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GENERAL GYNECOLOGY

Ultra-low-impact laparoscopy: a new concept for a minimally invasive surgery

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Abstract

Introduction Minimally invasive surgery is considered the gold standard for the treatment of gynecological diseases. Our study aims to assess the effectiveness of the new concept of ultra-low-impact laparoscopy as a combination of low-impact laparoscopy, consisting in the use of miniaturized instruments through 3–5mm ports and low-pressure pneumoperitoneum, with regional anesthesia to evaluate the perioperative outcomes.

Methods A cross-sectional study was performed from May 2023 to December 2023, to enroll 26 women affected by benign gynecological disease and threated by mini-invasive surgical approach. The surgical procedures were performed following the low-impact laparoscopy protocol and the regional anesthesia protocol. The postoperative pain, nausea, and vomiting and the antiemetic/analgesic intake were evaluated. Postoperative surgical and anesthesiological variables were analyzed.

Results Operative time was within 90 min (41.1 ± 17.1 mean ± standard deviation (SD)) and no conversion to laparotomy or general anesthesia was required. According to VAS score, the postoperative pain during the whole observation time was less than 3 (mean). Faster resumption of bowel motility (6.5 ± 2.1 mean ± SD) and women's mobilization (3.1 ± 0.7 mean ± SD) were observed as well as low incidence of post-operative nausea and vomit. Early discharge and patient's approval were recorded. Intraoperatively pain score was assessed on Likert scale during all stages.

Conclusion Ultra-low-impact laparoscopy showed to provide a satisfying recovery experience for patients in terms of short hospital stays, cosmetic result, and pain relief, without compromising surgical outcomes. The encouraging results lead us to recruit a greater number of patients to validate our technique as a future well-established produce.

Keywords Miniaturized instruments · Mini-laparoscopic approach · Postoperative pain · Analgesic consumption · Regional analgesia

What does this study add to the clinical work

A new trend in minimally invasive surgery: low impact laparoscopic approach for a successful result, from the point of view of the patient, surgeons and anesthetists.

Introduction

Laparoscopic surgery is playing a pivotal role in gynecology, related to the great advantages in terms of surgical outcomes, success of the procedure, and lower costs for healthcare system. [1]. In recent years, surgeons aimed to achieve more benefits from laparoscopy to be as mini-invasive as possible and to obtain the best results with the maximum satisfaction of patients. It was possible because of the use of novel techniques and the improvement of new instrumentation. Nowadays, mini-invasive surgery includes different approaches such as robot-assisted surgery, single-port laparoscopy, and the more recent laparoscopy under regional anesthesia [2]: the combination of these innovations led to minimize the hospitalization of the patients and to promote the outpatient management over the inpatient management [3, 4]. Some authors have recently introduced a new concept of 'low impact laparoscopy' in colorectal surgery [5]. It is

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an innovative surgical protocol which uses the combination of miniaturized instruments through 3–5mm ports and low-pressure pneumoperitoneum (8 mmHg). Therefore, all the risks related to the surgical trauma and the intra-abdominal pressure are avoided. The immediate consequent is a lower postoperative pain with rare assumption of opioids, shorter hospital stays, and higher esthetic satisfaction of the patient [5, 6].Sroussi et al. reported the effectiveness of low-impact laparoscopy for reducing shoulder pain after benign gynecological surgeries [7]. The authors described the use of low-pressure pneumoperitoneum in gynecological surgery with the use of 5–10 mm laparoscopic instruments. More recently, Dabi et al. conducted a study on 32 patients who underwent low-impact laparoscopy with miniaturized instruments in gynecological surgery [8]. Minimally invasive procedures can be combined with minimally invasive anesthesia, such as regional anesthesia (RA), to amplify the mentioned advantages and, at the same time, to reduce the consequences connected to the use of general anesthesia (GA), including late mobilization, delayed bowel canalization, resort to infusion of rescue analgesics, and antiemetics [9, 10]. Moreover, if we consider the relative contraindications of GA, such as chronic obstructive pulmonary disease, muscular disorders, and respiratory syndromes, RA turns out to be a good alternative for patients with these diseases [11]. Furthermore, one of the aspects that is frequently detected in patients undergoing GA is anxiety and fear for the unconscious state during the procedure. This anxiety is overcome by the RA [12, 13]. According to this, recently Giampaolino et al. reported the use of RA in laparoscopic gynecological surgery [2, 14, 15]. Despite all these surprising advantages, there is still few data in the literature on using the aforementioned protocols in gynecologic surgery. In this study, we assessed the feasibility and the effectiveness of a new concept that we call ultra-low-impact laparoscopy (ULIL) consisting in the combination of the use of low-impact laparoscopy under minimally invasive regional anesthesia to evaluate the intraoperative and postoperative outcomes.

Methods

Population

A cross-sectional study was performed in a tertiary-level referral center for minimally invasive surgery, and 26 women were enrolled from May 2023 to December 2023.

All the women included underwent surgery for benign gynecological disease such as ovarian cysts (endometrioma, dermoid cyst, simple serous cyst), sactosalpinx, ectopic pregnancy, primary and secondary infertility, BRCA mutation carrier aged more than 18 years old.

The excluded women had contraindications to RA, suspected malignant disease, allergy to local anesthetics, abnormal intracranial pressure, body mass index (BMI) > 35, poor compliance because of psychiatric or neurological pathology.

Preoperative evaluation

The surgical procedures were performed following the ultra-low-impact laparoscopy protocol. More in detail, the surgical steps, including the laparoscopic accesses, are comparable to conventional laparoscopy. The novelty lies in the use of low-impact laparoscopy, which involves the use of miniaturized instruments through 3–5 mm ports, but in this case associated with low-pressure pneumoperitoneum, low Trendelenburg degree, and regional anesthesia, whose protocol has already been previously validated [14]. The combination of these factors results in the development of ultra-low-impact laparoscopy protocol that received significant approval from participants to the study.

They were planned as outpatient surgeries and all the participants signed an informed consensus to participate in the study.

The protocol provided for a first clinical preoperative evaluation with sonographic examination and a magnetic resonance imaging (MRI) prescription if necessary. Before surgery, the patient signed a written informed consent after a detailed counseling with the surgeon as well as the anesthesiologist.

Preoperative anesthetic evaluation included classifying women according to American Society of Anesthesiologists (ASA) Physical Status Classification System by attributing an ASA score from 1 to 6. This is a scale used to access and communicate the preoperative physical fitness of a patient before undergoing anesthesia for surgery and it identifies six classes of patient from a normal health patient (ASA score 1) to a declared brain-dead patient whose organs are being removed for donor purposes (ASA score 6) [16–18].

Surgical and anesthesiologic protocol

Twenty-six women met the inclusion criteria and were enrolled in the study. The surgical procedure was carried out under an outpatient regimen by a single operator with proven experience in laparoscopic gynecological surgery (PG). The whole video procedure was projected on a high-resolution color screen so that the patient could follow the surgery step by step and be informed about its progress. Once in the operating room, a venous access was placed (18 G), antibiotic prophylaxis was administered (Cefazolin 1 or 2 gr. iv, or in case of allergy, Clindamycin 600 mg iv) 30 min before skin incision, Dexamethasone 4 mg iv and midazolam

1 mg iv were injected. Vital parameters were collected every 5 min: heart rate, SpO2 and blood pressure. RA was performed in the sitting position at the T9–T10 or T10–T11 level. Ropivacaine 0.375% 18 mg, Sufentanil 7 mcg, and Clonidine 20 mcg were injected in the subarachnoid space after the vision of clear cerebrospinal fluid (CSF) in the spinal needle 27 Gauge. First, pneumoperitoneum was obtained at the intraumbilicus using open laparoscopy access (Hasson technique) instead of closed technique (Veress technique) to prevent high intraperitoneal pressure during the positioning of the first trocar and to reduce the risk of vessels' damage [19]. The pneumoperitoneum was achieved with the specialized AirSeal system. An AirSeal 5 mm valve free trocar was introduced so that a stable pneumoperitoneum was maintained during the entire procedure even under suction. The intraperitoneal pressure did not exceed 10 mmHg for the entire procedure. A 5 mm optical lens was inserted in the AirSeal's trocar. The woman took the Trendelenburg position with an inclination angle no higher than 20°. Under vision, three ports were placed in the right and left iliac fossa and above the pubis. All trocars at visible areas of the pelvis were 3.5 mm, whereas the 5 mm optical trocar was in the belly button. To perform the ULIL, a 3.5 mm instruments Ab Medica-Evolap with a 0 degree 5 mm Karl Storz optical scope has been used (Fig. 1, A-B).

Outcome measures during and after procedure

During the procedure, patients has been asked to give a score to the pain felt at various stages of the surgery using the Liker scale which is the most important and frequently used psychometric tools in scientific research. It quantifies the pain relief into 5 levels, from 0, which corresponds to the absence of pain, to 5, which is the maximum pain felt [20]. Pain assessment is carried out during each phase of the intervention: the introduction of uterine manipulator, the introduction of Hasson trocar and induction of pneumoperitoneum; the introduction of ancillary trocars; the view of pelvic organs; the actual surgical procedure. The skin sutures have been performed using a surgical glue to obtain the best esthetic result.

Postoperative management provided the injection of different type of analgesics depending on the intensity of pain measured with the Visual Analog Scale (VAS) [21]. The injection of Paracetamol 1000 mg in cases of VAS < 5 and Ketorolac 30 mg in case of VAS > 5. If analgesia was not obtained after 60 min, women received Tramadol 100 mg i.v. Women, who developed PONV, were treated with Ondansetron 4 mg i.m, and Dexamethasone 4 mg i.v after 60 min if PONV still continued.

Primary and secondary endpoint

The primary endpoint was to quantify postoperative pain through Visual Analog Scale (VAS) and the time to mobilization. The secondary outcomes were antiemetic and analgesic drug assumption, postoperative nausea and vomiting (PONV), esthetic satisfaction of the women length of hospital stays, bowel canalization, intraoperative pain score asked during surgery using Likert scale from 1 to 5.

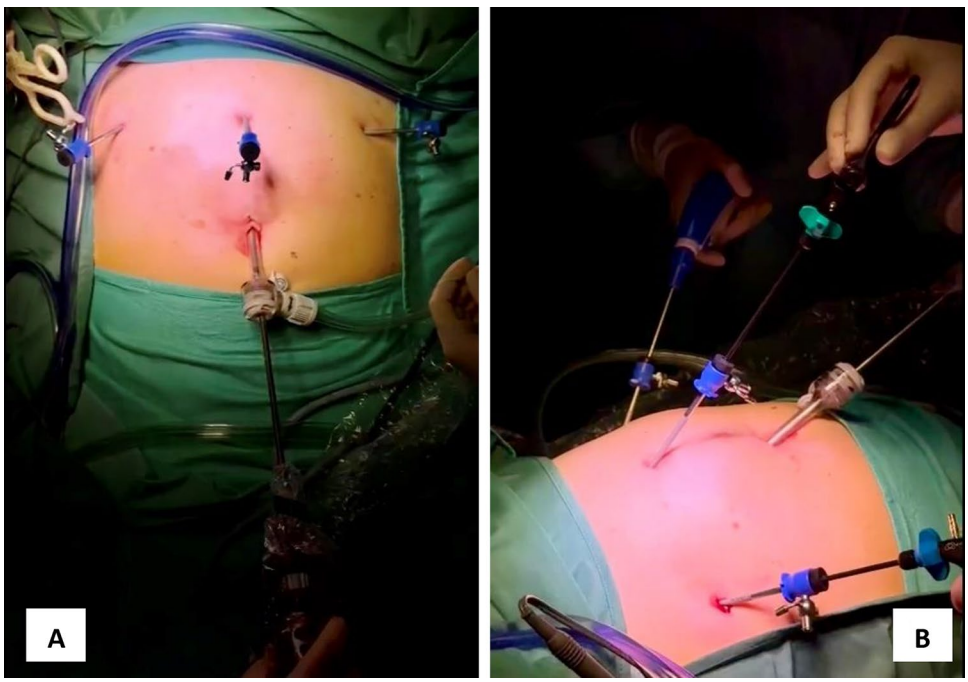

Fig. 1 Ultra-low-impact laparoscopy: ports (**A**) and instruments (**B**)

Statistical analysis

Sample characteristics were analyzed using standard descriptive statistics. Mean ± standard deviation (min to max) in case of numerical variables and absolute frequencies and percentages in case of categorical factors. Numerical variables showing highly skewed distribution were described using median with interquartile range (25th–75th percentile).

Results

Clinical characteristics and surgical parameters

All women who met the inclusion criteria underwent ultra-low-impact laparoscopy. The sample characteristics and clinical data are presented in Table 1. Among the gynecological diseases, most of the ladies were affected by ovarian cysts (15/26, 57.7%), 5 BRCA mutation carriers, 2 sactosalpinx, 2 endometriosis and 2 ectopic pregnancies (11/26, 42.3%).Surgical variables are displayed in Table 2. Regarding the type of surgery, the majority of women underwent adnexectomy (13/26, 50%). The median degree of Trendelenburg's position was of 15.6 (range 13–20). Also, operative time was < 90 min in all cases (41.1 ± 17.1 min) with no significant differences between women. The mean intraoperative pressure was generally maintained very low in all women.

No participant required laparotomic or anesthesia conversion and there was no need of accessory ports. No intraoperative surgical complications were observed. Only one woman developed anesthesia complication, such as hypotension after spinal puncture.

Table 1 Main women characteristics

	Ultra-low-impact laparoscopy *N* 26 (%)
Age (mean ± SD)	37 ± 8.7
BMI (mean ± SD)	23 ± 3.7
ASA physical status *N* (%)	
Class 1	8 (30.8)
Class 2	17 (65.4)
Class 3	1 (3.8)
Comorbidity *N* (%)	
None	19 (73)
Hypertension	1 (3.8)
Diabetes	2 (7.7)
Thyroid disease	2 (7.7)
Other	2 (7.7)
Gynecological disease *N* (%)	
Ovarian cyst	15 (57.7)
Sactosalpinx	2 (7.7)
BRCA mutation	5 (19.2)
Endometriosis	2 (7.7)
Ectopic pregnancy	2 (7.7)

Table 2 Surgical variables and intraoperative data

	Ultra-low-impact laparoscopy *N* 26 (%)
Type of intervention *N* (%)	
Ovarian cyst enucleation	8 (30.8)
Mono/Bilateral adnexectomy	13 (50)
Mono/bilateral salpingectomy	4 (15.3)
Adhesiolysis	1 (4)
Operation time *N* (%)	
within 60 min	19 (73)
60–80 min	6 (23)
> 80 min	1 (4)
Trendelenburg's position (°) Mean (range)	15.6 (13–20)
Anesthesia complication N (%)	
None	25 (96)
Hypotension	1 (4)
Surgical complication *N* (%)	
None	26 (100)

Postoperative data and analgesics consumption

The main postoperative outcomes are shown in Table 3. Most of the women undergoing the ultra-low-impact laparoscopy were managed as outpatients (16/26, 61.5%) and they were discharged within 12 h. The remaining ten women (10/26, 38.5%) stayed in hospital for 24 h. All the women were mobilized in 4 h (3.1 ± 0.7, mean ± standard deviation (SD) and the resumption of bowel motility was always ≤ 8 h (6.5 ± 2.1, mean ± SD). Only three women developed PONV but it was threated in just one case.Concerning the postoperative pain (Table 4), the VAS score showed an increase at 6 h [2.3 (0–6)] followed by a reduction at 12 h [1.9 (0–6)]. The ten women not discharged at 12 h referred a median VAS score of 2.2 (0–6) at 18 h, definitely reduced at 24 h [1.1 (0–4)]. Regarding the assumption of analgesics after surgery, the women discharged within 12 h benefited from intraoperative pain relief and they did not ask for more analgesic injection. Among the group of women discharged after 12 h, two patients who reported VAS score > 5 were administered Ketorolac 30 mg, five patients who complained about the persistence of postoperative discomfort asked for

Table 3 Postoperative data and women satisfaction

	Ultra-low-impact laparoscopy *N* 26 (%)
Length of hospitalization (h) *N* (%)	
< 12	16 (61.5)
24	10 (38.5)
Resumption of bowel mobility	
Mean ± SD	6.5 ± 2.1
Mobilization	
Mean ± SD	3.1 ± 0.7
PONV *N* (%)	
No	23 (88.4)
Yes	3 (11.6)
Patient satisfaction (would you do the same anesthesia again?) *N* (%)	
Yes	26 (100)
No	0 (0)
Esthetic satisfaction (would you undergo the same 3mm laparoscopy? *N* (%)	
Yes	26 (100)
No	0 (0)

Table 4 VAS (Visual Analog Scale) score and analgesics intake

	All women
VAS score (mean, range)	
0 h	0.4 (0–2)
6 h	2.3 (0–6)
12 h	1.9 (0–6)
18 h	2.2 (0–6)
24 h	1.1 (0–4)
Analgesics intake *N* (%)	
Paracetamol 1 g	
No	21 (80.8)
Yes	5 (19.2)
Ketorolac 30 mg	
No	24 (92.3)
Yes	2 (7.7)
Tramadol 100 mg	None

more Paracetamol 1 g. The intraoperative pain score was obtained with the Likert scale (Table 5), typically divided into 5 points (0: no pain, 5: maximum pain) during the various stages of surgery: introduction of uterine manipulator, introduction of Hasson trocar and induction of pneumoperitoneum; introduction of ancillary trocars; exploration of pelvic organs; and actual surgical procedure, as already reported in our previous series. All patients showed a pain score of 1 during the introduction of uterine manipulator, Veress needle, and trocars. Some of them reported a pain score of 2 during the induction of pneumoperitoneum, manipulation of organs, and surgical procedure. The patient satisfaction was analyzed by asking them if they would do the same anesthesia again together with the same 3.5 mm mini laparoscopy (Table 3): the totality of patients agreed with both surgical and anesthetic protocol.

Table 5 Likert scale in all women

Likert scale	Value (0–5)	Number of women (%)
Introduction of uterine manipulator	1	24 (100)
Introduction of Veress needle	1	26 (100)
Introduction of Hasson and ancillary trocars	1	26 (100)
Induction of pneumoperitoneum	1	19 (73)
	2	7 (27)
Exploration of pelvic organs		22 (85)
	2	4 (15)
Surgical procedure	1	21 (81)
	2	5 (19)

Discussion

The interest in using ultra-low-impact laparoscopy stems from the objective of accomplishing outpatient management and minimalizing the postoperative analgesic consumption. Our data confirm the suitability of combining regional anesthesia with low-impact laparoscopy in gynecological surgery with undoubtedly positive results. To date, similar case histories have not been available in literature. It is now well known that mini-laparoscopy can be used by surgeons for varied procedures so much so that it has now become a well-established process, especially in general surgery, such as appendicectomy, colorectal resection, cholecystectomy [5, 6, 22]. Recently, mini-laparoscopy is starting to play an important role in the gynecological field as an effective option over conventional laparoscopy. Casarin J. et al. reported in an interesting review that mini-laparoscopy can represent a good alternative in selected patients affected by both benign and malignant indications. [23] Dabi et al. confirmed this innovative concept by subjecting patients to total laparoscopic hysterectomy, comparing conventional laparoscopy with low-impact laparoscopy. They concluded that low-impact laparoscopy could be considered the best option in terms of patient satisfaction and shorter hospital stays [8]. However, the innovation of our data is combining during the same surgery, both the low-impact laparoscopy and the minimally invasive anesthesia so that we are able to

introduce this revolutionary concept of 'ultra-low impact laparoscopy'. RA is an advantageous approach over GA in terms of overall safety and shorter hospitalization, it allows for early ambulation, quick resumption of bowel, and best control of postoperative pain [24, 25]. Although RA can generate some side effects such as neurological effects (cauda equina syndrome), or circulatory effects (low blood pressure, bradycardia), it remains a faster procedure with minimal probability of failure, which does not require intubation and high doses of sedatives and narcotics [26]. Therefore, from the anesthesiological point of view, our results have to be considered satisfactory: only an intraoperative hypotension was documented and successfully managed. Another advantage of RA is the long-term analgesic effect so that none of the women ask for intravenous opioid administration. Less pain has been registered in the immediate postoperative hour, and this can be considered of primary importance as long as the early onset of pain right after surgery can affect the whole recovery time. The optimal pain control can be especially explained by the persistent neuraxial blockade. To improve this effect, in our study clonidine, an α2 adrenergic agonist used as an adjuvant in anesthesia was administered. According to some researchers, the action of α2-agonism of clonidine causes vasoconstriction and enhances the spinal block via synergistic interaction between α2 receptors and sodium channels, contributing to a prolonged and more effective analgesia [27, 28] Furthermore, according to the literature [29], in the postoperative time, only three cases of PONV were recorded, suggesting that RA could reduce this adverse effect of GA, and no cases of urinary retention were registered. In our opinion, ladies' motivation and willingness to accomplish surgery under RA are the keys for the achievement of the procedure; therefore, randomization of women at the moment has to be considered challenging. In our experience, for all the participants, the procedure was well accepted. From the surgical point of view, in the last decade, the challenge has been to increase surgical skills by the introduction of novel techniques to reduce the surgical morbidity. In particular, the miniaturization of laparoscopic instruments and the use of 3.5 mm ports do not represent an obstacle for experienced surgeons, since the lower grasping ability is quickly overcome. Although the reduction in diameter of ports from 5 or 10 to 3.5 mm provide a better cosmetic advantage, confirmed by the total approval of the women especially toward the application of the surgical glue on the skin, we establish that the best result lies in the reduction of postoperative pain. To date, intraperitoneal pressure commonly used in the convention laparoscopy is 12–15 mmHg or more [30]. Conversely, in our case, we used a pressure ranging from 6 to 10 mmHg in the majority of cases. And despite the guidelines recommend using the lowest pressure allowing appropriate vision of the surgical field [31], our work showed that low pressures are feasible for a good vision and the final success of the intervention. In addition, the introduction of AirSeal system contributes to maintain a stable pressure during the entire procedure. These innovations imply a lower and less long-lasting exposure to the complications that pneumoperitoneum provides, such as hemodynamic alterations. Operative time does not seem to be affected by this updated surgical practice if we consider an acceptable operative time within 60 min in most of the cases. Trendelenburg position required for the gynecological surgeries worsens the pulmonary compliance and the discomfort for the lady, thus it appears to be limiting for the implementation of this technique [32]. Strength of our study is placing women into a minimal Trendelenburg position, maximum 20° with a median of 15.6°, just able to ensure a sufficient visualization and bowel retraction and at the same time to avoid the complications related to a huge inclination such as hypercapnia and respiratory acidosis [33]. No case of hypercapnia or pulmonary complication was registered. However, the main limitation of this procedure is the BMI of the participant being less than 30. This condition is necessary to use lower intra-abdominal CO2 pressures and a Trendelenburg position not exceeding 20 degrees. Based on our results, an adequate and lasting postoperative pain control is crucial to enhance recovery. We confirmed the findings already recorded in laparoscopy cholecystectomy under RA [34–36]: lower pain felt in the first postoperative phase, thanks to the improvement of intraoperative pain control required from our anesthesiological protocol, is associated with the success of the whole recovery time.Moreover, the early mobilization of the ladies has been encouraged just 3 h after surgery and a fast resumption of bowel and bladder movement has been observed within 7 h. These results are encouraging given that one of the main goals of the study was to provide an outpatient management with a same-day patient discharge. Effectively, more than half of the women were at home at 12 h.

Conclusion

To the best of our knowledge, this is the first study evaluating the ultra-low-impact laparoscopy in women affected by gynecological disease. The success of our results is linked to the adequate preoperative counselling, the woman willingness as well as the balanced collaboration between a trained surgeon and a proven anesthesiological practice. In our experience, the combination of these factors contributed to the successful achievement of the full woman satisfaction in terms of outpatient management, cosmetic result, and pain relief. Aware that our participants have been carefully selected, further studies are required to evaluate the suitability of our innovative protocol with more complex cohort of women and in longer surgical procedures. Despite it is

a preliminary study focused on a small study sample, the encouraging results lead us to recruit a greater number of women to validate our technique as a future well-established procedure.

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Data availability The datasets generated during the study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose.

Ethical approval All procedures performed in the study 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. The study received ethical approval from the local research ethics committee of the University of Naples Federico II on June 2019 (protocol number: 75/19).

Consent to participate Informed consent was filled out as required for the execution of this study.

Consent to publish The authors affirm that human research participant provided informed consent for publication of the images in Fig. 1.

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