

Clinical Paper
 Reconstructive Surgery

Three-dimensional CAD/CAM reconstruction of the iliac bone following DCIA composite flap harvest

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Abstract. This article reports a new technique to restore iliac bone integrity with a customized titanium device designed by CAD/CAM, in patients undergoing deep circumflex iliac artery (DCIA) composite flap harvest. Eight consecutive patients who underwent the repair of major head and neck defects with DCIA flaps were enrolled retrospectively. Computed tomography scans of the pelvis were obtained preoperatively. Starting from DICOM data, each personalized device was designed using modelling software and was finally made by additive manufacturing using a laser sintering machine. After surgery, the patients were followed up at 3-month intervals to evaluate the incidence of complications and the long-term outcome at the donor site. A subcutaneous seroma developed in one patient and an inguinal skin burn occurred in another. At a median follow-up of 12 months, the patients did not report pain, or any gait or sensory disturbance at the donor site. There was no occurrence of bulging, herniation, or instability or inflammation near the device for the entire follow-up duration. All patients were satisfied with the aesthetic result. In conclusion, reconstruction of the iliac bone with a customized device is safe and well tolerated. We recommend use of this device in patients deemed at high risk of herniation. Further studies are needed to confirm the stability of the device in the long term.

Key words: bone flap; deep circumflex iliac artery; bone; computer-aided design; computer-aided manufacturing; prosthetic device; donor site morbidity.

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Microsurgical reconstruction of the missing bone is the present standard of care for large skeletal defects. Bone-including composite defects of the head and neck are, however, a big challenge for the reconstructive surgeon, because of the limited available donor sources.

The external iliac artery vascular system is a reliable source of composite tissues for head and neck reconstruction¹. The harvest of iliac bone stock based on the deep circumflex iliac artery (DCIA) was first performed in the 1970s to treat mandibular bone defects² and was

later extended to the reconstruction of other bone defects. Unfortunately, the DCIA composite flap is associated with important short- and long-term complications at the donor site³.

Modifications of the DCIA flap harvesting technique have improved donor site

morbidity, but the technique remains challenging and potentially harmful to the patient⁴⁻⁷. The risk of hip instability depends on the site and amount of harvested bone⁸. Shifting the harvest site posteriorly protects the anterior superior iliac spine (ASIS) and reduces the functional disability caused by the detachment of the adductor muscles^{9,10}. However, a bone gap remains, together with a weakened lateral abdominal wall, especially when the internal oblique muscle (IOM) is included in the flap.

Mild to severe postoperative donor site complications are reported, mostly related to inadequate wound closure, especially when harvesting large bone and muscle components¹¹. The bone dead-space may cause haematoma, delayed healing, wound dehiscence, and infection¹². Early or late abdominal herniation is not uncommon and requires surgical treatment^{8,13}. An iliac bone fracture may be produced by mechanical overload of the weakened bone¹⁴. Painful neuropathies, gait disturbances, and deformities of the abdominal contour are among the late sequelae of the intervention¹⁵⁻¹⁷. The restoration of bone integrity at the donor site may reduce early and late complications, making the DCIA composite flap more acceptable to both patients and surgeons.

The aim of this study was to report on a new technique to restore iliac bone integrity using a customized titanium implant designed with computer-aided design and computer-aided manufacturing (CAD/CAM) technology.

Materials and methods

Study design and setting

This multi-centre retrospective cohort study was performed in the maxillofacial surgery units of Padua University Hospital (Padua, Italy) and “S. Anna” Hospital (Como, Italy). The Ethics Committee for Clinical Study (CESC) of the University Hospital of Padua, Italy, approved the study (protocol number 24435-AOP 1814, April 2019). All patients gave their written informed consent.

Patients

Consecutive subjects among a cohort of patients who underwent the repair of major head and neck defects with DCIA flaps were eligible for the study if they had undergone immediate reconstruction of the iliac bone defect with a customized titanium implant.

Data collection and variables

The clinical charts of the patients treated in the study units between February 2016 and December 2018 were reviewed. Relevant clinical data were extracted and entered into an electronic case report form. The following data were collected from the clinical charts: age, sex, reason for surgery, date of surgery, type of flap harvest, side of the flap harvest, size of the harvested bone, number of surgical drains, time to removal of the surgical drains, time until resuming assisted walking, time until resuming autonomous walking, length of stay, and intensity of pain at the donor site as determined using a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (unbearable pain).

CAD/CAM of titanium implants

Multidetector computed tomography (MDCT) of the pelvis was performed preoperatively. DICOM data from the MDCT were exported into Mimics Innovation Suite software (version 19 with updates; Materialise, Leuven, Belgium), providing a virtual three-dimensional (3D) template of the iliac crest. The CAD of each individualized iliac titanium implant was performed using Geomagic Freeform Plus software and a Phantom Desktop Haptic device (version 2016; 3D Systems Inc., Rock Hill, SC, USA). The first step of CAD consisted of the design and planning of the defect at the recipient site, followed by the creation of cutting guides for bone resection and iliac bone harvesting.

The titanium device was designed to accurately replace the missing iliac bone volume of each patient and to bridge the gap between the ASIS and the remaining iliac bone. The titanium device is made of an empty girder titanium framework that reduces the overall weight and allows the reinsertion of the abdominal wall and gluteal muscles. To increase the stability of the bone-device system, the retention titanium structures at the lower border of the device are coupled with a minimum of three screw-holes on the anterior and posterior margins (Fig. 1).

Each patient-specific device was made by additive manufacturing in fine-powder layers of titanium alloy (EOS Titanium Ti6AlV4) using a laser sintering machine (M270 EOS DMLS; Electro Optical Systems GmbH, Munich, Germany).

Surgery

Harvesting of the bone-containing DCIA flaps was performed as described elsewhere⁹. In brief, the ASIS was always spared and the bone was harvested 3 to 4 cm from it. If an independent skin island was needed for the reconstruction, it was harvested based on a single and sufficiently long muscle perforator originating from the DCIA pedicle and piercing the skin mostly at the level of the iliac tuberosity. The muscle perforator was located preoperatively by CT angiography or Doppler ultrasound and was confirmed intraoperatively to include the skin paddle for the chimeric DCIA flap, with or without the IOM component. The CAD/CAM surgical

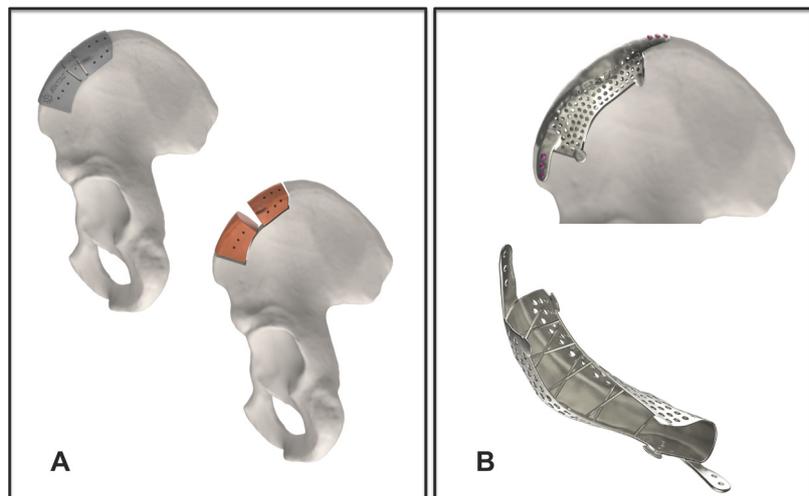


Fig. 1. Computer-aided design (CAD) of the iliac bone prosthesis. (A) 3D virtual model of the iliac bone with the cutting guide in place (upper image) and the remaining bone defect after osteotomy (lower image). (B) 3D lateral view of the iliac bone with the custom prosthesis in place exactly filling the bone defect (upper image). Multiple bone-anchoring titanium structures are used to increase the stability of the prosthetic device on the inner and outer cortices. Close-up view of the prosthetic device and its lightened framework (lower image).

guide was screwed to the stripped lateral surface of the iliac bone (Fig. 2A). The screw holes from the custom device were drilled and bone cuts were performed with an ultrasound scalpel. After the flap has been transferred to the recipient site, the customized titanium device was implanted and fixed with at least three 2.0-mm-diameter screws on the ASIS and the posterior iliac crest (Fig. 2B).

The iliac and gluteus medius muscles were reinserted on the inner and outer tables of the custom device, respectively, using 2-0 non-resorbable sutures. One or two suction drains were then inserted, and the transverse muscle and IOM were sutured back to the prosthesis to restore muscle integrity (Fig. 3). When a portion of the IOM was included in the flap, a non-resorbable polypropylene mesh was used to restore muscle integrity. The mesh was sutured back to the superior profile of the prosthesis laterally and to the remnants of the IOM superiorly, medially, and inferiorly. Lastly, the external oblique muscle (EOM) and the tensor fascia lata muscles were sutured back in place and staples were used to close the skin.

Postoperative follow-up

After surgery, all patients underwent X-rays of the iliac crest in the anteroposterior and lateral views. Pain intensity at the donor site was evaluated using a VAS at discharge and at each follow-up visit. Follow-up visits were performed after 1 month and every 3 months thereafter.

Main outcome

The aim of this study was to evaluate the safety of the new reconstruction technique in terms of the following: (1) incidence of perioperative and postoperative complications at the 1-month follow-up, and (2) functional and aesthetic results of the restoration of the iliac bone defect at the latest available follow-up. Patients were asked to judge the aesthetic result in the groin region in terms of scarring, symmetry of the pelvis, and overall abdominal contour, looking at themselves in a mirror. A scoring system with grading of 1–3 was used to define poor, satisfactory, and good results, respectively.

Statistical analysis

Most continuous variables were not in a Gaussian distribution, and all are reported as the median and interquartile range (IQR). Discrete variables are reported as the number of subjects with the

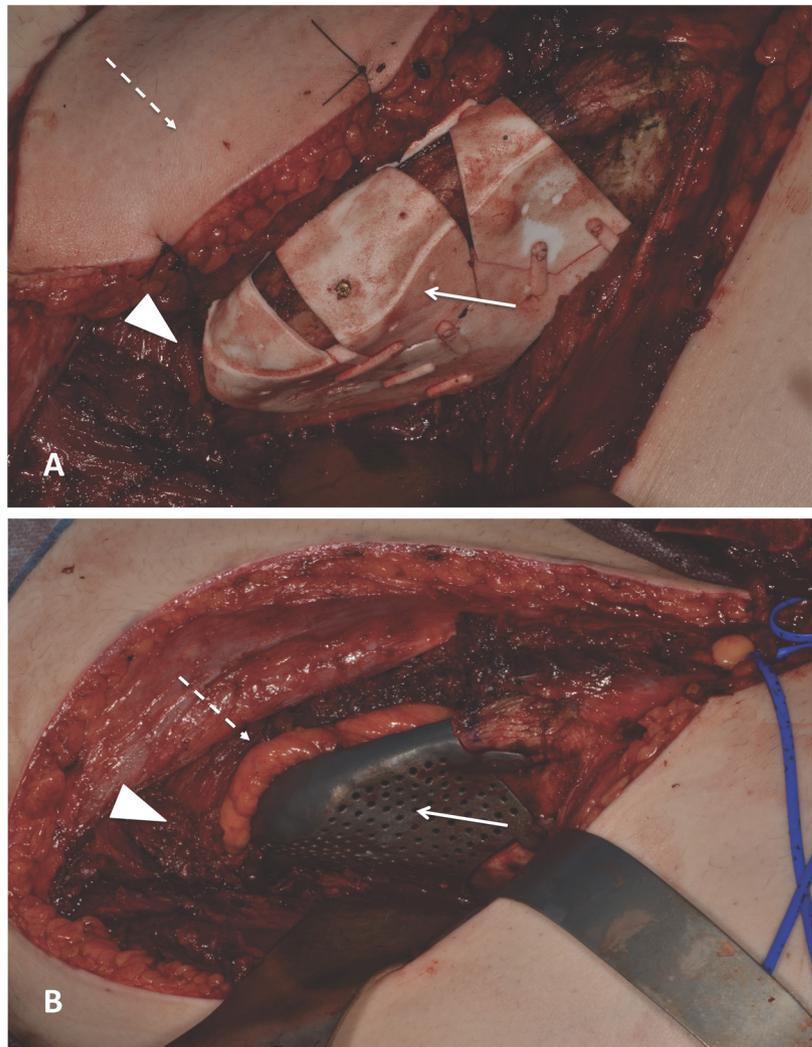


Fig. 2. Iliac bone reconstruction. (A) Intraoperative view of the iliac bone cutting guide in place (white arrow), with the anterior superior iliac spine displayed for reference (white arrowhead); the skin paddle of the chimeric DCIA is shown (dashed white arrow). (B) Insertion of the prosthesis is straightforward; the prosthesis exactly replaces the bone defect (white arrow) and forms a natural barrier against lateral herniation of the abdominal contents (dashed white arrow).

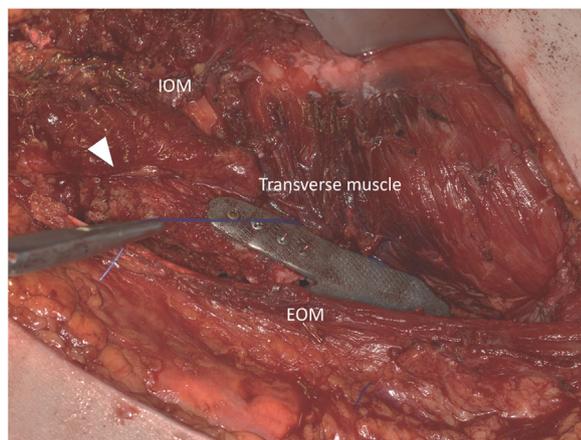


Fig. 3. Abdominal wall reconstruction. Reconstruction of the transverse muscle integrity to the customized prosthesis (inner side) with non-absorbable sutures, before reinforcement of the internal oblique muscle residual defect with polypropylene mesh and approximation of the gluteus medius, tensor fascia lata, and external oblique muscle. See the anterior superior iliac spine for reference (white arrowhead).

characteristic of interest. The statistical analysis was performed using Stata 15.1 (StataCorp, College Station, TX, USA).

Results

Patients

Table 1 reports the clinical features of the eight study patients. The median age of the patients was 38 years (IQR 21–66 years) and six of them were male.

Table 2 reports the features of the surgical interventions. Two patients underwent

Table 1. Clinical features of the patients.

	Total N = 8
Sex	
Female	2
Male	6
Age (years)	38 (21–66)
Underlying disease	
Ameloblastoma	2
Fibrous dysplasia	1
Gunshot injury	1
Odontogenic keratocyst	1
Oral squamous cell carcinoma	1
Sequelae of previous surgery and radiotherapy	2
Bone with defect	
Midface	5
Mandible	3
Side of defect	
Bilateral	2
Left	3
Right	3
Type of defect	
Body	2
Hemimandibulectomy defect	1
Midfacial type IIIb defect	4
Midfacial type IIa defect	1
Abdominal wall reconstruction with mesh	
No	2
Yes	6
Signs of complications after intervention	
No	8
Time to removal of iliac drain tube (days)	8 (7–10)
Time to resuming assisted mobility (days)	10 (8–10)
Time to recovery of independent walking (days)	30 (28–30)
Length of stay (days)	24 (20–29)

Continuous variables are reported as the median and interquartile range (IQR) and discrete variables are reported as the number of subjects with the characteristic of interest.

bilateral iliac crest reconstruction because of sequential DCIA flap harvesting, so surgical data were available for 10 interventions.

Perioperative donor site complications

A subcutaneous seroma developed in one patient when he restarted walking; the seroma was small and healed rapidly after needle aspiration and local compression. An inguinal skin burn following warm compress treatment occurred in one patient, which healed without sequelae. The median length of stay was 24 days (IQR 20–29 days). The median time to resuming assisted walking mobility was 10 days (IQR 8–10 days). Full recovery of walking was achieved at a median time of 30 days (IQR 28–30 days).

Postoperative donor site complications

The median postoperative pain score at the donor site recorded by VAS was 0 (IQR 0–1) at the 1-month follow-up. All of the patients were satisfied with the result of the reconstruction (Fig. 4).

At a median follow-up time of 12 months (IQR 4–23 months), the patients did not report any pain, or any gait or sensory disturbance at the donor site. No bulging or herniation occurred in any patient and no signs of instability of the iliac bone prosthesis or inflammation near the titanium implant were detected for the entire follow-up duration (Fig. 5).

Discussion

Computer-assisted surgery has recently emerged as a useful tool in head and neck reconstruction, and several CAD/CAM technologies are available to aid the reconstruction of the recipient site^{17–21}. CAD/CAM has, however, not yet been applied to restore the integrity of flap donor areas. This study introduces a novel use of CAD/CAM technology to help restore the integrity of the iliac bone after DCIA composite flap harvest. This study evaluated the safety of the implantation of the customized titanium prostheses designed by CAD/CAM after a median follow-up of 12 months.

Harvesting of the IOM, obesity, and a heavy smoking history have been identified as risk factors for acute or late hernia formation¹³. Reconstruction of the lateral abdominal wall is usually achieved by suspending muscles and using non-absorbable sutures and polypropylene mesh transfixed to the remaining iliac bone^{1,11}. In particular, the iliac and trans-

Table 2. Surgical features.

	Total N = 10
Flap	
Osseous	3
Osteocutaneous (chimeric)	1
Osteomyocutaneous (chimeric)	2
Osteo-muscular	4
Bone stock (mm)	
120 × 50	1
40 × 35	1
48 × 30	1
51 × 25.5	1
53 × 38	1
53 × 40	1
60 × 55	1
83 × 31	1
85 × 60	1
90 × 31	1
Donor site pain at 1-month follow-up (VAS)	0 (0–1)
Donor site short-term complications	
None	8
Seroma	1
Skin burn	1
Donor site treatment of short-term complications	
Dressing	1
None	8
Ointment and dressing	1
Follow-up of donor site (months)	12 (4–23)
Donor site late complications	
None	10
Donor site pain at last follow-up (VAS)	0 (0–0)
Donor site aesthetic judgement	
Satisfactory	1
Good	9

VAS, visual analogue scale. Continuous variables are reported as the median and interquartile range (IQR) and discrete variables are reported as the number of subjects with the characteristic of interest.

verse muscles are brought together and stitched with non-absorbable sutures, to prevent bowel obstruction and strangulation. Then, the IOM and EOM are reconstructed and transfixed to the iliac bone, without any attempt to restore the bone volume. Plating of the iliac bone defect has been proposed to reduce late complications⁵. This technique does provide extra support for muscle reattachment but cannot replace the missing bone volume and, in our experience, carries the risk of late bulging and herniation, similar to the standard approach.

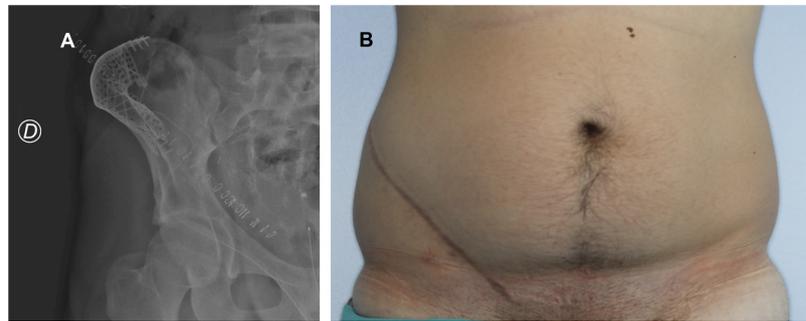


Fig. 4. Donor site. (A) Postoperative plain radiograph (postero-anterior projection) of the reconstructed iliac crest. (B) Donor site 1 year after surgery in the same patient: there are no signs of abdominal bulging and the abdominal wall contour is acceptable as compared with the contralateral untreated side.

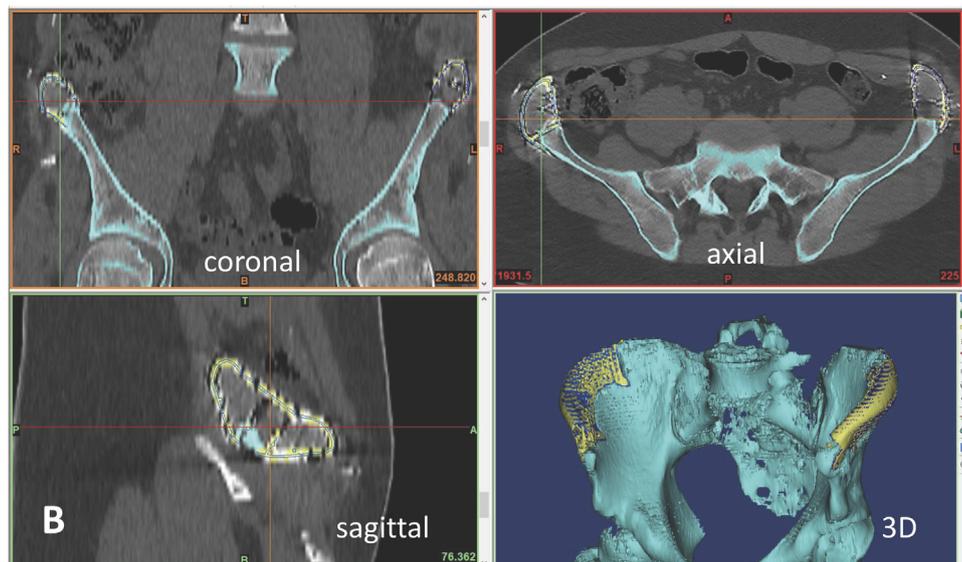
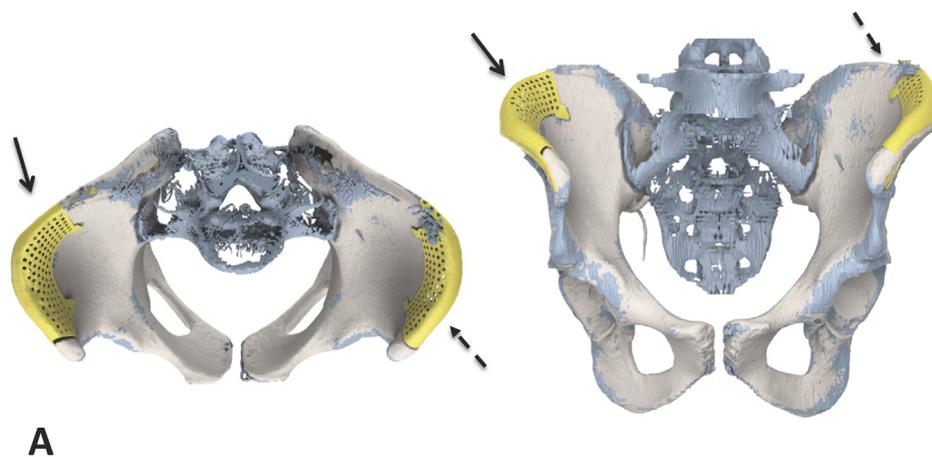


Fig. 5. Long-term 3D imaging of the reconstructed iliac bone. (A) 3D reformatted images from the STL file of a bilateral iliac bone reconstruction, 24 months (black arrow) and 12 months (dotted black arrow) following sequential DCIA flap harvest. (B) Superimposition of preoperative and long-term postoperative CT scans showing stability of the construct on both sides. The final positions of the prostheses (blue line) resemble those of the planned reconstructions (yellow line) (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

The CAD/CAM-aided replacement of iliac bone volume has several advantages over the standard technique of abdominal wall reconstruction. First, the customized bone prosthesis provides an excellent anatomical barrier against lateral herniation of the bowel, impeding its obstruction and strangulation. Second, it greatly increases the strength of the lateral abdominal wall and avoids late herniations and chronic pain due to increased wall weakness. Third, it prevents iliac bone fracture and ASIS detachment, which may happen because of mechanical overload of the weakened bone framework¹⁴.

A potential limitation of CAD/CAM to aid the replacement of iliac bone volume is the added cost, especially for national health systems. It is possible, however, that the concurrent use of CAD/CAM to aid surgery both at the recipient and donor sites in the same patient will allow a favourable cost-benefit ratio.

In conclusion, reconstruction of the iliac bone with a customized titanium device is safe and well tolerated. We have shown that this technique can improve donor site morbidity and make the use of the DCIA composite flap more reliable. At present, we would recommend its use in patients deemed at high risk of herniation. Further studies are needed to confirm the stability of the device in the long term.

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Competing interests

The authors declare that they have no competing interests.

Ethical approval

The Ethics Committee for Clinical Study (CESC) of the University Hospital of Padua, Italy, approved the study (protocol number 24435 -AOP 1814, April 2019). All patients gave their written informed consent.

Patient consent

Written patient consent was obtained to publish the clinical photographs.

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