1. TITLE

“Clinical effectiveness of an off-the-shelf single REnal Scalloped sTent-graft for HOstile NEck infrarenal abdominal aortic aneurysm: clinical pivotal trial.”.

NCT number ###

2. FUNDING

The study is physician-sponsored. The medical device to perform endovascular exclusion of the AAA will be provided by the national health system. The clinical workup, hospitalization, and operation costs will be delivered under the national health system without any additional cost compared to standard care. A specific insurance for the patients being part of the study will not be required.

3. STUDY STAFF

Principal Investigator (PI):

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PI will be responsible for funding. PI will supervise all clinical and research phases (enrollment, treatment, clinical follow-up, data collection, data analyses, validation of the results, and publication).

Investigators:

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Role: Validation of the results and publication. The Investigator will be part of the data monitoring committee.

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Role: protocol writing, clinical screening, enrollment, treatment, data collection, clinical follow-up, data analyses, and publication. The Investigator will be part of the data monitoring

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Role: protocol writing, clinical screening, enrollment, treatment, data collection, clinical follow-up, data analyses, and publication. The Investigator will be part of the data monitoring committee and the second data manager

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Role: protocol writing, clinical screening, enrollment, treatment, data collection, clinical follow-up, data analyses, and publication. The Investigator will be the first data manager.

4. BACKGROUND

Endovascular aneurysm repair (EVAR) is currently the preferred choice to treat the abdominal aortic aneurysms (AAA) with a feasible anatomy[1,2]. However, approximately 40-60% of AAA patients presented unfavorable characteristics for EVAR, mainly due to 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 an adverse neck anatomy[6]. Short (<15-mm), angulated (>60°), and wide (>28-mm) aortic necks are the main features concurring to the proximal HNA[6].

The recourse to standard EVAR is currently routine for patients who are not eligible for OR, with acceptable short- and mid-term outcomes, but the long-term durability of EVAR depends on maintaining proper sealing between the endograft and the aortic neck as well as the iliac arteries[7]. HNAs demonstrated worse results when compared to "favorable" ones in terms of technical success (94% vs. 98%) and type-Ia endoleak rate (10% vs. 2%).[6] The issue linked to an unfavorable anatomy can be addressed with more complex techniques, but these are limited by high production costs and considerable complexity. [8-9] .

TREO (Terumo Aortic, Inchinnan, Renfrewshire, UK; formerly Treovance, Bolton Medical, Sunrise, Fla) is a standard bifurcated, modular stent-graft that has shown compelling early- and mid-term results[10-11]. It seems clear that several physicians are still looking for a feasible solution for HNA patients to keep the complexity of the procedure comparable to standard EVAR while yielding improved results.

Moreover, there is a lack of publications addressing the issue of mismatched take-off of the renal arteries (RAs). This morphology seems to influence the sealing length and could justify

the introduction of dedicated devices. A recent study from our group currently under review for publication demonstrated that 25% of patients eligible for EVAR presented with mismatched RAs and that a dedicated device could improve sealing significantly. The study group sealing zone's length increased by about 25% when applying a hypothetical prototype with a single 10x10mm (wide x high) renal scallop. The same approach could be applied to the sealing surface with similar results.

The present study aims to evaluate the clinical effectiveness of an off-the-shelf standardized single renal scalloped stent-graft (Treo, Terumo Aortic) to treat infrarenal AAA. The final objective will be to employ the data obtained in this cohort for a future eventual development of an "off-the-shelf" device dedicated to patients with mismatched renal arteries. Such an endograft could keep the complexity of the procedure as similar as possible to standard EVAR while improving sealing.

5. STUDY AIM

BASIC RESEARCH

To evaluate the clinical effectiveness of EVAR with an “off-the-shelf” single-renal-scallop endograft (TREO, Terumo Aortic) in the treatment of AAA patients with mismatched renal arteries. These data will be used to evaluate the clinical advantages of the adoption of a dedicated device for this kind of patients. See the protocol below for methods.

CLINICAL STUDY

To assess the real-world, in-vivo, clinical effectiveness of the use of a single-renal scallop endograft to treat infrarenal AAA. The study population is subjects with infrarenal AAA eligible for EVAR, of both sexes, aged 18>years, and with mismatched renal arteries. The mismatch was defined by a distance between the takeoff of the two proper renal arteries $\geq$ of 10mm. The study group is intended for patients receiving EVAR with the pre-mentioned dedicated custom-made endograft (from now called Prototype). The clinical intervention will be performed in the study participating centers and for our competence at the Unit of Vascular Surgery (Ospedale Civile di Baggiovara, Azienda Ospedaliero-Universitaria di Modena, Via Pietro Giardini, 1355, 41126 Baggiovara MO, Italy).

Expected results and risk/benefit considerations

The results will demonstrate whether the “Prototype” is effective for the treatment of AAA with mismatched RAs. The effectiveness will be evaluated in terms of technical and clinical

success. Other objectives are the evaluation of procedure-related adverse events and re-interventions, as well as operative details.

The use of fenestrated and branched endograft has already been demonstrated to be safe and feasible for the treatment of HNA AAA[13-14]. However, the complexity of the repair, the high costs, and the significant risk of renal and neurological injury limited the widespread of these techniques[8,9, 15]. On the other hand, standard EVAR has been used in HNA AAA with acceptable results in short- and mid-term period[11-12]. The actual challenge is to improve the outcomes of patients with unfavorable anatomy for standard EVAR keeping the complexity as low as possible.

Literature evaluating the mismatch of renal arteries in AAA patients is lacking and a recent study carried out in our unit demonstrated that about one-third of these presented an infrarenal distance of more than 10mm. These particular anatomical characteristics seem to influence the length of sealing and justify the evaluation of a dedicated device.

The benefits could be relevant for the patients in terms of reduction of procedure-related adverse events such as endoleaks and related re-interventions. Furthermore, the use of custom-made standardized devices could produce a significant reduction in costs for health care providers and in the feature, it could be the base for an “off-the-shelf” endograft. Procedure-related complications were expected to be similar to standard EVAR and reduced in comparison with literature reporting adverse events in more complex techniques. To confirm this forecast all adverse events will be reported in our CRF and prospectively monitored. Moreover, complications directly imputable to device defects will be promptly communicated to the regulatory authority and managed following law dispositions.

6. STUDY DESIGN

This study is a multi-center non-randomized prospective observational post-marketing cohort study. The cohort of patients will be followed up for a minimum of 5 years after the treatment. The study aimed to test the EVAR with the “prototype” device in mismatched renal arteries AAA.

Inclusion/exclusion criteria were reported above.

7. **METHODS**

Setting

Patients affected by AAA with an inter-renal distance ≥ 10mm and eligible for EVAR within standard TREO (Terumo Aortic) IFU will be prospectively enrolled at the Unit of Vascular Surgery of the Ospedale Civile di Baggiovara (Azienda Ospedaliero-Universitaria di Modena) and in the participating centers. The Investigators (3 experts Vascular surgeons9 will screen the patients for inclusion. Once the patient's eligibility will be stated, informed consent will be collected and the study could take place.

Inclusion criteria:

- Patients affected by infrarenal AAA ≥ 50mm
- Treated in election for non-symptomatic AAA
- Anatomy inside Treo (Terumo Aortic) instruction to use (IFU)
- Distance between renal arteries ≥10mm on aortic center-lumen-line
- Age ≥ 18
- Patient fit to plead
- Both sex
- Written informed consent
- Treated in the coordinator center or in one of the study's participating centers
- Minimum follow-up requested: 3-months, 12-18 months and 5-years CTA; clinical and DUS examination at 6- and 12- and 36-months after the intervention and yearly thereafter

Exclusion criteria:

- Patients with aortic pathologies different from AAA (aortic ulcers, dissection, pseudo-aneurysm etc)
- Treated in urgent/emergent setting for symptomatic or ruptured AAA
- AAA < 50mm
- Outside TREO (Terumo Aortic) IFU
- With an inter-renal distance measured of the center-lumen-line <10mm
- Age <18
- Unfit to plead
- Refused to sign the informed consent
- Treated outside the coordinator centers or in one of the study's participating center's
- Refusal to adhere to the requested follow-up

Device description

TREO (Terumo Aortic) was described in different papers.[100-11] It is a tri-modular device composed of self-expanding nitinol Z-stents sutured to woven polyester graft fabric. The stent-graft has a proximal bare stent with each edge presenting barbs. The second row of barbs is placed at the external surface of the proximal edge of the fabric. The barbs are nitinol, caudally-directed, sealing adjuncts promoting a better fixation.

The Manufacturer allows customization of the standard design. The investigational endograft was ideated with a single renal scallop (10x10-mm and 15x10-mm, height and width,

respectively). Three highly visible platinum-Iridium markers were placed around the fenestration to improve visibility and precision during deployment. The clock position of the scallop should be at 15 o'clock (45° on anteroposterior view). The remaining design characteristics and delivery systems features

Pre-operative work-up

The subjects will undergo a complete clinical examination, including pathological and pharmacological anamnesis. A complete doppler ultrasound examination will be performed before admission to the ward.

High-quality CTA scans (6th rib to groin spanning and 1-mm slice thickness) not older than 6 months from the scheduled intervention is mandatory for every included patient.

The mentioned CTA will be carefully evaluated independently by two vascular surgeon experts in endovascular aortic procedures. Multiplanar and curved reconstructions were obtained for each CTA in a dedicated workstation plugged with Therenva Endosize reconstruction software (Therenva, Rennes, France). All the measures were based on the orthogonal centerline reconstruction.

The aortic measurements taken were reported above:

- Diameters – measured intima-intima. The measures were taken at different levels: the inferior edge of the upper RA's ostium (D1), the inferior edge of the lower RA's ostium (D2), and the distal end of the proximal sealing zone (D3);
- Lengths – measured with the lower edge of the RA as reference. Polar RAs were assumed as "proper renal" if the diameter was >4mm; if not, they were ignored. do not differ from the standard TREO. Infra-renal (L1) was the length between the lower RA and the distal end of the proximal sealing zone. Inter-renal length (IRL; L2) was

the distance between renal arteries' lower limits. L3 resulted by coupling L1 and L2 and represented the hypothetical sealing length available in patients suitable for investigational devices.

- Angulations – Alpha angle (or suprarenal) was the inflection point between the neck and suprarenal aortic axes. Beta angle (or infra-renal) was the inflection point between the neck axis and the aortic sac axis.

All the measurements were used to plan the interventions and to engineer the proper "prototype" device. The device description and characteristics were detailed above.

All supra-mentioned data were collected in a dedicated eCRF.

According to our standard clinical practice all the patients were admitted to ward the evening before surgery day to exclude possible acuity.

Surgical procedure

All the procedure were carried out in a standard operating room equipped with a mobile C-Arm, or in a Hybrid theater under local sedation or general anesthesia on the basis of comorbidity and/or surgeon preference. A bilateral percutaneous access was obtained, even if based on the specific case a cut-down and contralateral percutaneous access is possible. Hemostasis was achieved using the Proglide/Prostyle (Abbott Vascular, Abbott Park, IL, USA) if percutaneous access was used. Intraoperative heparin dosing varied by the center. However, generally, heparin was administered to maintain an activated clotting time > 250 seconds, when possible.

Techniques for delivery and deployment of the standard device have been well described by different papers[10-12], but for the "prototype" some attention is required.

Once the device was advanced at the level of the lowest RA the C-Arm has been moved to correct the parallax effect and positioned orthogonally to the origin of the artery. This procedure permits perfectly matching the scallop with the artery takeoff.

A selective angiogram was performed to assure the patency of the lower RA.

After the deployment of the main body proper iliac extensions were delivered to completely exclude the aneurysm as standard practice.

The complete exclusion of the AAA was checked with a final angiography and then all devices were removed. Heparin was antagonized with the appropriate dose of protamine and access was closed.

According to our standard of care, patients are discharged on the second postoperative day on either aspirin or clopidogrel, if not already on one of these medications.

Follow-up

The first clinical evaluation (before surgery) was performed before discharge primarily to check the femoral access. All the patients will be assessed clinically and with a high-quality CTA (from 6^{th} rib to groin) within 3 months from surgery and yearly for 5 years thereafter for a total of seven evaluations. All the visits will be performed by Investigators.

The patients will be followed up via telephone call to strictly adhere to the present scheme. A telephone number of the Vascular Surgery Unit will be daily available for any patient's clinical issue during the study period. The clinical and radiological follow-up will continue regularly as a standard practice also in case of patients' voluntary withdrawal.

Endpoints

Primary endpoint: Clinical effectiveness measured in terms of technical and clinical success. Technical success was defined as defined on an intent-to-treat basis and requires the successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or III endoleaks, or graft limb obstruction. A technical success thus implies the following qualifying details: 1. Successful access to the arterial system using a remote site (ie, the femoral, external iliac, common iliac, or brachiocephalic arteries with or without the use of a temporary or permanent prosthetic conduit to access these arteries); 2. successful deployment of the endoluminal graft with secure proximal and distal fixation; 3. absence of either a type I or III endoleak; 4. patent endoluminal graft without significant twist, kinks, or obstruction (>30% luminal stenosis or a pressure gradient >10 mm Hg) by intraoperative measurements; 5 patency of both renal arteries and at least one hypogastric artery. Primary technical success can include the use of additional modular components, stents, angioplasty, and adjunctive surgical procedures. However, if unplanned endovascular or surgical procedures are necessitated it must be noted.

Clinical success requires the successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I or III endoleak, graft infection or thrombosis, aneurysm expansion (diameter >5 mm, or volume >5%), aneurysm rupture, or conversion to open repair, occlusion of the renal arteries. The clinical success was measured at every follow-up interval. Any additional maneuvers, planned or unplanned, aimed to maintain clinical success must be carefully reported.

Secondary endpoints:

- Evaluation of the intra-operative and peri-operative (within 30 days) adverse events

- Collection of eventual adverse events related to the treatment procedure and eventual post-hoc analysis
- Evaluation of reintervention (time elapsed since index operation, type, and indication);
- Evaluation of potential risk factors (baseline, anatomical features, procedural technique) potentially related to adverse events
- Evaluation of the main procedural and fluoroscopy time, evaluation of the average contrast medium (CM) dose as well as Dose Area Product (DAP) (mGym3).

Adverse events are defined as any systemic or local complication directly related to the procedure. Adverse events that occurred in the first 30-day were considered procedure-related, unless differently demonstrated.

Any surgical, open, or endovascular, procedure aimed to address adverse events was named re-intervention.

The secondary endpoints represent specific technical aspects related to the procedure and the endograft.

Treatment-related adverse events and re-interventions are important to state the safety of the procedure over time and its external reproducibility.

The procedure and fluoroscopy time, as well as the contrast-medium dose, will be used to evaluate the complexity of the procedure, comparing it with the same reported in the literature for standard EVAR.

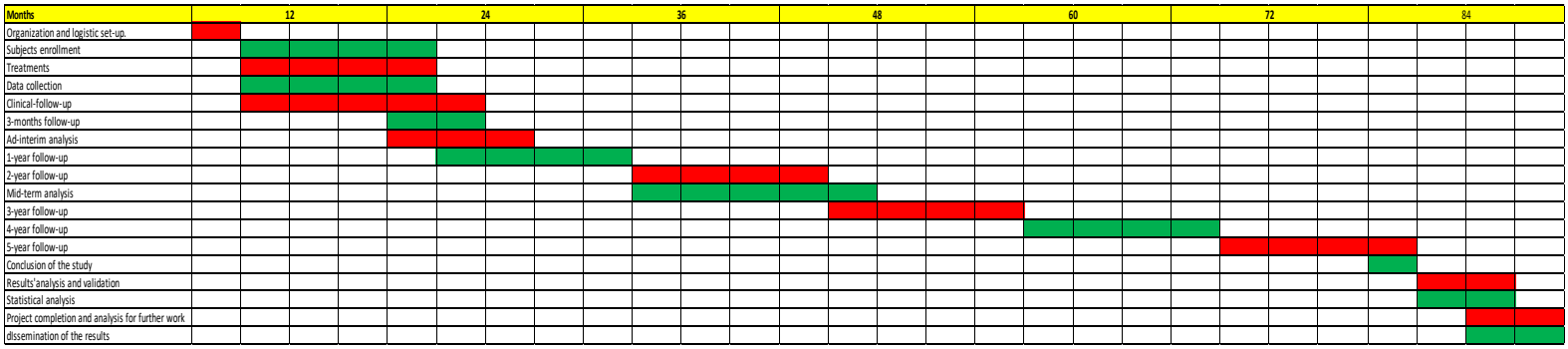
Timeline

Months 1-3	Organization and logistic set-up.
Months 3-15	Subjects enrollment, data collection, treatments, clinical follow-up.

Months 15-18 Conclusion of recruitment, first (3 months) follow-up end for every patient, ad-interim analysis

Month 27-39 2-year follow-up end, mid-term analysis

Month 63-75 Conclusion of the follow-up, analysis of the results and their validation, statistical analysis, project completion and analysis for further work, dissemination of the results



Gannt chart:

Sample size

No statistical analysis of the sample size was carried out. Considering the number of AAA responding to the inclusion criteria treated in the participating centers and the enrollment period (1 year) a sample size of 50 patients was estimated. This number should be sufficient to evaluate the endpoints reported in the appropriate section.

The estimated number of patients recruited for the present center is 15 patients

Recruitment

All the involved centers represent the third referral level of complex Abdominal Aortic Aneurysms.

For what concerns our center all patients affected by AAA responding criteria for treatment were evaluated at the Vascular Surgery Unit of the Azienda Ospedaliero Universitaria di Modena. Those meeting the inclusion criteria will be singularly recruited.

Taking into account a mean of 120 endovascular procedures on the abdominal aortic and 10 complex procedures with custom-made devices, a safety 12-month recruitment should be considered. The entire Medical staff of the department is informed about the present project and will refer the potential subjects to the Investigators.

8. MANAGEMENT OF THE DATA

The collected data will be managed into a dedicated electronic case report form (CRF). The CRFs will be stored on a dedicated and validated website. Only the Investigators will have access to the data with a personal password. Only the PI and the first data manager will be able to see all the data, while the other investigators will have permission to manage only the data of the patients enrolled in their center.

To ensure the correct data collection two Investigators will perform the clinical and radiological assessment at each follow-up visit. Before the conclusion of the visit, a double-check will be performed by the Investigators. The CRF will be completed at the time of enrollment and each follow-up visit thereafter. The CRF required data are declared below.

A personal code will be generated at the enrollment. The CRF will be filled anonymously. The following anamnestic data: age, sex, comorbidities (hypertension, cardiopathy, hyperlipidemia, peripheral arterial disease, previous surgery, etc). Procedure planning details were detailed previously. The procedure details: planned and unplanned adjunctive procedure, the adverse events, the skin-to-skin time, the fluoroscopy time and DAP, the type of anesthesia, the dose, and characteristics of CM used. Primary and secondary endpoints will be registered as defined previously.

The following indicators will also be collected: time of recovery from the intervention and the number of an hour passed in the Intensive Care Unit if needed.

In case of the patient's voluntary withdrawal, the CRF will be discontinued. The patient will undergo standard clinical practice follow-up.

In case of device-related adverse-events, a detailed description of the event will be performed to inform the regulatory authority. The clinical follow-up and the CRF proceed as stated.

In case of death, the study personnel will investigate the cause and any eventual relation with the treatment or device will be declared to the regulatory authority and carefully reported on the eCRF.

Statistical methods

Continuous variables will be expressed as mean, andstandard deviation, and differences tested with the two-sided t-test or the Mann–Whitney U-test, if appropriate. Categorical variables will be expressed as counts and percentages and the chi-square test or Fisher's exact test will be used for analysis. All data will be entered into the logistic regression model if they had a univariable P-value of <0.05. Data resulting significative in this model will be put in a multivariate one. In the multivariable analyses, clinical factors or potential confounding variables will be expressed as odds ratios with 95% confidence interval (CI). The goodness of fit of the logistic regression models will have been assessed by calculating the C-statistic. Survival analysis and freedom from adverse events will be assessed through the Kaplan-Meier analysis with their relative 95% CI. A P-value< 0.05 defined the statistical significance The analysis was carried out using STATA 15.1 (StataCorp College Station, Texas, USA).

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9. MONITORING

The monitoring committee will be composed of Investigators. The PI will supervise the committee. The committee will monthly revise the data until the end of the study. The committee will collectively resolve any issues related to the data collection.

The committee will produce ad interim analyses. Eventual adverse events (mild and/or severe) will be internally investigated by the monitoring committee and externally communicated according to the local regulatory authority disposition. The auditing process will be independent.

The study will be stopped in case of early signs of arm. The PI will decide on the early interruption. The PI will communicate the decision within 15-day as the local regulatory authority advise (DM 21.12.2007). The interruption will be conducted under the local regulatory authority.

The Investigators will diffuse the data even in case of early interruption.

10. ETHICAL ASPECTS AND DISSEMINATION

The study will be registered on Clinicaltrial.gov and conducted under the principles of the Helsinki Declaration and the Local Ethics Committee approval (CE AVEN, Comitato Etico dell'Area Vasta Emilia-Nord). The Investigators will promptly communicate to the CE AVEN any changes to the present protocol. The CE AVEN will decide on ad-interim modification. The patients' enrollment will require informed consent collection. The consent could be provided by a legal guardian. The Investigators will be responsible for the signed document collection. The informed consent will specify the possibility to be treated with the investigational device, basic research analyses, and clinical follow-up adherence. The procedures will be delivered in an eligible setting. So, emergent patients are not the object of the present investigation. The study data will be managed anonymously. Only the Investigators will have access to the data. The electronically gathered data will be depersonalized aiming for anonymous analysis and interpretation. All Investigators have no disclosure to declare. All Investigators will have access to the final database as well as the regulatory authorities on reasonable request. The study will not provide specific insurance. The eventual clinical complications will be managed under national health insurance. Results of the study will be disseminated by scientific publications, congress presentations, and medical meetings. The dissemination will proceed to the general audience through general journals, and hospital and university websites. The dissemination will be anonymous. Publication costs are not expected to exceed 3000 euros. The authorship will be defined by the PI based on each publication. The Investigators will be

included among the authors of the scientific publications. Medical writer, it is not expected.

The dataset will be shared in a data repository according to the journal's requirements for publication.

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