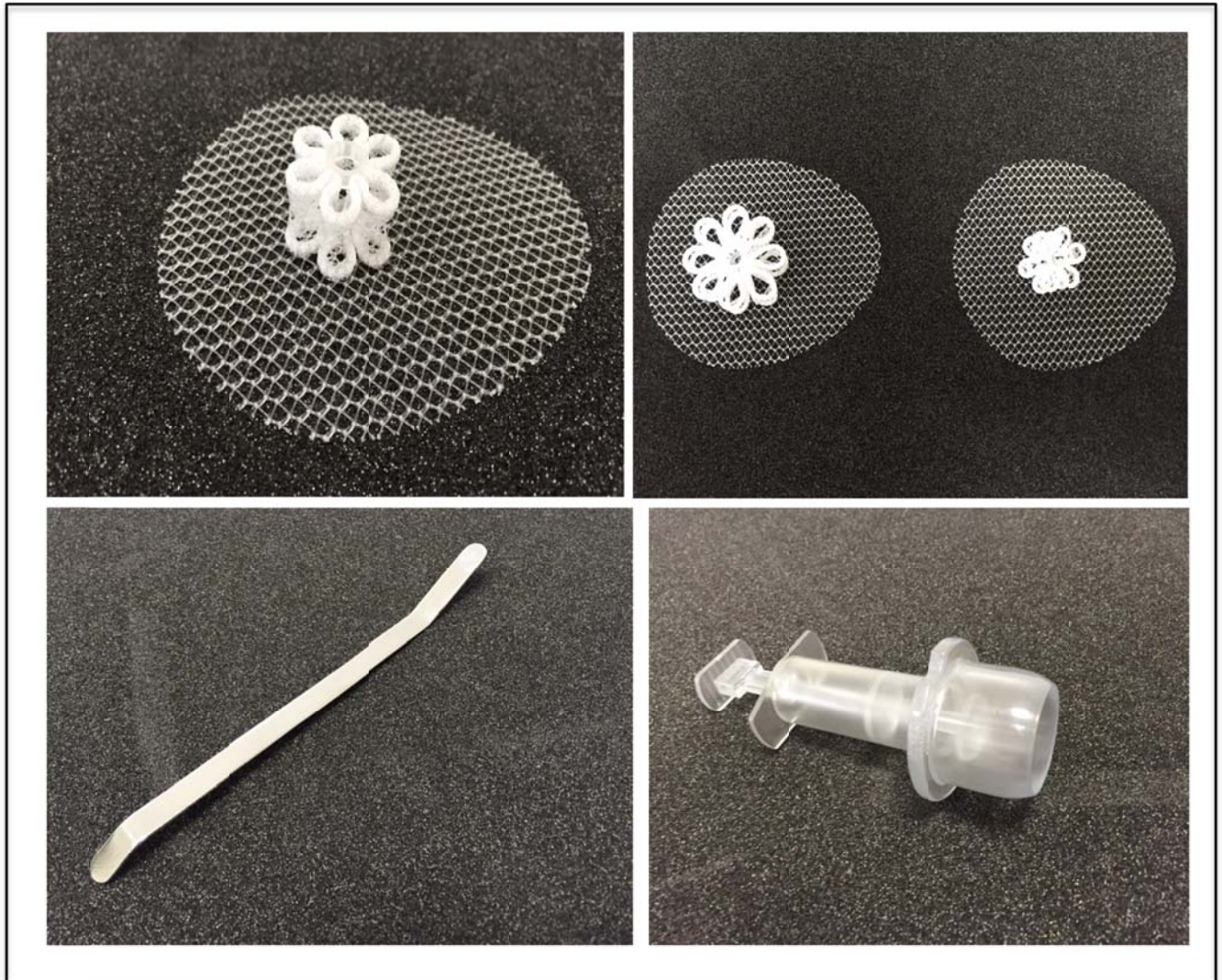
**Table 2:** Peri-operative results

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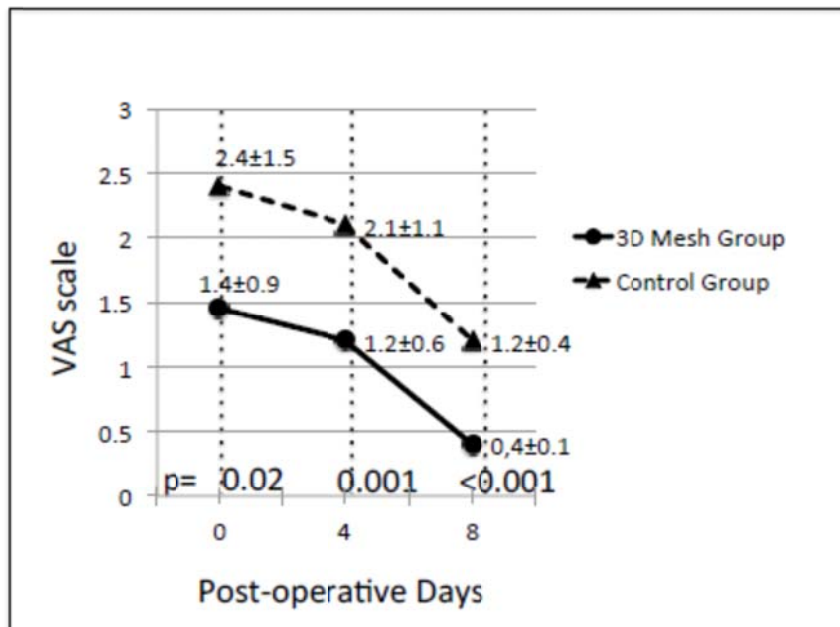
**Fig. S1. A)** The 3D Multilamellar ProFlor Mesh **B)** Two different sizes of mesh **C)** Dissection device **D)** Deployment tool

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**Figure 2:** Post-operative VAS scale evaluation comparison