TITLE	Anatomical feasibility of an off-the-shelf scalloped stent-graft for infrarenal abdominal aneurysm with a hostile neck (ReSTHoNe study)
PARTECIPATING CENTERS AND INVESTIGATORS	Coordinator centre: AOU di Modena, Main investigator Prof. Roberto Silingardi (UNIMORE). Other investigators: Stefano Gennai, MD (AOU), Giuseppe Saitta, MD (AOU), Francesco Andreoli, MD (UNIBO), Mattia Migliari, MD (UNIBO), Francesca Rossi, MD (UNIBO) and Nicola Leone, MD (UNIBO).
RATIONAL	Endovascular aneurysm repair (EVAR) is currently accepted as the preferred choice to treat the abdominal aortic aneurysms (AAA) with a feasible anatomy[1,2]. Although approximately 40-60% of AAA patients are not considered anatomically feasible for EVAR, mainly in reason of a "hostile neck anatomy"[3–5]. In ''real-world'' clinical practice, up to 44% of EVAR cases are performed outside Instruction For Use (IFU) for adverse neck anatomy[6]. The off-label use of standard EVAR is currently used for patients who are not eligible for OR, with acceptable short- and mid-term outcomes, but the long-term durability of EVAR depends on the maintenance of the seal between the endograft and the aortic neck as well as the iliac arteries[7]. Some aortic neck characteristics contribute in the definition of ''hostile neck,'' particularly length shorter than 15

	mm and angulation among others[8]. From a recent Consensus Conference, the influence of each characteristic on early or late EVAR failure is not clear, but hostile neck morphology is generally associated with higher rates of aneurysm-related adverse events and mortality[9]. A recent independent Expert Panel, applying the Delphi methodology Indeed, agreed to define 10 mm as the threshold value below which standard EVAR should not be considered feasible[9]. Moreover, the same experts agreed on the fact that an angulation above 60° is considered a hostile criterion for EVAR procedure. Finally should be considered that some "hostility" factors can be present at the same time and creating the ideal condition for EVAR failure[9]. The issue linked to the anatomical not feasibility of standard EVAR in patients not eligible for OR can be solved with custom made devices (CMD), but they were limited by high production costs and long time for creations (10-12 weeks)[10]. Nowadays no one off-the-shelf device aimed to overcome neck hostility in AAA is available on the market. The present study aims at evaluating the anatomical applicability of an off-the-shelf scalloped stent-graft (Treovance, Terumo Aortic) to treat infrarenal AAA with a short and/or angulated neck.
Schedule	Step 1: Ex-Vivo phase - Step 1.0: Protocol proposal and CE approval - Step 1.1: CTA measurement - Step 1.2: CTA data analysis - Step 1.3: Models fitness evaluation

	- Step 1.4: Preliminary publication and endograft production
STUDY DESIGN	Step 1-Single center retrospective observational study on the anatomical applicability in the coordinator center of an off-the-shelf scalloped device to treat infrarenal AAA with short and/or angulated neck.
EX VIVO AND IN VIVO TREATMENT	Step 1: All patients affected by AAAs and electively treated with EVAR or OR in the Vascular Surgery Unit of Modena e Reggio Emilia from 2010 to 2020 were considered eligible for the ex-vivo feasibility study. Preoperative contrast-enhanced computed tomography scans (CTAs) were independently reviewed by 2 vascular surgeons (investigators) experienced in the planning of aortic procedures using a dedicated workstation with dedicated vascular software (EndoSize, Thereva). Multiplanar and curved reconstructions of each CTA were used to assess the required measurements. In addition to standard measurement taken to plan an EVAR procedure the center-lumen-line distance from the inferior margin of the upper renal artery to the inferior margin of the lower renal artery was taken in order to estimate the gain of neck length permitted with the scallop. An inter-examiner or intra-examiner error of 5% was accepted. In case of a variation >5%, a third investigator of the study would in- dependently reanalyze the CTA. To study the suitability of the device, 2 different endograft models were constructed and fitted in the CTA-based

	measurements made as described to evaluate the anatomical feasibility of these models.
INCLUSION CRITERIA	Step 1: - Patients Electively treated with EVAR or AAA at the coordinator center - Age >18 -Both sex -Preoperative 2.5mm CTA available -Written informed consent.
SAMPLE SIZE	Step 1: No statistical analysis of the sample size was carried out. Considering the number of AAA treated in the coordinator center each year and analyzing a time interval of 10 years a sample size of 1000 CTA was estimated. This number should be sufficient to carry out the anatomical feasibility analysis.
OUTCOMES/ENDPOINTS	Step 1 Outcome: Anatomical feasibility evaluation
STATISTICAL ANALYSIS	To study the suitability, 2 different endograft designs were constructed. The preoperative measurements were made according to a previously described methodology. The models were matched with each preoperative CTA measure in order to evaluate if they fit or not in the index patients. Continuous variables are expressed as mean, and standard deviation and

	differences were tested with the two-sided t-test or the Mann–Whitney U-test, if appropriate. Categorical variables are expressed as counts and percentages and the chi-square test or Fisher's exact test was used for analysis. All data were entered into the logistic regression model if they had a univariable P-value of <0.05. Data resulted significative in this model were put in a multivariate one. In the multivariable analyses, clinical factors or potential confounding variables were expressed as odds ratio with 95% confidence interval (CI). The goodness of fit of the logistic regression models has been assessed calculating the C-statistic.. The analysis was carried out using STATA 14.
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