Additive Manufacturing to Advance Functional Design: an Application in the Medical Field

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ABSTRACT

The improvement and the massive diffusion of Additive Manufacturing (AM) techniques have fostered the research of design methods to exploit at best the feature introduced by these solutions. The whole design paradigm needs to be changed taking into account new manufacturing capabilities. Additive manufacturing is not only an innovative method of fabrication, but it requires a new way to design products. Traditional practices of mechanical design are changing to exploit all potential of AM, new parameters and geometries could be realize avoiding technologies constrains of molding or machine tooling. The concept of “manufacturing for design” increasingly acquires greater importance and this means we have the chance to focus almost entirely on product functionality. The possibility to confer inhomogeneous properties to objects provides an important design key. We will study behavior and structure according to desired functions for each object identifying three main aspects to vary: infill type, external topology and shape, and material composition. In this research work we focus on FDM technology.
of 3D printing that easily allow to explore all previous conditions. We present a new way to conceive design process in order to confer variable properties to AM objects and some guidelines to control properties of deformation and elasticity using classic infills. The ultimate aim is to apply new design rules provided by AM in the prosthetic field of lower limb amputees. The socket of the prosthesis represents a deformable interface between the residual limb and the artificial leg that must be optimize according to geometry and loads distribution of patient. An application for a transfemoral patient will be discussed.

INTRODUCTION

Manufacturing processes exploiting additive-layered production have been used across three decades to create rapid prototypes. In the last years, technological improvements in production systems have increasingly allowed to gather finite products as well as prototypes. Conventional fabrication systems dramatically condition the way any structure, device or system is designed. Engineering students are still taught to respect a set of rules or guidelines strictly derived from a certain production options. Some of such rules are clearly stated, while some others are intrinsic to industrial practice and design tools (e.g. 3D CAD features) and depend on the experience and practice gathered in decades of use of manufacturing technologies. Moreover, production systems are generally conceived to realize high volumes of standard products to cut costs.

Nowadays, the challenge junior designers are facing is to overcome the traditional fabrication paradigm to include the possibility to manufacture product with additive technologies. Additive manufacturing (AM), today, embraces a number of technologies that are redefining the way technicians will design and make future
Additive manufacturing technologies are changing the traditional approach to design and manufacture products. The realization of physical objects models is simplified for the reason that printed prototypes are already usable for testing and
simulation or even final products. Thus, the global market is full of 3D printing modes, materials, machines and other variants. All contexts are interested by AM such as industrial, medical [1], scientific, design [2] or daily scopes.

In particular, in biomedical field we can find interesting scientific articles in which researchers use 3D printers to realize models of anatomical district useful to test a prosthesis before implanting it on the patient, as explained in [3]. As a consequence, to this large diffusion, a large variety of materials is available on the market: plastic filaments, biomaterials, ceramic, clay, cork are just a few among the filaments that can be printed nowadays [4]. We are interested, in particular, to FDM (Fuse Deposition Modeling), an AM technology that permits to create an object, extruding fused material on the printing plane by layers from the bottom up. It is created by overlapping a lot of layers. The typical structure of a FDM printer is illustrated in Figure 1.

In the pre-processing of the 3D printing phase, the model exported from a CAD or a 3D scan system needs to be manifold: it means that the meshed model must not have holes, degenerate triangles and overlapped faces. After that, a slicing algorithm subdivides the object in a sequence of layers to overlap. PLA (Polylactic acid or polylactide), a biodegradable thermoplastic polyester derived from renewable resources and ABS are the most used materials. There are also some special filaments for particular uses such as flexible filaments made by a rubber material permitting great deformation, or water-soluble filaments useful to realize supports to be easily removed. An interesting challenge is the possibility to use and integrate multiple materials in the
same object; in this way, it is possible to realize products with different composition areas.

Exploiting the potential of flexible materials, it is possible to integrate them with classical materials using a 3D printer with multiple extruders. This allows creating models with soft and hard parts or with layers of different composition [5]. Infill is another fundamental element for FDM printing; in fact, it could offer some improvements concerning different aspects, such as mechanical properties, filament saving, objects lightening and internal structure optimization. In particular, internal structure confers to the printed element rigidity and deformability related to external stress distribution. Rectangular shape, honeycomb or concentric paths are only a few of internal infills available with common 3D printers (Figure 2).

FDM is an easy way to print, but there is a large set of parameters to be managed that influences the result such as heated bed temperature, infill ratio, printing temperature, layer height and printing speed.

METHODOLOGY

Since the main change AM provokes is on design methods, this paragraph is dedicated to the definition of those aspects that may be leveraged to innovative design method, starting from FBS (Function-Behavior-Structure) model [6].

FBS offers an interesting and useful point of view on objects design. It is an ontology that conceptualizes design objects in three ontological categories: function (F), behavior (B), and structure (S) as shown in figure 3.

These are defined by authors John S. Gero e Udo Kannengiesser in [6] as follows:
• Function (F): describes the teleology of the object, i.e. what it is for.

• Behavior (B): describes the attributes that are derived or expected to be derived from the structure (S) variables of the object, i.e. what it does.

• Structure (S): describes the components of the object and their relationships, i.e. what it is.

Each designer creates some correlation between these three classes basing on own experience; in particular s/he ascribes function to behavior and derives behavior from structure. A direct connection between function and structure, however, is not established. The FBS framework provides several processes linking function, behavior and structure together.

In this work, we approach the design process evaluating the behavior of the object in correlation with the features of the structure, basing on Gero’s FBS framework. Additive manufacturing is the ideal field in which this approach can be used. The innovative design process finalized to create an object with AM is different from the conventional one, because it shifts the focus to design thanks to the reduced limitation of new fabrication technologies.

In this way, the behavior of the object, i.e. the way it fulfills the function, is the central aspect to take in consideration and to connect with the rules to realize the structure. Therefore, it is possible to obtain the desired function (F) of the object by finding the proper structure (S) guaranteeing the behavior (B).

In order to obtain this aim, within an AM perspective, we identified three main aspects to approach the design process. In the following paragraphs, we provide an explanation
concerning the structure of each one of these three aspects that are related to infill, shape and material as shows in figure 4.

**Infill optimization**

Infill is the pattern of material inside the object. It is characterized by both the geometric pattern and density of material within the object. Some additive manufacturing technologies like FDM allow filling object with standard types of patterns such as honeycomb, rectilinear or triangular, or with ad-hoc designed structures. In the followings, we present several infilling algorithms used to optimize product behavior in a functional way.

**Cross sectional analysis**

Li et al. [7] developed an innovative method whose aim is to optimize the internal structure of 3D object according to their real usage. They started from a meshed geometry derived from a CAD system or other modeling software and they execute a cross-sectional stress analysis to identify zones in which fracture could occur (Figure 5). This process is based on the Euler-Bernoulli assumption, thus, avoiding the use of Finite Element analysis. In this project, they introduced a method to obtain an approximated neutral axis perpendicular to each section that allows calculating cantilever structural stress.

After that, they estimated the density by evaluating the moment of inertia: they constructed the relationship between geometry shape parameter of the cross section
and the moment of inertia. Internal structure will be made of porous infill and its density is regulated according to stress applied that is inversely proportional to the moment of inertia of cross section. Infill ratio changes between different volumes of the same object, divided according to cross sections. A local gradational infilling made by a mathematical algorithm and Boolean operations to integrate the shell model and the porous structure are executed. The output file is a .stl file that is usable with commercial 3D printers.

Umetani and Schmidt [8] in an Autodesk research illustrated a similar method based on weak sections of the object. They introduced a method to give a real time feedback to the designer about critical zones and also to optimize the creation of 3D printed objects. In this way, they offer a way to identify the best infill direction that guarantees the highest resistance to the applied loads. If there are several weak sections, maybe it is not possible to find only a single orientation of the model so it required privileging the weaker section. Therefore, this solution does not modify infill ratio and, thus, the quantity of material, but it controls the growing direction of the model, as shown in Figure 6.

Both methods have the most important advantage in their rapid execution and this is because they analyze only the weak sections of the object. By the way, this solution is not yet addressing the important approximation of the structure, e.g., improving of other properties such as tensile stress, torsional stress and center of mass. These and other research groups are already working on such issues and improvements are expected in a near future.
Medial axis tree method

Zhang et al. [9] defined an interesting approach to internal supporting structure for 3D printing. Their work is based on the use of medial axis concept: biologically, it is the skeletal structure that absorbs and disperses loads applied to the object; mechanically, it is the axis of the volume that represents the support of the structure. The 3D printed object has a structure made by three different parts: the medial structure, the boundary framework and the group of connecting bars. The algorithm used to reach the aim is at first the scale axis transform developed by Giesen et al. [10] to extract the medial axis of the structure; then, the Restricted Centroid Voronoi Tessellation allows creating the external hexagonal frame structure. The last process consists in linking all vertices of the hexagonal structure to the corresponding points on the medial axis. After that, they compute the optimization process of the medial axis tree according to external loads applied. The process is divided into three parts: convex hull analysis and load combination, mechanical analysis and radii classification and, topology and volume optimization (Figure 7).

The aim of this procedure is to reach the desired printable shape able to support pre-determined or estimated loads. Following the steps of this method and, thus, saving material and improving strength does not affect 3D printability in general, but it could be challenging with FDM technology because of the limited quantity of material composing any layer. Using dissolvable supporting material could face the problem.
Hollowing and rotation method

Christiansen et al. [11] present an automatic balancing of 3D models focused on low cost FDM printers. They provide two steps to optimize mesh geometry and internal structure. First, the model optimization is made creating cavities filled of lighter or heavier material in a process called hollowing. Using triangular meshed model, it is possible to discretize it into tetrahedral elements obtaining a simplicial complex (Tetgen algorithm). Thus, using DSC method (Deformable Simplicial Complex), which is a Lagrangian method, cavities are created in the tetrahedral structure without modifying the external shape. After that, for complex models, they introduce another type of optimization that recommends the rotation of model during the 3D printing process. The rotation gives stability to the object that, after the hollowing process, may result unbalanced. This could cause a little deformation in the contact zone with the printing board, but the phenomenon is neglectable, because most of the cases a rotation of few degrees from the original position is enough.

This contribution shows a simple but effective methodology to obtain a particular infilled model. By the way, it has a limitation with FDM technology; actually, internal hollows are not always self-sustained and in these cases, they need a support that changes the internal structure and is not removable.

Voronoi tessellation method

Lu et al. [12] demonstrated how a 100% filled object is not the best solution in any condition and they proposed to create an ad-hoc structure that support loads applied to
the object. The aim is to obtain a model that supports loads while minimizing weight and cost. They reached it in some steps. At first, the triangular mesh is converted in a tetrahedral system through Tetgen library. This allows analyzing the model with FE software to evaluate stress distribution. The stress map admits to place some sites in the object volume according to stress values; thus, they applied a Centroidal Voronoi Tessellation (CVT) to subdivide the volume into cells. In order to hollow each Voronoi cell, they compute a harmonic distance field in the cell that allows generating porous surfaces in the best way. The last step is the strength-to-weight optimization that is a Monte Carlo stochastic sampling of the site distribution density and the hollowing value in each cell. This process refines and extracts optimal value for lighter volume and maximum stress. To validate their method the research group executed a test campaign based on compression tests and strains evaluation. The optimal models extracted with this process are generally supporting higher stress than models infilled in standard way. The workflow is illustrated in figure 8.

Some other challenges remain to be solved, in particular those caused by the approximation of the stress acting on the model. For example, secondary order effects due to outside temperature or material fatigue are not investigated. Furthermore, the Monte Carlo sampling does not guarantee a global minimum for the optimization. Surely, despite it, they developed a method that includes all aspects needed for infill customization according to loads.
Elastic textures method

Panetta et al. [13] give an important contribution to the infill optimization research. Actually, they propose an ad-hoc internal structure according to the object usage. Even if they focus on Stereo Lithography and not on Fused Deposition Modeling printers, this work is noticeable for particular internal structure modelling process. Thus, the process should be handled with different 3D printing technologies. The model is subdivided in a number of cells and for each of them Young modulus and the Poisson coefficient are calculated to identify the correct and desired elasticity. In this way, all pattern cells have a different structure that must be connected to the others to obtain a single object with defined deformation features. Researchers found and solved all problems related to these structures and they presented objects capable of anisotropic deformations.

The microstructures developed are surely an interesting subdivision of the space and offer a particular anisotropic behavior, but they discretize the space in a pattern reducing the continuous properties. This method creates thin structures or layers with singular points, which are not easy to be printed with a FDM machine, but some precautions or proper supporting structures may be designed to make this possible.

Microstructures to Control Elasticity

Schumacher et al. [14] in a recent Disney research present a very similar method to previous one. They proposed a method for fabricating deformable objects with spatially varying elasticity using 3D printing. Using a single relatively stiff material, they conferred elasticity in order to desired behavior of the structure. To reach this aim, they exploited
Metamaterials properties and topological optimization, and they identified standard microstructures families visible on the graph of Poisson’s coefficient – Young Modulus as shown in figure 9. Metamaterials are assemblies of microstructures that take their properties from the shape of the structure. After preprocessing, they created a database of families each one based on a standard structure. The operative phase consists in a connection between desired properties of the model and elasticity classes. For each zone or cell, it associate a microstructure basing on Young modulus and Poisson coefficient, thus an optimization of thickness is made to adapt in the best way the shape to the behavior of the structure. Repeating this process for all cells of the model is possible to create a printable model as result. This process too is not thought for FDM technology of printing, but they offer a very interesting way to approach this problem.

Biomimetic method

The biomedical world inspired a lot of industrial and mechanical applications. An example is the work presented by Murphy [15] for generating a foam structure to be used as an infill pattern for 3D printing applications. He started the project with a detailed research on the internal structure of human bones, from which he was inspired. Actually, 3D object can be infilled with a porous pattern like bones. The method to construct this geometry starts with the analysis from a file in .obj format that contain all vertexes coordinates and all faces features. Protosphere algorithm solves the problem of creating porous pattern by subdividing the geometry in the desired foam structure. It randomly inserts the desired number of spheres in the volume until the
algorithm converges. The major advantage is that it is executable with parallel computing mode that consists multiplying the calculation power of a single laptop/desktop computer using NVIDIA GPU with CUDA framework. In this case, the object is divided in parts and they are parallel computed reducing the calculation time. The output of this process is a model ready to be 3D printed. The author also made some tests validating the possibility to print the porous structure without internal supports.

The disadvantage of this process is that there is no attention to load distribution, but it is only an alternative 3D infill method. Future works could relate this geometrical method to a stress map.

**Topology optimization**

Optimization algorithms are based on iterative processes that modify at each step optimization parameters. Taking in consideration constrains and rules, optimization process provides the best solution of the problem from a mathematical point of view. In particular, topology optimization is used in the design phase of a project. This mathematical approach is used to define the best material density in the design space imposed by the user, taking in consideration product requirements and constraints. The results obtained with commercial solvers are generally a grey map showing required density of material in each cell of a mesh. Each level of grey gives a feedback on essential density (0 means no material, 1 means 100% density).
In general, a threshold level discriminates where to put material and where material is not required.

The full process is made of a number of steps after topological optimization that are useful to transform the exported model into a realizable model through a smoothing and a validation exam with FE method, as shown in figure 10. Optimizing the shape is a way to connect applied loads to desired behavior of the structure and, for this reason, topological optimization represents one of three main approaches to design the object. By the way, most of the times, mechanical parts resulting from topological optimization are not realizable for limitations due to conventional manufacturing techniques. Moreover, the mechanism of setting the density threshold to define where there will be material and where not may affect the optimization level. Additive manufacturing can be the solution to address both problems. In fact, in AM “complexity comes for free” and optimized topology can be fabricated with no changes. Density of AM product variable to 10% to 100% and no further simplification are needed.

Multi-material approach

Conventional manufacturing consists in the realization of mechanical components with a single material. With this approach, each part has a homogeneous composition, constant material properties and we usually create assembly of items with different material to gather the desired result.
Additive manufacturing provides a new way to approach the problem. In fact, it allows printing each single layer with more materials and this means to construct an object with mechanical properties that change in a continuous tridimensional manner. The transformation from virtual prototype to the printing geometry is the base to obtain multi-material object. The variation of mechanical properties inside the object, obtained mixing two or more materials, is the most important effect from the designer point of view. Two parts of an object may have dissimilar stiffness or weight, or even smoothness, color or transparency. Multi-material approach can be used to confer a particular function to the 3D printed object. For instance, the realization of a hinge joint can be executed in a single part varying the material between the frame (rigid) and the bending element providing the rotation (elastic).

In addition, some other features can be managed, as, for instance, the electric conductivity to create electric circuits inside a single printed object made of insulating material.

**FUNCTIONAL DESIGN**

The design process based on the correlation between behavior and structure to derive the function can be identified according to new features introduced by AM. Actually, we can define some classes, at behavior level, that correspond to a way the product can react to load and constrains. Bending, torsion, tensile and compression are examples of these classes. Each of these can be implemented in several ways at
structural level; according to previous explanation, we can change internal structure, 
external shape and material composition.

Concerning bending, for instance, in literature there are many ways for creating 
a bending zone into an object. The common manufacturing way that admit bending 
involves making it with multiple components connected by a joint. Using FBS method for 
AM, we can consider new ways of achieving the same behavior. In the followings, for 
each class some design guidelines and examples are shown.

**Bending**

It is possible to realize a hinge joint with a single component varying parameters of 
structure, shape and material. Changing structure, an object could be design for a 
controlled deformation, infilling the model with standard cells as presented in the 
research work of Panetta et al. [13]. Each cell has a particular elasticity and contributes 
to give to the global model, assembly of multiple cells, and the desired features as 
shown in figure 12a.

Changing material, we can realize hinge joints with multiple materials in different 
zones, for example a core made with soft material and an external covering of hard 
plastic material. Another way to confer bending features to an object is to implement a 
new modality of design and manufacture that is called ‘4D printing’. It consists in the 
use of different materials that deform themselves in reaction to temperature. Objects 
printed on a plane change their shape once heated exploiting deformation of joints
material due to high temperature. For example, it should be useful for automatic flexion caused by controlled rising of temperature.

A mixed approach that combines internal structure and materials choice is the use of functionally graded material (FGM). This method allows conferring properties by gradually changing composition and disposition of material.

Other solutions are available taking into account the shape of the object. Laser cutting should create a lattice in a sheet metal that reduce material strength and admit bending behavior as shown in figure 12b.

If we completely revolutionize the shape of hinge joint, we could find solutions similar to Merriam at al. [16] that in their research work explains a new way to design a compliant adopting a particular shape like in image 12c.

There are also other ways to create joint of a single component able to confer flexibility used, for example, in robotics and medical prosthetic devices such as robotic hand joint [17] or complaints that emulate bird beating of wings [18].

Tensile Strength

In this section, we study ways to reduce tensile strength and to make the object able to stretch without cracking. The first important solution is the use of auxetic materials (Figure 13) that are not characterized by composition, but by material disposition. In fact, internal patterns make sure that Poisson coefficient is negative and this means that they expand along transversal axis, if subjected to a tensile force and vice versa.
Asymmetrical structures contribute to provide tensile capabilities and in particular, metamaterials represents a way to control deformability as exposed in [19]. Metamaterials, that include auxetic ones, are smart materials engineered to have properties not yet found in nature. They are made from assemblies of multiple elements repeated in pattern. The shape of structure gives them properties of deformation that should be controlled varying it. An example of metamaterials combines the use of more materials and the internal structure. Rafsanjani et al. [20] presented a way to design material overlapping layers of different shape and composition. The combination of these features ensures to the object to support tensile force and to have a large stretching as shown in figure 14.

Elastic textures made by Panetta et al. [13] and functionally graded material too are usable to realize this property.

Compression

Compression property can be obtained as well with auxetic materials; in fact, they reduce their section area on the transversal plane if they are subjected to a compression force. Taking in consideration internal structure, elastic textures, FGM and asymmetrical patterns of metamaterials allows giving to the object a controlled compression behavior. An example of metamaterials applied to compression design is presented by Bafekrpour et al. [21]: they studied cavities in the material that induce compression in the desired direction (Figure 15a).
From the point of view of external shape choice, Shim et al. [22] developed a way to discretize spheres and to control compression through encapsulation of structured elastic shells (Figure 15b).

**Torsion**

The torsion is the action of twisting of one end of an object relative to the other. These properties should be obtained with some of previous methods, like functionally graded material or 4D printing, but the most relevant method is the elastic textures design. In fact, displacing different standard cells in a particular way, it is possible to predict and control torsion of the object. The figure 16 shows the obtained result.

**APPLICATION IN THE DESIGN OF MEDICAL DEVICES**

The opportunities introduced by AM have been tested in the design of a component of the lower limb prosthesis.

Nowadays amputee patients, due to continuous prosthetic devices improvement, have the possibility to live a better life and execute everyday activities without major limitations. The quality of lower limb prostheses determines patients’ ability to walk. For this reason, prostheses need to be optimized and well designed according to life style, gait features and contact pressure on residual limb. The aim of this application is to improve prosthesis manufacturing and designing processes.

In previous works [23-24], our research group investigated on contact pressures between the prosthetic socket and the residual limb, offering also a way to simulate the
donning of the prosthesis with a FE method. Exploiting this knowledge, it is possible to create a socket composed by load and off-load zones. The approach of this paper proposes a way to realize a socket varying infill ratio, pattern and orientation to obtain the desired local behavior in each part of the socket.

The contact pressure is correlated to desired elasticity in each area. Load areas are required to bear the dynamic load of the person walking, while off-load zones are required to adhere to the residual limb to guarantee comfort. Knowing Young-Poisson graphs for the different infill configurations, we have a wide range of choice to each design portion of the socket with the optimal infill. Therefore, we can have a single material structure for the prosthesis that is optimized in every single detail with the required mechanical characteristics. Alternatively, we can combine more materials to reach the same goal. To gather the desired behavior a few detailed tentative designs have been proposed, and the most promising have been built with a FDM machine.

Concerning a single material model of socket, we focused on the optimization of internal structure varying the infill ratio. As shown in figure 17a, we investigated on different infill percentages to choose the best one for each area. In these conditions, we can determine deformability varying the inner structure of a shell thick less than 10 mm. We realized a prototype socket manufactured with a 3D printer Leonardo Cube Meccatronicore [25] that was used by a patient with a transfemoral amputation to the left leg.

Another way is to confer softness not only varying the internal structure, but also using materials of different compositions in separate zones. Our 3D printer allows
extruding with multiple materials thanks to multiple extruders. We realized a 3D printed multi-material socket, as shown in figure 17b, composed by an external coating made of hard material and an internal surface subdivided in different area made of soft material. Off-load zones are not supposed to support high loads; they just have to ensure structural stability and comfort to the patient. Load zones, on the other hand, must receive and transmit the walking loads without major deformations and, at the same time, guarantee a complete pain-less contact. This socket was realized with FlexiFil by FormFutura with 100% of infill density for soft zone and with PLA with 10% infill density for hard structural zones.

CONCLUSIONS

The challenge of additive manufacturing is to be able to properly design goods to exploit the new ways of realizing them. Flexibility and quick production is only a part of the potential benefits new production solutions are introducing. The most difficult but promising aspect relies on the chance to create non-homogeneous and multi-material objects. The paper shows some ways to accomplish this task by introducing the FBS formalism. The Function fulfilled by the product is obtainable characterizing the Behavior of specific parts with a Structure architecture that only AM technologies can provide. The preliminary results obtained show how we can classify behaviors and achieve them exploiting known algorithm for infill definition, topology optimization a multi-material grading. Using such an approach, the technicians will have the chance to better focus on functions and behaviors because structures are more easily obtainable
and free from conventional fabrication constraints. Moreover, different structures can be used to obtain the same behavior and, thus, designer will chose the one optimizing external requirements (e.g., weight, reliability, fabrication time).

The case of manufacture with FDM technology a lower limb prosthesis component, which ha a shell type organic shape, shows how the variation of material and infill features can be used to gather innovative products. Some socket prototypes have been printed with an FDM machine and preliminary empirical results have been evaluated positively.

A robust and reliable set of design rules is still far from being reached and further studies are required to create a complete method and proper software tools. The following activities will be focused on numerical simulation and experimentation of structures variants to create a reference database and a toolset for designers.

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REFERENCES


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Be = expected behaviour
Bs = behaviour derived from structure
D = design description
F = function
R = requirement
S = structure

1. R → F
2. 1 → 2
3. 3 → 1
4. 4 → 3
5. 5 → D
6. 6
7. 7
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⎯⎯ ⎯⎯ = transformation
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