Robotic Laparoscopic Myomectomy with Placement of Lyophilized Dehydrated Complete Human Placental Membrane Allograft

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TECHNOLOGY PLATFORM

Placental membrane allografts have increasingly been used as coverings for acute and chronic wounds and as protective barriers in various surgical applications.[1] StimLabs' lyophilized dehydrated complete human placental membrane (dCHPM) allograft is the first intact, complete placental membrane allograft to be commercialized.[2] The lyophilized dCHPM allograft is processed using Clearify™, StimLabs' breakthrough approach to processing birth tissue without ever delaminating the membrane. This patented technology effectively cleans the allograft and preserves the native 3D architecture without compromising integral structural components.[2]

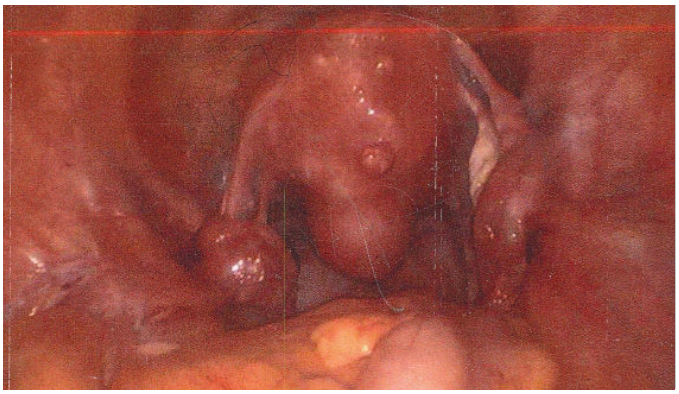

Figure 1. Posterior uterine fibroids.

CLINICAL HISTORY

46-year-old female with a history of obesity, hypertension, thyroid disease, Hodgkins lymphoma, endometriosis, uterine fibroids, ureter stricture, bowel obstruction, and hydroureteronephosis was diagnosed with multiple fibroids during an emergency room evaluation after experiencing severe pelvic and back pain. The patient was scheduled for a Da Vinci Robotic Laparoscopic Myomectomy, excision of endometriosis, lysis of adhesions, with placement of lyophilized dCHPM and instillation of platelet rich plasma, and dilatation and curettage.

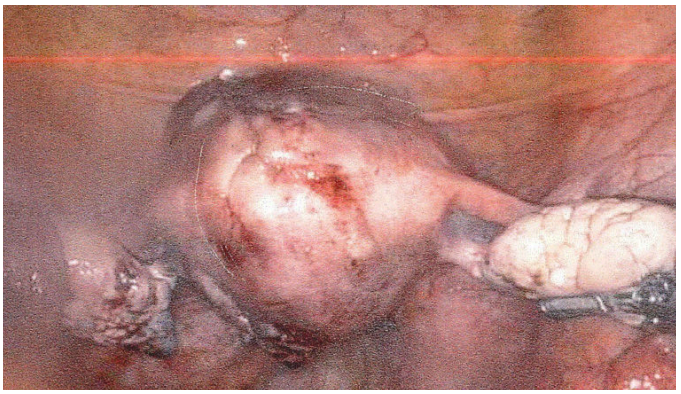

Figure 2. Post reconstruction using a vertical and horizontal suture line.

PROCEDURE

The patient was prepared for surgery using standard procedure, and a uterine manipulator was placed. An 8 mm robotic camera port was placed above the umbilicus, and the peritoneal cavity was insufflated with carbon dioxide gas after intraperitoneal placement was confirmed. The remaining ports were then placed. The pelvis was surveyed and found to have adhesions in the upper quadrant, endometriosis lesions in multiple areas, four small to medium subserosal fibroids on the posterior surface, and two anterior intramural fibroids.

A solution of Vasopressin and injectable saline was injected in the serosa overlying the subserosal and intramural fibroids (Figure 1.). Electrocautery was used on the cut settings to open the serosa and myometrium. The fibroids were removed, and the endometrial wall was left intact. The myometrium and serosa were sutured closed (Figure 2.). The areas of endometriosis were excised.

After irrigation and good hemostasis was noted, a 6x8 cm lyophilized dCHPM was cut into two 4x6 cm pieces. One 4x6 cm piece was applied to the vertical suture line and left to hydrate as the second piece was prepared (Figure 3(a).). After the application of the second piece to the horizontal suture line, there was a noted difference in appearance and improved adherence to the uterine surface between the two pieces due to hydration level (Figure 3(b).).* The ports were then removed, closed, and dressed in standard protocol.

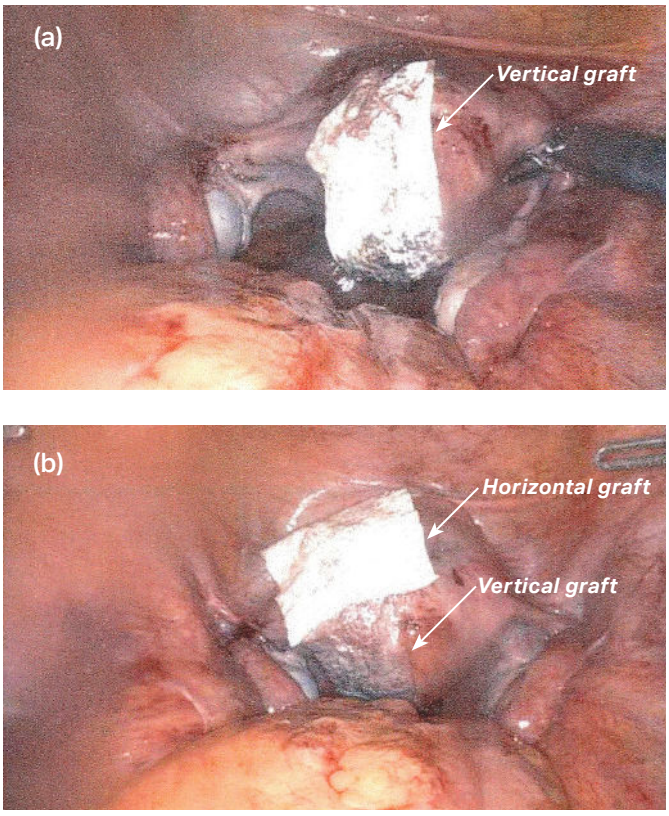

Figure 3. (a) Lyophilized dCHPM placed over vertical suture line. (b) Lyophilized dCHPM fully hydrated on vertical suture line, and second piece placed over horizontal suture line.

PROCEDURE OUTCOME

Eight weeks following the myomectomy, the patient reported no redness of the incisions, no vaginal bleeding, and significant improvement of the pain described prior to surgery. The patient was able to return to normal activities with routine follow up.

LYOPHILIZED dCHPM EXPERIENCE

The lyophilized dCHPM was easily placed through the robotic port and onto the uterine surface. The graft adhered and conformed well to the uterine surface after hydration. Overall, the lyophilized dCHPM demonstrated excellent handling characteristics during the surgical procedure.

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* Refer to Instructions For Use for intended use. 1. Roy, A., Mantay, M., Brannan, C., & Griffiths, S. (2022). Placental Tissues as Biomaterials in Regenerative Medicine. BioMed Research International, 2022, 6751456. https://doi.org/10.1155/2022/6751456 2. Data on file.
Patents: www.stimlabs.com/patents