Description of the CAD-AM Process for 3D Bone Printing: The Case Study of a Flat Foot

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Abstract

This work is focused on the study of 3D prints applied in the orthopedic-pediatric field. The focus is therefore on all the processes that lead to obtaining 3D bone printing starting from the three-dimensional digital CAD model. Specifically, the case study concerns patients with flat foot pathology from tarsal synostosis. The final result of the printing process is a three-dimensional bone model reflecting the original anatomical structure. This is a useful tool for surgeons who can carry out a preventive analytical evaluation of the relative intervention methods. 3D printing can be useful both in the preoperative planning phase and during the operation. Depending on the case, it may be more convenient to use one material than another. For this reason, another goal set by this work concerns the study of materials used for 3D printing of bones.

Keywords

3D Printing; Pediatric Orthopedics; surgery; diagnostics

1. Introduction

This work is the outcome of a partnership between the Department of Industrial Engineering of the University of Bologna and the Rizzoli Orthopedic Institute of Bologna.
The aim of this collaboration is using medical engineering tools during orthopedic surgeries.
In order to get engineering technical skills in CAD-AM Process for 3D Bone Printing it will be described the case study concerning patients with flat foot pathology from tarsal synostosis (Caligiana, G. *et all, CAD-CAM integration for 3D hybrid manufacturing;* James B. Carr II *et all, "Pediatric Pes Planus: A State-of-the-Art Review "*).
As final outcome we'll see the importance of having a 3D model of a bone both in pre-operative phase and during surgery.
In fact, a surgeon can only view a piece of bone corresponding to the part to be operated.
Having the reproduction of the entire bone allows an overall assessment of the effects of the operation.
So the usefulness of the application will be the repeatability in the preoperative phase of the result of a surgeon (Auricchio F, *et all*, *3D printing: clinical applications in orthopaedics and traumatology*).

2. Materials and Methods

2.1 Clinical case

The flat foot is an anatomical malformation indicated by an evident leveling, total or partial, of the medial plantar vault. In the first phase of walking, up to 3 years of age, the condition is completely normal and is part of the physiological growth of the foot. After 3 years, failure to form a normal plant vault is necessary to act to favor maturation, such as using a plant. Surgery is necessary when, after 8-9 years of age, there is still a relevant form of flat foot and the child manifests painful disorders such as to prevent him from walking carefully. A particular case is the flat foot congenital by tarsal synostosis which occurs with an incidence of about 1% of the population and is bilateral in 50% of cases. Tarsal synostosis is a connection bar between two or more bones of the foot which can be bone, cartilaginous or fibrous in nature (Docquier PL *et all, "Surgical navigation in paediatric orthopaedics*"; G. Ippolito *et all, "Il piede* *piatto congenito da sinostosi tarsali, controllo a lunga distanza di 10 casi trattati chirurgicamente*"; A. Pellegrino, "*Chirurgia del piede e della caviglia. Testo informativo per i pazienti";* R. Gindro, *"TAC, mezzo di contrasto, rischi e altre domande frequenti"*). Clinically managed as a flat foot but they differ in an important rigidity with almost complete blocking of the rotation movements of the foot accompanied by an important painful symptomatology. The presence of synostosis is the most frequent cause of painful rigid flat feet (Figure 1).

Figure 1. Difference between normal and flat feet

2.2 From CT to 3D Digital Model

The first step concerns the conversion of tomographic images into a three-dimensional model.
The program used is *Invesalius*, a medical software that generates virtual reconstructions of structures of the human body. The first operation to be performed in *InVesalius* is importing a DICOM (Digital Imaging and Communications in Medicine) format file. Following the import, the software allows to visualize the biological structure of interest in the three main axes of the human body (Osti, Francesco *et all*, *CT Conversion Workflow for Intraoperative Usage of Bony Models: From DICOM Data to 3D Printed Model*; M. Cameron, *"Process to Convert DICOM Data to 3D Printable STL Files"*). By setting the density range, the software highlights a specific region and creates its three-dimensional model, consequently eliminating the anatomical parts not included in the range considered. Masks with predefined density ranges can be chosen (for example: compact bone, spongy bone, skin, muscle tissue) or the density range can be changed manually.
In the particular case of the foot, a predefined density value is initially used for the overall 3D reconstruction. It's necessary to change the density value to edit the complex geometries of cuneiform bones, metatarsal bones and phalanges. This procedure is essential in order to simplify the subsequent use of mesh repairing software. In fact, in these areas, the holes and segmentation errors are significant and the automatic mesh repairing algorithms could not repair the mesh in a consistent way (Figure 2 and 3).

Figure 2. Segmentation errors in the cuneiform bones of a child foot

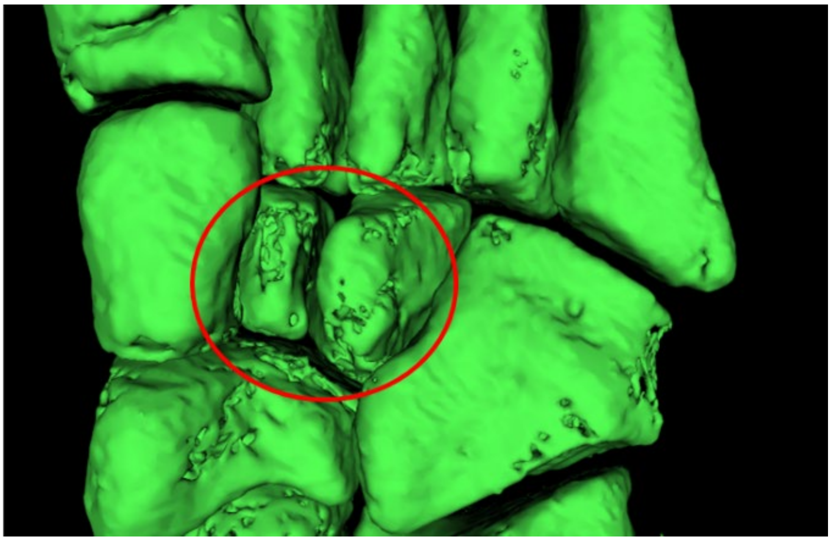

Figure 3. Holes in the mesh in the cuneiform bones of a child foot

With *Invesalius*, three-dimensional surfaces are generated, called meshes in STL (Standard Triangulation Language) format that offer a geometric model, not a mass one. Any mesh irregularities can be corrected through the use of graphics software such as *MeshLab* that provides a series of tools for cleaning, remodeling and remeshing the structure. The use of *MeshLab* is essential for the removal of material inside the object. Many faces of the mesh are, in fact, hidden, not visible externally and, therefore, to be eliminated in order to make the 3D surface hollow and, consequently, lighter.
However, the structure obtained had holes, cavities and, in general, imperfections. To remove further irregularities of the mesh another 3D modeling software called *Meshmixer* can be used. Finally, the optimized 3D digital model was exported in STL and OBJ format (Figure 4).

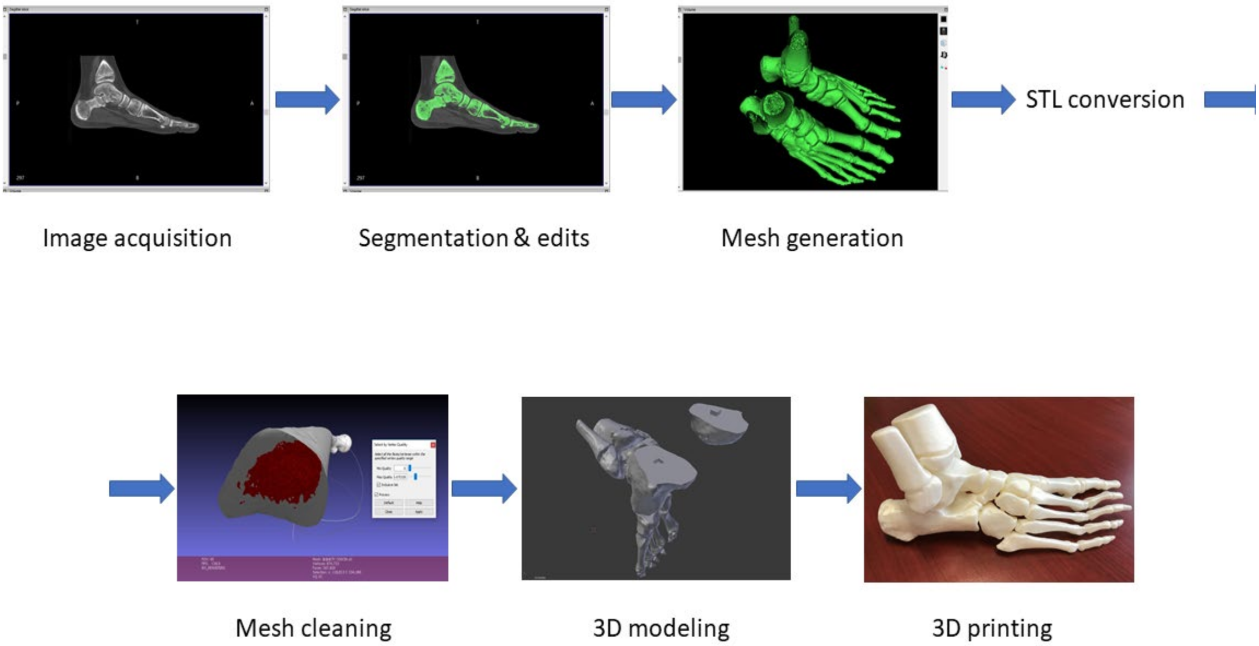

Figure 4. Steps to convert a 2D CT scan to the final 3D simulation

2.3 3D printing

The optimized model is ready for printing. The *Ultimaker Cura* slicer is used to switch from the visualization of the three-dimensional model to 3D printing. The models that must be produced within the printing area are displayed in the 3D environment of the software once the type of printer to be used has been defined. The printer used in the case in question is an EZT3D of the Delta type, that is, a 3D wire printer that uses fused deposition modeling - FDM as a printing system. This system has as extruder a heated nozzle which raises the temperature of the selected thermoplastic material before depositing it on the printing bed. The printer guarantees an excellent surface finish due to the low inertia between the moving parts. The nozzle diameter is 0.4 mm and the extrusion temperature is 180º. Heated bed is not required. Another relevant data is the print speed. The EZT3D Delta printer has a typical print speed of 20-80 mm / s and a maximum print speed of 90-100 mm / s, depending on the object to be printed (N. Bizzotto *et all*, "*Three-Dimensional Printing of Bone Fractures: A New Tangible Realistic Way for Preoperative Planning and Education*" ; K. C. Wong, "*3D-printed patient-specific applications in orthopedics*"). The material extruded from this printer model is in the form of filaments coiled to form a reel which is progressively unrolled during printing. The polymeric materials generally used for the creation of anatomical models are ABS, PLA and HT-PLA. These have different properties that inevitably influence their cost. ABS and PLA, which cost less than HT-PLA, are used in the pre-operative planning phase when the presence of the 3D model is not necessary in the operating room. The object, made of ABS or PLA, has good general characteristics: it has good mechanical strength and hardness, it is very light and smooth to the touch. The bone model obtained does not however resist high temperatures. It is not recommended to expose it to temperatures of 50 ° C, and already at 60 ° C it enters a glass transition.

The HT-PLA molded model requires complete annealing. The cooking phase takes place in a laboratory oven. The 3D printed model is heated for 30 minutes to 115º and remains at this temperature for an hour. Finally, it is cooled for 30 minutes. After annealing, the HTPLA model can withstand up to 140º. The use of HT-PLA is necessary in the case of models to be brought to the operating room for which a sterilization process is essential. HT-PLA is the only autoclavable material, therefore sterilizable at high temperatures. In the case examined, a steam heat was used, setting the temperature at 134º C and the total duration of the cycle at 60 minutes (Table 1).

Table 1. Material properties

Material	**Extrusion Temperature (ºC)**	**Cost (€/kg)**	**Autoclavable**
ABS	220-260	18	No
PLA	180-185	18	No
HT-PLA	200-250	100	Yes

3. Results

Following the printing of the bone model, the following problems are encountered.

The model of the foot to be printed has protrusions, cantilevered parts or complex ends. It is necessary to insert supports from the slicing program to hold the structure together during prototyping. Added media can be easily removed once the print job is complete. When there are many support structures with a very limited and fragile base, the head that deposits molten material can cause it to fall. Without a support, the deposited material does not have a base on which to rest and the print is compromised. In order to have a less limited base, it is useful, before printing, to separate the heel of the foot from the remaining part of the model. The insertion of cubes through Boolean operations allows the mechanical connection of the parts (Figure 5).

Figure 5. Example of supports in the foot print. The image shows the heel of the foot separated from the rest of the model.

The printed model is created one layer at a time: each subsequent layer is printed above the previous layer until the desired three-dimensional shape is created. However, to have a strong and reliable final part, it is necessary to ensure that each layer binds adequately to the underlying layer. If the layers do not join well enough, the final part can be divided or separated.

The table 2 and 3 show the calibration parameters. It is highlighted how these parameters can influence the finish of the printing surface. The extrusion of too much material could cause an excess of plastic which can ruin the external surface of the wall (Figure 6). Conversely, if the Infill parameter is assigned too low a value, gaps or holes can be noticed between the extrusions that make up the layers.

Figure 6. Blobs and zits on the external walls.

Table 2. Layer thickness calibration (extruder multiplier 100%; infill 15 %)

Layer Thinkness [mm]	**Printing Time [h:m]**	**Measured Error**
0.05	28 h and 28 min	0.23% ± 0.32%
0.1	15 h and 7 min	0.45% ± 0.15%
0.2	7 h and 37 min	0.68% ± 0.45%
0.3	4 h and 58 min	0.83% ± 0.52%

Table 3. Extruder Multiplier calibration (layer thickness 0.2 mm; infill 15%)

Extruder Percentage [%]	**Printing Time [h:m]**	**Type of Error**
90	7 h and 37 min	Weak Infill; Under-Extrusion; Gaps in Top Layers; Gaps Between Infill and Outline
100	7 h and 37 min	None
105	7 h and 37 min	Blobs and Zits; Over-Extrusion
110	7 h and 37 min	Blobs and Zits; Over-Extrusion; Curling or Rough Corners

3.1 Costs Analysis

The realization of the 3D model involves a series of expenses that depend on the cost of the printer, on the labor, on the material used for printing and on the software used (Leonardo Frizziero, *et all*, *Paediatric Orthopaedic Surgery with 3D Printing: Improvements and Cost Reduction*). The costs related to the realization of one of the foot models printed at DIN are summarized in the table 4, considering that:

• The cost of the Delta type EZT3D printer is 220 € and its useful life is supposed to be about 2000 hours of printing.
• The labor time needed to convert and clean the DICOM file is on average 4 hours.
• To date, a graduate student from DIN with a fee of € 20 / h is involved in the transformation.
• An average of 0.250 kg of material is required to print the one-foot model.
• The actual printing time to obtain the 3D model of a foot is on average 22 hours.
• The software used in the proposed procedure are all open source and downloadable online.

Table 4. Cost of a three-dimensional model

	Cost (€ / foot model)	**Cost (€ / foot model)**
Printer	2.42	2.42
Labor	80	80
Software	0	0
Material (ABS/PLA)	4.5	
Material (HT-PLA)		25
Total	86.92	107.42

4. Discussion

The work carried out allowed the realization of the model of a bone structure in HT-PLA which perfectly reflects the anatomical structure of the CT images. The model is a useful tool for surgeons by facilitating preoperative planning and subsequently helping to increase surgical precision and reduce operating times. This leads to an improvement in the clinical outcome, lower risks for the patient and reduced post-operative recovery times. The reduction in the timing of the intervention allows a lower use of anesthetic dose for the patient and subjects him to a lower risk of infections (HR Epps, "3D printing helps with complex hip surgery: pediatric orthopedists also find it useful for patient education "). Using 3D models in the pre-operative phase the surgeon proceeds with more confidence during the operation thanks to

the greater knowledge of the anatomy of the case. The specialist identifies synostosis more easily and can improve the orientation of the cut and the method of positioning the screws. All this leads to a reduction in the number of cases of recidivism. In the pre-operative phase, the material to be used can also be evaluated. This leads to a decrease in the material to be sterilized and a reduction in room costs.
The use of the 3D model allows a decrease in the patient's exposure time to X-rays. With the new procedure, the R.X. exam is not performed, and intra-operative irradiation is reduced thanks to less use of fluoroscopy. Table 5 summarizes the advantages of using 3D models.

Table 5. Advantages deriving from the use of 3D models

Benefits for the patient	Benefits for the surgeon	Benefits for the hospital company
✓ Lesser X-ray exposure ✓ Reduction duration of the intervention ✓ Anesthesia reduction ✓ Lesser risk of getting infections ✓ More awareness of the clinical condition ✓ Lower recurrence rate ✓ Reduction recovery time	✓ Better knowledge of the difficulties of the case ✓ Ability to choose tools before surgery ✓ Greater safety in the operating room ✓ Greater satisfaction	✓ Staff more satisfied ✓ Reduction of direct costs

A crucial point of the work carried out concerns the analysis of the economic impact due to the introduction of this technology in the traditional workflow. The production costs currently required for an autoclavable model are around € 110 / model. Overall, we can talk about relatively low costs, thanks to the use of open source software and low-cost 3D printers. Table 6 and Figure 7 summarize the improvement rates with the relative savings accumulated in one year for each procedure that benefits from the introduction of the three-dimensional model.

Table 6. Economic advantages deriving from the use of the 3D model

	Reduction with the use of the 3D model (%)	**Savings with the use of the 3D model (€ / year)**
Orthopedic visits	33,4	450
Radiological visits	50	525
Duration of intervention	25	5168,75
Recidivism	15	5111,82
Total	-	11238,07+20%(1) =13485,7

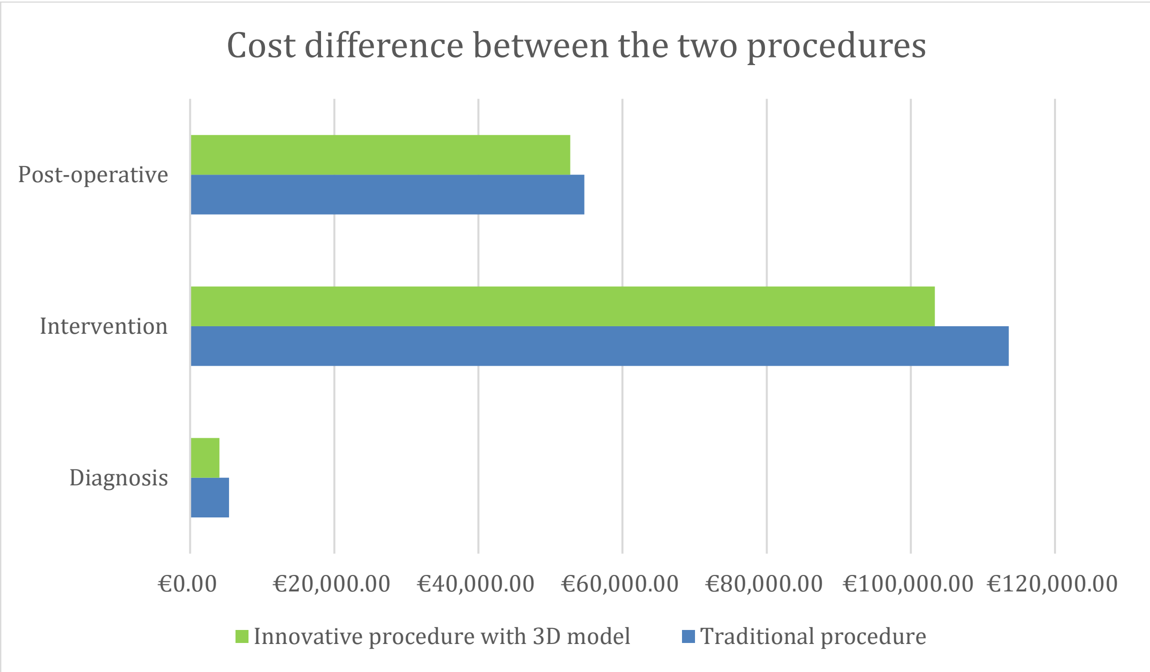

Figure 7. Cost difference chart between the two procedures

5. References

Caligiana, G.; Francia, D.; Liverani A.; *CAD-CAM integration for 3D hybrid manufactoring*. Lect. Notes Mech. Eng. 2017, 329-337.

Osti, Francesco; Santi, Gian; Neri, Marco; Liverani, Alfredo; Frizziero, Leonardo; Stilli, Stefano; Maredi, Elena; Zarantonello, Paola; Gallone, Giovanni; Stallone, Stefano; Trisolino, Giovanni, *CT Conversion Workflow for Intraoperative Usage of Bony Models: From DICOM Data to 3D Printed Models, «APPLIED SCIENCES»*, 2019, 9, pp. 708 – 720.

Leonardo Frizziero, Gian Maria Santi, Alfredo Liverani, Valentina Giuseppetti, Giovanni Trisolino, Elena Maredi, Stefano Stilli, *Paediatric Orthopaedic Surgery with 3D Printing: Improvements and Cost Reduction, «APPLIED SCIENCES*», 2019.

Docquier PL, Paul L, TranDuy V. "*Surgical navigation in paediatric orthopaedics*", EFORT Open Rev 2016; 1:152-159. DOI: 10.1302/2058-5241.1.000009.

G. Ippolito, M. Benedetti Valentini, R. Caterini, P. Farsetti "*Il piede piatto congenito da sinostosi tarsali, controllo a lunga distanza di 10 casi trattati chirurgicamente*", 2009.

Auricchio F, Marconi S. *3D printing: clinical applications in orthopaedics and traumatology*. EFORT Open Rev 2016; 1:121–127. DOI: 10.1302/2058-5241.1.000012.

M. Cameron, *"Process to Convert DICOM Data to 3D Printable STL Files"*, 2008.

James B. Carr II, Scott Yang, Leigh Ann Lather, "*Pediatric Pes Planus: A State-of-the-Art Review " [Available Online]:* https://pediatrics.aappublications.org/content/137/3/e20151230

A. Pellegrino, "*Chirurgia del piede e della caviglia Testo informativo per i pazienti", 2011.

R. Gindro, *"TAC, mezzo di contrasto, rischi e altre domande frequenti"*, 2019.

H. R. Epps, *"3-D printing helps with complex hip surgery: pediatric orthopaedists find it helpful for patient education too*" AAOS Now, 2014.

N. Bizzotto, A. Sandri, D. Regis, D. Romani, I. Tami, and B. Magnan, "*Three-Dimensional Printing of Bone Fractures: A New Tangible Realistic Way for Preoperative Planning and Education*" Surg. Innov., vol. 22, no. 5, pp. 548–551, 2015.

K. C. Wong, "*3D-printed patient-specific applications in orthopedics*", Orthop. Res. Rev., vol. Volume 8, pp. 57–66, Oct. 2016.

Biographies

Leonardo Frizziero is a Senior Assistant Professor of the Department of Industrial Engineering, at Alma Mater Studiorum University of Bologna. He promotes the scientific issues related to the Mechanical Design and Industrial Design Methods (CAD 2D, 3D, Advanced Design, QFD, TRIZ, DFSS, DFD, DFA, ecc.). In 2005, he was recruited by Ferrari Spa, as project manager of new Ferrari cars projects. In 2009 he came back to University, obtained the Ph.D. degree and started collaborating with the Design and Methods Research Group of Industrial Engineering becoming Junior Assistant Professor in February 2013 at DIN of AMS University of Bologna. He teaches and follows researches in the design fields, participating at various competitive regional, national and international research projects. Since 2018 he has been a Senior Assistant Professor. Since 2017 he is qualified Associate Professor of Design and Methods of Industrial Engineering (ING-IND/15). Prior to the role of university professor, he held relevant positions for some industrial companies.

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Alfredo Liverani is a Full Professor and Chief of Mechanical Engineering Degree Course at the Department of Industrial Engineering of Alma Mater Studiorum University of Bologna. Prof. Alfredo Liverani is a member of CbEM (Computer-based Engineering Methodologies) research group and he is involved in several activities related to Computer Aided Design (CAD), Computer Graphics, Virtual and Augmented Reality. In detail he focuses on realtime visualization and interaction with particular attention to mechanical, aeronautical applications and also Industrial Design. Surface modelling, reverse engineering, mesh generation (FEM) and manipulation, virtual prototyping and live simulations are fields investigated in the several publications available at http://diem1.ing.unibo.it/personale/liverani.

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Valentina Giuseppetti completed her bachelor’s degree in Management Engineering at Alma Mater Studiorum University of Bologna. She is currently a master's student in Management Engineering.