A Systematic Study on TRIZ to Prepare the Innovation of 3DPVS

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Abstract

Regarding the innovation of biomimetic cell culture scaffold, 3DPVS, namely 3D printed vibratory scaffold, has been proposed as a present-to-future novel product. It currently stands at the stage of conceptual development. Design studies on 3DPVS Concept Generation show high value, and one essential part inside this could dwell at establishing design methodological knowledge that has innovation merits. TRIZ with its tools has proven value on creation and design innovativeness while they have not yet been utilized for scaffold design at mature level. In this paper, we attempt to study and explore the design aspects of TRIZ and its most relevant tools on the context of 3DPVS, as well as preliminarily indicating a TRIZ-based methodology, which could tailor the design aspects of 3DPVS. It also, to some extent, fills a gap in scaffold engineering and TRIZ literature and provides a comprehensive overview of a timely topic.

Keywords: 3D scaffold, conceptual design, engineering design, 3DPVS, product innovation, TRIZ, bio-design, artificial biomimetics

1. Introduction

An important product in bioengineering is 3D scaffold, which mimics the real tissue in vitro to achieve the external cultivation of cells. Design studies focusing on 3D scaffold have drawn increasingly attention in past decade, and increasing number of researchers show interest toward developing novel scaffold product. Inside scaffold innovation, 3DPVS, namely the 3D Printed Vibratory Scaffold, has been proposed as a present-to-future novel scaffold design, which currently stands at the stage of conceptual development [1]. To achieve the novel conceptual design of 3DPVS, TRIZ methodology with its essential tools will be explored in this study, hopefully contributing to a scientific-sound ground for future conceptual generation works using TRIZ. In this connection, the paper is structured as follows. Firstly, several background information will be introduced, including 3DPVS, its conceptual design process, traditional methodology for scaffold design with the limitations. Second, from main context, we will study TRIZ and relevant tools for 3DPVS innovation, the philosophy behind TRIZ, TRIZ contradiction-solving process. Several core tools inside TRIZ will be studied and analyzed in both general context and the specific one in 3DPVS design. This includes Altshuller Contradiction Matrix (ACM), TRIZ Innovation Principles, Substance-field modeling and Analysis (SFMA), Innovation standard solutions (ISS), ARIZ, and so forth. In the end, future work regarding ways
of establishing TRIZ methodology will be discussed, as well as the proposals for validating the eligibility of applying TRIZ-based method from traditional engineering field into bio-design. The structure of this paper as well as the interconnection of each parts can be illustrated as follows:

**Scaffold engineering and 3DPVS.** Cell culture scaffold is defined as a class of artificially created biomimetic products used for culturing cells in vitro, through mimicking some real tissue properties. Scaffold engineering has developed in two directions. One is “from static into dynamic,” and another from “2D into 3D” [2]. Existing scaffolds basically have a nature of being passive (also called “static”), which have several inevitable limitations. Taking this as well as the evolutional ladder of scaffold engineering into account, the novel concept 3DPVS (3D Printed Vibratory Scaffold) has been put forward, indicating that traditional 2D or 3D scaffold as the lower part of ladder while 3DPVS could stand at a relatively higher positionality. This was also justified via studying previous traditional scaffold as well as by penetrating that into the “Laws of System Evolution (LSE).”

In terms of the 3DPVS, concept indicates that a trinity of separate elements, namely vibration, scaffold, and 3DP, would turn into a unified systematic functioning with promising “vibratory properties” endowed by the scaffold itself, instead of through external mechanical ways such as connecting scaffold with a vibrator to acquire some vibrations on cell culture. Further, 3DPVS might concern with transforming the role of scaffold passively receiving vibration into potentially generating vibration at active or proactive way. In brief, localized vibratory function, as one core inside 3DPVS, was indicated as one of the most useful factors from evolutionary point of view; and 3D printing (3DP), another core, was pointed as the technology bridging traditional scaffold into future novel vibratory scaffold. Consequently, 3DPVS would possess the existing merits of traditional scaffold while innovatively providing tailored vibratory functions on different kind of external cell cultures.

**Conceptual design process of 3DPVS.** In author’s previous work, where details about the conceptual process and design schematics were illustrated, conceptual design of 3DPVS could be proposed into three main stages, namely Design Initiation, Concept Generation, and Concept Evaluation [3]. The main task of Concept Generation phase is to innovatively create possible solutions or principles that help realize all or most desired functions designated for 3DPVS. Methodology and tools for generating innovation concepts compose the core of this stage [4]. In terms of Concept Evaluation, work of which is to create criteria, rank concepts, evaluate to what extent the generated concepts satisfy proposed requirements while providing feedback to design as a circular-improving process. To guarantee the quality of these two stages, one stage needs to be completed at relatively mature level, and it is called as Design Initiation, where the literature study, problem selecting and requirement identifying have been its chief focus. Regarding the methodology of each stage, Design Initiation chiefly takes Literature Review as its methodology for gathering all possible inputs and establishing relevant base models. For Concept Evaluation, tools such as Quality Function Deployment (QFD) to generate concept criteria, rank scores, and select optimal concept could be used. Experimental or computer simulation method would be useful regarding evaluation. It is perceivable that only after a relatively thorough work of studying and establishing methodology, it could logically come to an effective concept generating work followed by near future design.

**Traditional methodology for scaffold conceptual design.** Through previous literature study on two areas, namely the area of design methodology and the area of 3D scaffold’s design, it reveals that there might exist a gap between these two fields [5].
Using design methodology, such as TRIZ, for instance, it has been already applied for a wide range of research fields, including electronic product design, mechanical objects innovation and industrial designs, and so forth, but little studies have investigated it for the design of 3D scaffold. Reasons could partially lie on the fact that firstly traditional scaffold engineering is not very demanding when novelty or innovation is concerned, so changes on scaffolds can be acquired through CAD software or experimental tests; and secondly, TRIZ researchers probably did not draw much attention on scaffold innovation. In this connection, a formal design methodology has not yet been applied for the design of novel scaffold. Although several attempts have been made by using some part of QFD, TRIZ, or Axiomatic Design, the work generally remains immature, and much more effort in this direction is needed [6–8]. The typical works during the scaffold development, such as using CAD software or tools to modify parameters based on existing old models, as well as through experimental “test and error” method to investigate proper properties of scaffold then make relevant changes, might largely be considered as design approach while neither can be viewed as formal methodology.

At last, it is important to mention that selected methods or tools should be convenient for engineers without strict background on designs. Due to the complicated and cross-domain properties of 3DPVS, as an already-proven fact, it might be not practical, or effective, to use another complicated system for designing it. Therefore, the approach of this paper is expected to provide an all-in-one, fully, or to large extent, TRIZ toolset where future research studies on conceptual design of 3DPVS could directly be benefited with convenience and feasibility.

2. Selecting TRIZ for 3DPVS innovation

2.1 Innovation as the essence of 3DPVS design

Following the laws and principles of scaffold evolution, it is reasonable to reach the conclusion that traditional 3D scaffold system, vibration system, as well as cell culture system, will develop simultaneously and meet at a crossing-point at near future, which gives the indication for the appearance of novel 3DPVS. There have been no previous studies that concerned 3DPVS, either on its conceptual philosophy or product realization. In this connection, a proper methodology, or a methodological system needs to be selected, adapted, or even invented in first place to help achieve the 3DPVS at conceptual design level.

Comparing with traditional scaffold, the development of novel product 3DPVS is an innovation process, which is different from that of other bio-products, which can be better approached by experimental “trial and error” strategy from beginning. Experimental focus at this stage of 3DPVS is considered as less vital compared with a conceptual design at philosophical level. In other words, the former can be useful and efficient only after a success approach of the latter. Also, the core task of 3DPVS conceptual design revolves around the idea “innovation,” which means that creating new concepts where the newly proposed vibratory functionality could innovatively integrate with the 3D fabricability and 3D scaffold. This integrating process is novel, and it is more promising to be achieved when selected method that especially tackles with this “novelty.” TRIZ therefore can be potential since it was especially developed with the blueprint for “creativity” and “innovation.”

Compared with TRIZ, another innovation method is Extenics, which focuses on solving incompatible problems by formularized methods in management and
engineering. Extenics has solved many engineering incompatible problems and has been practiced as suitable for special fields. However, there is no systematic theory on knowledge-based innovation [9]. Extension innovation methods need further improvement to be used as general operable methods for innovative activities. Regarding bio-innovation, TRIZ shows more applicability. Therefore, TRIZ is considered as better approach for 3DPVS scenario.

On other hand, as studied early [2], tackling contradiction in GMBV (geometric-, mechanical-, biological-, and vibratory-) characterization of 3DPVS, increasing ideality level of 3DPVS to gradually approach its ideal model as well as viewing the whole design process from the idea of system evolution, could be several essential focuses that the selected methodology needs to fulfill. In this way, TRIZ methodology has been identified as highly proper since inside TRIZ the “contradiction matrix,” “innovation principles,” and “evolution patterns for ideality” exactly tailor the requirements of those three cores, which can be also the consideration criteria when selecting design method. Considering these, TRIZ will be used for the innovation process of 3DPVS development. Contents of TRIZ and its innovation mechanisms will be studied in following section.

2.2 TRIZ innovation mechanisms

TRIZ, namely “Theory of Inventive Problem Solving,” a is set of tools used by engineers, inventors, and scientists to systematically create new innovative ideas and solutions. It has been used on analyzing and studying artificial engineering systems [10, 11]. Instead of waiting for random inspiration or using trial and error to innovate, TRIZ enables designers to attain breakthrough ideas, methods, and solutions on demand. Created in Russian, Tools of TRIZ have been developed from the study of millions of patents. Rather than playing psychological games, brainstorming, or guessing-and-trying as in ordinary designs [12], TRIZ solutions are systematically derived based on the information abstracted from studying how others solved problems and created innovation.

TRIZ methods, as discussed, have been created, tested, and analyzed based on millions of patents and innovations, aiming to transform the subjective innovation process, to some extent, into a relatively objective, scientific, and easy-handling one. Basic philosophy of TRIZ indicates that, when innovation problem is broken into required elements inside TRIZ as input, following a series of “alchemical work,” the being of the original problem filled with contradictions, splits, and conflicts, can turn into a new being, which is of integration. In brief, TRIZ analyzes the hidden determinants of creative works done by previous innovators and packages the essence of which into TRIZ. Technical and physical contradictions are the cornerstones of TRIZ. Traditional TRIZ generally contains three mechanisms as follows (Table 1) [13–15]:

To be specific, the categorization of mechanisms depends on the essence type of the contradiction. Process of using the contradiction matrix to solve a problem occupies the most significant role in TRIZ methods [7, 13, 16]. In this connection, system contradiction (technical contradiction) is the conflict between two or more parameters inside a system, while physical contradiction is the conflict between two or more values of one parameter. A technical contradiction could mean when improving one design parameter of the product, the other design parameter will deteriorate, so improving one parameter could be conflicting with the properties of others. In the design of 3DPVS, for instance, when the pore size is increasing to a desired level to cooperate with vibration, the geometric stability may decrease and negatively affect cell culture process. Thus, the elimination of this conflict could indicate that designers need to find
a solution that fulfills both requirement of scaffold’s pore size for possible vibration and avoiding the deterioration property of its geometric stability. In contrast, a physical contradiction of which could mean that when pore size changes to a desired level, say, highly precise at nano-micro level, the fabricability of this pore at such size deceases or even becomes impossible, so how to identify the proper size of pore, being both precise as required and with its fabricability ensured, will be the key in this scenario.

As far as system evolution is concerned, it is guided by the defining and resolving System and Physical Contradictions in terms of performance demands. Software Contradictions are modified from System Contradictions tailored for software and informational-technology-related problems [17]. If there is contradiction, then based on its nature, that is, whether it is physical contradiction or technical one, the problem can be approached using either the Five Separation Principles (physical) or Contradiction Matrix and 40 principles (technical). If no contradictions can be recognized or contradiction is at beyond level, tools such as evolution principles and laws, 76 standard solutions, etc., can be potentially applied to solve the problem. To conclude, the process of using Contradiction Matrix can be briefly summarized as in Figure 1.

For another instance, when enhancing the print resolution of 3DP, we usually need more printing materials, and the resource consumption of 3D printer will thus increase. The conflict between printing resolution (to increase) and material consumption (to decrease or preserve) requires that both “more and less” printing materials should be used, which is a technical contradiction. In terms of customer aspect, 3D printer tends to be complex and sophisticated equipment and more operations are required to maintain the functions of printer. However, customers might be unwilling to spend excessive time operating this, and they prefer to use simple, easy ones while these could not fabricate the fine-resolution samples. Low maintenance and fine resolution therefore become a system contradiction. In terms of physical contradiction, enhanced resolution does not always lead to a high-quality printed sample. Cells might not pass through fabricated scaffold if the resolution is too fine. A resolution, neither too fine nor too coarse, leads to a physical contradiction.

2.3 Possible cons and pros of applying TRIZ on 3DPVS design

Despite the potential benefits of TRIZ for product innovation and novel design, there inevitably exist some limitations of TRIZ. Identifying these limitations at first place could help provide designers with better clarity of TRIZ in terms of pros and cons. This section we will study two aspects, that is, firstly, the limitation of TRIZ in general engineering, and secondly, the possible challenges when using TRIZ for specific scaffold design.
2.3.1 Possible limitations of TRIZ in general

Based on the literature reviews on TRIZ and TRIZ-design case studies, the limitation is chiefly recognized by its difficulty of utilization in several aspects. This includes firstly translating problems or innovation issues from specific into generic, secondly, identifying TRIZ-based solutions for these generic problems, and thirdly,
translating the generated solutions back to the specific problems or issues. In terms of using TRIZ innovation principles or standard solutions, a careful work and thorough preparation of “translating” them into the context where product innovation can directly take advantage are always necessary [18–20]. This usually takes much time and effort. Though TRIZ innovation principles and philosophy remain the same for every designer, the expertise or understanding of which varies from one to another. Lack of efficiency and precision in this translating work therefore can be an obstacle for those who attempt to TRIZ on innovation designs. Also, it tends to be challenging when applying TRIZ for innovation in bioengineering scenarios, since TRIZ has not been explored and utilized for this context mainly.

From another perspective, first, it is rare to find previous studies regarding the utilization of TRIZ methods on novel scaffold innovation. Although TRIZ methods have been used and approved by researchers in the miscellaneous, knowledge of TRIZ on scaffold innovation is lacking. To be specific, there lacks formal research in terms of analyzing contradictions and selecting principles for scaffold innovation. Considering this, a TRIZ-based system for scaffold design is therefore needed, aiming to translate TRIZ principles into scaffold-tailored scenarios specifically for 3DPVS. On other hand, TRIZ methodology has been used cooperating with other proven supportive design methods, such as Quality Function Deployment, Root Cause Analysis, System Function Analysis, Hybrid System Design, FMED, and Trimming, etc. [5, 21] . There lacks a systematic study regarding how to link these proven supportive methods on scaffold innovation cases. Therefore, a thorough process combining TRIZ and these supportive methods for scaffold innovation remains as a gap and is therefore of urgency to be developed.

### 2.3.2 Advantages of TRIZ for scaffold innovation

Comparing TRIZ methodology with traditional methods inside Engineering design process (EDP), which is a series of steps that engineers follow to generate solutions to a definite design problem, there exist several advantages. Traditional ways of generating product design concepts or solutions could base on the process such as Brainstorming, “Trial and Error” methods, and so on [22, 23]. Though such approaches are easy to implement, they tend to lack the innovation essence resulted from core of creativity [24]. In addition, following traditional problem-solving path, which can be considered as “linear” [25], we might find something negative and start making efforts to alter it; we may succeed in obtaining a certain result, but together with this result another result might occur, which we did not in the least expect or desire and which we could not have suspected. Using cell scaffold, for example, an additive added to scaffold could directly help cell adhesion, but this may cause unknown proliferation effects, which designers could not predict previously. Correcting this usually means re-conducting the cell culture experiment, which makes the whole process repetitive, costly, and time-consuming. Due to this fact, a more efficient approach in terms of generating innovative, useful, and effective concepts for scaffold design has attracted much attention. In this connection, TRIZ has been proposed as right method, and the four-route process is established.

On the other hand, for a scaffold engineering system, everything within could be interconnected and every function might be inevitably counterbalanced by some other function or by a whole series of other functions, though they could not be easily detectable in linear patterns. In this connection, the new path to be developed should not be linear, but dimensional, which means that the possible supplementary changes,
or side effects, as far as possible contradictions inside GMBV is concerned, need to be considered beforehand. Since TRIZ allows a nonlinear contradiction-solving path, it could logically help designers become better aware of the interconnection of the various properties within the cell culturing scaffold system. Further, due to the rather complex, sophisticated design issues for 3DPVS as bio-design and cross-domain, ARIZ inside TRIZ could be highly suitable tool since it was specially developed for complex design questions. Introducing ARIZ into complex bio-product innovation thus could possibly break a new ground.

2.4 Transferring TRIZ elements into 3DPVS context

The innovation work at current stage of 3DPVS needs to focus on its conceptual design. To ensure a high-quality innovation process, a systematic methodology is of significance [26]. In this connection, TRIZ has been identified as potential methodology for 3DPVS innovation, and in the following sections, we aim to tailor the traditional TRIZ method and the related tools into a systematic methodology which can be specified for the conceptual innovation and design of 3DPVS. Using this methodology system, designers could possibly generate required solutions and concepts for 3DPVS. To establish such methodology, work is structured as follows. First, TRIZ and its basic mechanisms will be introduced, with the justifying work why TRIZ would be an optimal means to help accomplish the conceptual innovation of 3DPVS. Following this, it comes to the core part of the research work, which is to tailor and adapt original TRIZ-based methods into structured methodology, which tackles with the innovative tasks inside the conceptual design of 3DPVS. Since the nature of 3DPVS currently remains as a future novel concept and that its reality product has not yet been approached by utilizing TRIZ, major proportion of elements inside TRIZ consequently need to be transferred, at least to some extent, into a set of specific languages, codes, or forms that can be straightly applicable on novel scaffold design. Besides the novelty of 3DPVS, the very process of this transferring might also be considered as a novel aspect.

3. TRIZ contradiction-solving process for 3DPVS context

For TRIZ, systems evolve toward gaining ideality by overcoming contradictions. Conceptual solutions of 3DPVS would be the output of TRIZ Innovation process, and vital part of this innovation process is achieved by identifying “contradictions” then solving them [27]. Contradiction-solving is the unique mechanism of TRIZ, which might be considered as an evolutionary aspect advantaging other design method.

In this research, large part of work in conceptual development of 3DPVS would revolve around the “center of gravity,” namely “contradiction-solving,” which is achieved through generating identified contradiction and conflict pairs and solving them in a scientific manner. The philosophy behind could be that the innovation and problem-solving process is the process of eliminating contradictions, which is achieved through right intensification of conflicts, not by smoothing them or using buffers to “avoid seeing.” In this connection, the contradiction solving process will potentially penetrate every stage regarding the conceptual scenario of 3DPVS.
3.1 TRIZ contradiction-solving into scaffold innovation

A systematic approach regarding how to apply TRIZ in 3DPVS design. Compared with traditional single-direction problem-solving by TRIZ, in this study we expand a four-route process, which is better tailored for sophisticated design scenarios. Since the very nature of 3DPVS being miscellaneous, the innovation process requires cross-domain knowledge and expertise, which makes the 3DPVS innovation relatively complex and sophisticated compared with single-domain product innovation. In brief, the innovation of 3DPVS firstly requires integrating three core set contradictions, that is, the contradictions between 3D scaffold and 3D printing, between 3D scaffold and vibration mechanism, and between vibration and 3D printing; secondly, the set of pair-based contradictions inside GMBV characterization of 3DPVS, namely the contradiction between relations of G-B, G-V, B-V, B-M, G-M, M-V, needs to be carefully addressed.

Figure 2 below shows the scope this Contradiction Resolving Approach of six-set contradictions between four design aspects, that is, geometric, mechanical, biological, and vibratory properties. It is worth noting that, besides these six contradiction relations, for each G-, M-, B-, V- characteristics inside 3DPVS design, they could produce conflicts within to contradict with themselves, and this will create four sets of most typical physical contradictions, that is, G-G, B-B, M-M, and V-V contradictions (Figure 3).
3.2 ACM applying on 3DPVS conceptual design

As essential part of TRIZ, ACM helps solve System Contradiction (SC), where improving one parameter of a system conflicts with the requirements of other parameters. To define an SC for system and find relevant parameters consisting of SC, four steps are required, and to select effective Inventive Principles for this contradiction, another four steps will be needed, which makes up an eight-step process for the whole contradiction defining and solving. In this connection, we could embed the 3DPVS design into this eight-step process as follows (Table 2).

For step 3, the question comes as which pair of the contradicting parameters ought to be analyzed as priority. The possible ranking order will depend on requirements and conditions of the given cell culture case scenario, and the different aims in different stage of 3DPVS design would also give different selecting priority.

3.3 Corresponding characteristics of 3DPVS with list of TRIZ parameters

To have a better understanding regarding 3DPVS parameters, it is important to know what parameters TRIZ summarizes as most vital ones. The traditional TRIZ uses 39 parameters for Engineering and Technology, and for 3DPVS context, predominant majority of them could be appropriately applicable.

At stage of Design Initiation, relevant parameters for 3DPVS would be collected and analyzed regarding the possible contradicting interconnection between each of the two parameters. For the selected 3DPVS parameters, which compose a System Contradiction, they need to transform from commonly used attributes of 3DPVS into the general parameters recognized by TRIZ. Further, here might be gaps between the commonly used parameters for scaffold engineering and the TRIZ parameters generated universally possible realm of engineering and science. Parameters of latter tend to be more generic and conclusive and could be directly utilized together with the 40 TRIZ principles, which exist as generalized innovative abstracts or concepts for triggering innovation. In brief, GMBV characterization of 3DPVS needs to transfer into TRIZ language at first place. Table 3 shows the GMBV types into potentially corresponding TRIZ parameters.

| Step No. | Tasks |
|----------|-------|
| 1.       | Generate the parameter list for the 3DPVS system, the detailed process of which could be generated in Design Initiation stage. |
| 2.       | Select a parameter at 3DPVS system level and change its value. |
| 3.       | Analyze the interconnection between the selected parameter and other remaining parameters; select out conflicting pairs, each of which will represent a System Contradiction. |
| 4.       | Choose the most appropriate parameters in the 39 parameters list, which correspond to the 3DPVS system parameters as selected above. |
| 5.       | Utilizing ACM, from the vertical list identify 3DPVS parameter whose value is to be improved. |
| 6.       | Identify the worsening or descending parameter inside the horizontal list. |
| 7.       | Identify the inventive principles from the matrix intersection. |
| 8.       | Study these principles in detail and analyze the applicability of each on 3DPVS design. |

Table 2.  
Eight-step process for the 3DPVS contradiction defining and solving.
3.4 Optimizing innovation principle selection from Altshuller’s contradiction matrix for 3DPVS

In terms of the Alshuller’s Contradiction Matrix (ACM) for 3DPVS context, a multi-level principle selecting mode can be used, compared with traditional ACM, which uses single-level one-to-two principle selecting mode. That is, traditional ACM selects one improving parameter and the decreasing another, which causes conflict, then manually searches the 40 innovation principles and gets recommended solutions, which tend to be a combo of 3–5 principles. For such method, several concerns exist. Firstly, there is no ranking or evaluating tools to judge the weight of the selected 3–5 principles; designers need to compare one with another by subjective experience, which probably makes the process time-consuming and inaccurate. Secondly, for the pair of parameters creating conflicts, each of which might be a combined or resultant parameter from several other parameters. Simply choose one parameter for “X” axis in ACM and another for “Y” would be inadequate. In other words, if the parameter “X” contains three elements, say X1, X2, and X3 parameters as a unit, and Y parameter to decease includes another three elements, say Y1, Y2, and Y3, then traditional ACM could find it challenging in solving this. Starting from this new Matrix-searching process comes into the Innovation Principle Analysis (IPA), which would contain the similar process of selecting generic parameters in the matrix through fitting with the parameters composing System Contradiction. Designers will obtain the inventive principles and the associated percentage ranking, which is an special trait of the new ACM, in order to help solve contradiction effectively. In this connection, each pair of parameters, which create conflict, would be possibly divided into one, two or three sub-parameters, based on the parameter evaluation criteria; that is, parameter weight calculated by specific design requirements as into four levels, respectively representing by symbol “S,” “A,” “B,” and “C.” For the IPA in 3DPVS context, we would use “S,” “A,” where S is for the chief feature parameter in given scenario, A for the secondary, and B for minor. “C” is considered as trivial determinant, which does not affect the decision-making in innovation process. If the conflicting parameter is the exact one inside the 39 parameters list, IPA Matrix can be used similarly as traditional Matrix, with one difference, that is, weight of principle...
by percentage among other principles would be calculated as well. For this instance, as well as transforming traditional ACM into new ACM-IPA, example is shown in Figure 4, which also illustrates the basic development from traditional single-dimensional Matrix into the Novel multidimensional one.

Inside IPA, two or three sub-parameters constituting the states or functions of the original parameters will be used for filling the X or Y ACM column before the principle searching starts. In this connection, the total searching time would be a number between nine to one; a proportion ratio based on the appearance frequency of selected principles in this one-to-nine scenario will be calculated. The Company Time to Innovate has used such calculation philosophy in their TRIZ application and proved higher design efficiency. Top principles resulted will the considered as prioritized solutions for the given scenario. For better understanding this as 3–3 Matrix, an example is given here regarding a specific 3DPVS scenario. In this scenario, cells move in fast speed in a culturing environment as the chief feature parameter (S), the definite duration (A) needs to be ensured as well as maintaining the cell temperature (B). In one fast-moving state, cells create negative pressure on the scaffold, making the stress or pressure as the chief feature parameter (S) of Descending Parameters (DP). Also, more energy could be used by such higher movement by cells so other cell process might be affected, making the Energy Lost as the secondary feature (A); the shapes of cells might also be negative affected, which will result in undesired morphological effect. Shape issue is not vital for this scenario, but also it is a negatively affected factor, so to make it as the support feature parameter (B). For designers, it requires how to ensure the Ascending Parameters (AP), namely speed of cells, speedy period, and cell temperature, while not descending the DP pressure, energy use/lost, and shape? In this instance, the IPA result from ACM is shown in Figure 5.

From this IPA, we could see, principles 19, 35 represent the highest weight and principles 15,14 and 6 follow gradually afterward. These principles would be considered as the most promising direction when solving the regarded problem as brought up, while the principles weighting less could be used as reference to help innovative thinking. In this case, a possible innovative suggestion is that dynamic materials could be used so scaffold’s physical and chemical parameters would change at periodic level. From this direction, we might be able to explore further in details.

To conclude, IPA is proposed to play vital role inside the four-route TRIZ-based methodology. In next section, we will illustrate the detailed knowledge about TRIZ.
innovation principles, as core contents for IPA and TRIZ, as well as discussing the most likely direction when applying each principle for future 3DPVS design.

4. Applying TRIZ innovation principles for 3DPVS design

After introducing IPA and its philosophy, in this section we would study the details of IPA and the most possible manifestation of each principle into 3DPVS design context. Firstly, the significance of translating TRIZ Innovation Principles will be discussed, secondly the 40 innovative principles, principle-related expansions, as well as 3DPVS design strategies utilizing corresponding principles will be illustrated.

4.1 Necessity of translating innovative principles into 3DPVS context

One core element of TRIZ is to recommend innovative principles, which potentially stimulate the designer’s creative thinking in solving design conflicts or contradictions. However, TRIZ-based inventive principles have not developed for bioengineering products, neither have they utilized for scaffold innovation. This means that existing principles might not be applicable to scaffold design including conceptual development of 3DPVS. Therefore, the key of identifying a TRIZ-based innovative solution for 3DPVS lies on translating a set of scaffold-based conflicts into the generic conflicts established in TRIZ. Simultaneously, the potential solutions, inspired from innovative principles, need to be translated into solutions tailored for 3DPVS scenario.

In this connection, a wide degree of analysis, interpretation, and new understanding on TRIZ innovative principles are necessary when utilizing TRIZ on 3DPVS design. So to speak, the process of translating solutions from generic TRIZ-based traditional ones into the specific, tailored solutions applicable for scaffold design specifically for 3DPVS, will be of highly significance and contents of which will be discussed in the following section.

4.2 Innovative principle analysis (IPA) and 3DPVS potential strategy

TRIZ-based techniques traditionally use 40 inventive principles to eliminate System Contradictions (SC). How to utilize these innovative principles on 3DPVS tends to weigh significantly regards its proportion inside entire design process. However, for the novel cross-domain aspects existing in 3DPVS, old explanations could be limited, and new interpretation tailored for novel bio-design seems of
urgency to explore. Aside from understanding 40 principles from traditional engineering perspectives [28], perception on 3DPVS based on bio-design especially for 3DPVS can be explored. In this connection, examples from general engineering world could be illustrated, in order to help clearly understand the definite principle.

4.3 Separation principles for solving physical contradictions of 3DPVS

While System Contradiction (SC) for 3DPVS is a conflict between two parameters at system level, namely different parameters either at 3DPVS’s super-system, system, or sub-system levels, Physical Contradiction (PC) is the conflict between two desired values of one parameter at same 3DPVS system level. These PCs could be eliminated by four separation principles as follows in Table 4. In terms of the relationship between Separation Principles and the 40 TRIZ innovation principles, we could also categorize the latter into four classes. This categorization fully suits with 3DPVS product.

Except from direct analysis on PCs, transition from SC into PC could help understand SC as well as transforming it to an easier-level problem for solving. For sake of efficiency in 3DPVS design, SC to PC for example can be coded as:

{A higher scaffold contains more cells, WHEREAS has poor stability during dynamic cell culture. Two conflicting parameters: ‘height’ of scaffold \(<\) ‘stability’ of the scaffold. Physical Contradiction: One parameter, “height” of scaffold, ought to have different values of low and high.}

5. SFMA into 3DPVS scenario

Substance-field modeling and analysis (SFMA) is one vital part composing TRIZ engineering. SFMA is potentially of high value to the four-route methodology established previously. In this section, several aspects regarding SFMA as well as its application on 3DPVS will be studied as follows.

5.1 Studying SFMA and its philosophy

Invention and Separation Principles inside the TRIZ methodology, as discussed, could be applied for 3DPVS design. Cooperating with this, another tool inside
TRIZ for innovation and problem-solving is substance-field modeling and analysis (SFMA), which aims to provide standard solutions not related to specific areas of technology but enable the solution transferring from one scientific branch to another. This system, namely System of Standard Solutions, is especially beneficial for solving complicated problems by using a combination of several standard solutions. Philosophy of which is built upon the foundation that in different domains of science and industry there exist a definite number of graphic models that describe the oceanic amount of problems, thus a definite number of transformed graphic models can illustrate possible solutions. Each Standard Solution will propose one pair of such graphic models for solving similar, standard problems when System or Physical Contradiction in Route 1 and 2 could not be effectively anchored. In brief, Substance-filed Analysis (SFA) is the unique language of this system. For tailoring the novel 3DPVS design, SFR could be potentially utilized inside the design algorithm with several steps, which will trigger innovation and help generate fine ideas.

5.2 SFM and three-class analysis

5.2.1 Studying SFM

SFA contains three elements in chief, namely S1, S2, and F, the representation of which and possible application examples on 3DPVS design are shown in Table 5.

The analysis on two SFM, one of existing problem and another for its possible solution, is called Substance-Field Analysis. Study of the evolution of substance-field structures is also a part of SFA. This model illustrates the situations, problems, challenges, limitations, and possible solutions in a graphic, abstract form with three basic components, as shown in Figure 6a.

5.2.2 A three-class analysis for function between S1 and S2

Understanding the basic components of SFA, it is important to have a clear picture regarding the interconnected relationship between these three components, namely the relation in S1, S2, in S1 and F as well as in S2 and F. Three classes could be summarized corresponding to the relations, with three definite symbols representing different types of functions, shown in Figure 6b.

| SFA elements | Description | 3DPVS application example |
|--------------|-------------|--------------------------|
| Substance S1 | a “tool” or “instrument” utilized for producing a product, manipulate a function, control, measure or change values of product’s parameters; | materials and solid items like water, cell, cell culture medium, scaffold, vibrator, 3D printer etc. |
| Substance S2 | the “product” or “object” which is to be produced, manipulated, measured or changed; | materials and solid items like water, cell, cell culture medium, scaffold, vibrator, 3D printer etc.; S1 in one design scenario could be S2 in another; |
| Field F      | the energy or energy field or medium utilized for the interaction between S1 and S2; | energy like magnetic, mechanical, electrical, chemical, thermal, acoustic field etc. |

Table 5.
SFA elements, description and 3DPVS application examples.
For the three classes inside the SFA, that is, the class concerning system with incomplete or inadequate element or function, the class concerning system to eliminate harmful or hindering actions, and the class where system is to strengthen insufficient action, they have been summarized as Table 6, which also illustrates proper application on 3DPVS.

| Class No. | System Indication                        | Description                                                                 | Direction for 3DPVS scenario                                                                                                                                                                                                 |
|-----------|-----------------------------------------|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Class 1   | system with Incomplete or Inadequate SFM | Merely S1 exist and the system lacks F and S2, therefore S1 could not generate the Desired Functions. To solve this issue, F and S2 can be introduced to create a complete model; | Take S1 as Scaffold for instance. S1 is to have vibratory Functions, so Field or Vibratory Filed F provided by S2 needs to be introduced to provide the Vibratory Functions to S1. F can be a magnetic field and S2 the magnetically vibratory materials. |
| Class 2   | System to Eliminate Harmful or Hindering Actions | The sub-field model is complete but exists harmful, negative actions. Designers need to integrate new substance or field to eliminate, counterbalance that negativity. That is, S1 here has normal and negative actions to S2 through original field F1. Solution might involves introducing new elements into system, i.e., S3 and F2 having positive or counterbalancing effect on S2 is introduced so original harms will cease to some extent. | For undesirable vibration frequency: S1 is vibrator, F1 the mechanical force to transmit the vibration and S2, the scaffold to be vibrated. Existing vibration is rough and imprecise; the function is not desirable since we want precise and subtle vibrations. Then a subtle vibration mechanism, a vibrator with higher controllability in frequency can be introduced as S3, and F2 will be a more subtle and controllable frequency effecting S2 scaffold. |
| Class 3   | System to strengthen or enforce insufficient Action | Model is complete with S1, S2 and F, but effect from S1 onto S2 through F is deficient or inadequate. Solution for this comes as introducing new Substance S3 and Field F2, so the combined effect from S3 and F2 act as the Neutralizing Force which strengthens the original Deficient Action. | Scaffolds made of Smart Materials may lack strength on mechanical properties, i.e. the structures remain unstable and easy to break; Smart materials as S1, mechanical influence as F and Scaffold's structural stability as S2. Realizing other materials S3 helps strengthen structural solidity not hindering original dynamic functions of S1 onto Scaffold; mixing traditional Materials S3 with S1, effect of F2 can strength F1 then help achieve the desired structural stability. |

Table 6.
Three levels of SFA with possible application on 3DPVS.
5.2.3 SFMA into analytical model of system conflicts (AMSC)

From the three-class SFA there are several models of typical conflicts for System Contradictions, which could be used in design methodology. These models are called AMSC. Due to study, 11 AMSC could have practical use for 3DPVS context. In this

| No. | AMSC             | Description and analysis                                                                 | Direction on 3DPVS                                                                                      |
|-----|------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| 1   | Counterwork      | Positive Action or function from S1 to S2 is accompanied by the reverse negative or harmful action or function. | Scaffold holds cells and cells gradually damage scaffold.                                             |
| 2   | Mated function A | Positive Function from S1 to S2 is combined with a negative function from S1 to S2, that is, same function can be both positive and harmful at different stages or aspects. | Vibration can accelerate cell growth while damage cells.                                                |
| 3   | Mated function B | S1 generate positive function to part 1 of S2, while damage part 2 of S2.               | For vibratory cell culture, a definite vibration can help cell proliferation but hinder gene expression. |
| 4   | Mated function C | For a S1, S2-A, S2-B system, function from S1 helps S2-A, while hinders S2-B.           | Heat from 3D can melt one material of the material mixture, but damage another.                        |
| 5   | Self-compensating function | While S1 generate useful function to S2, it generates negative aspects on itself. | Some magnetic materials act to magnetic field vibration while their magnetic power is running out. It needs to be charged during the period or after use. |
| 6   | Incomplete or Absent function | There are three types. First, S1 generates several useful functions but one or more is absent; second, S1 generates one useful function and strength of which is weak, and third means only product S2 exist while Tool S1 is missing. | Vibration could help proliferation but does little on differentiation; Vibration does not generate sufficient frequency; traditional 3D static scaffold which lacks vibratory stimulation; |
| 7   | Insufficient Function | Like the fifth model, useful function from tool S1 to product S2 is not enough.          | Cells require a 500HZ frequency of vibration, but mechanical stimulator can generate 300 at maximum.  |
| 8   | Excessive or Overloaded Function | There are excessive actions generated from S1 to S2 than required.                      | Mechanical vibration tends to be rough compared with subtle vibration means;                            |
| 9   | Uncontrollable or low-controllability Function | S1 generates useful action to S2, but it is not controllable.                            | Vibration generated is continuous, while cells need periodic vibration.                                |
| 10  | Incompatible Function | Two tools (S1-A and S1-B) generate useful functions for product (S2), while these two functions contradict or hinder each other. | Definite scaffold's material composition helps cell growth and definite pore structure of scaffold helps cell growth, while the material cannot be fabricated into that pore structure. |
| 11  | Mutual-damaging Function | S1 generates harmful action to S2, and S2 have negative effects on S1.                 | Scaffold hinders the movement of fluid medium for cell culture, while the fluid can corrupt some material of scaffold. |
section, we will illustrate these AMSCs with description, analysis as well connecting with 3DPVS scenario. Using these AMSCs, identifying types of problems and possible solutions tend to be easier and effective. Analyzing AMSC with potential ISS, which will be discussed later, designers could practically find innovation concepts for most design issues (Table 7).

6. Innovation standard solutions (ISS) assisting 3DPVS design

TRIZ Innovation standard Solutions (ISS) have been proved as powerful tool for product innovation and novel design [29, 30]. As illustrated in the four-route methodology, ISS could help solving contradiction especially in Route three, where contradiction could not be easily identified as technical contradiction or physical contradiction. Besides this, ISS could be used separately as a philosophy of general Innovation thinking, which could help designers be more practically creative.

6.1 Knowledge and concerns of the dual innovation standard solutions

In recent years, Oxford Creativity, by Karen Gadd and her teams, updated TRIZ Innovation standard solutions into new formats in order to make it relatively easier to implement [29]. Both types of solutions could benefit the design purpose, and in this study, we will firstly learn from the philosophy and then adjust the solutions tailored for 3DPVS design context.

Altshuller and his associates generated the “76 Standard Solutions” in TRIZ between 1975 and 1985. These solutions were grouped into five categories as shown (a) Table 8. Despite its high popularity, there are several concerns when trying to utilize them into the 3DPVS innovation context. Firstly, SFA connected with this solution system offers innovative solutions, but some of them tend to be difficult to apply when solving problems. For a given problem, researchers sometimes need to read through every principle to find the suitable one, that is, the traditional 5-class categorization might not be effective in quickly indicating the right direction for problem-solving. On other hand, some solutions could be too general, and others seem to be too specific and focused only in one application. For example, ferromagnetic was the novel product 30 years ago, so TRIZ used it as one of innovation solutions; but taking this to current innovation world is narrowed, that is, “ferromagnetic solution” needs to be put together with antiferromagnetic, diamagnetic, ferromagnetic, and paramagnetic, so to make this solution more generalized and practical. In this regard, for the tailored ISS used for novel design, especially 3DPVS, while the core philosophy remains, some of the solutions might need to be adjusted or rearranged, for more effectiveness and efficiency.

On other hand, studying Standard Solutions Adjusted by Oxford Creativity is also important for the restructuring work into 3DPVS context. Oxford Creativity restructured a new Standard Solution System from the traditional one, aiming to pattern the 76 principles into easily understandable formats so more people can use it quickly. Its classification is shown in (b) Table 8. The new standard solutions provide with high understandability, especially for those who are not familiar with TRIZ and those who want instant solutions. However, there are several concerns in this categorization. Before adjusting their solutions to ISS of 3DPVS, understanding this is considered as necessary. That is, first, TRIZ solutions focus on system development, which
contains sub-system components, system, and super-system. Oxford Creativity does not prioritize in system. And in this connection, some definition of solutions might be vague. For example, formula of solutions as, “1.1 Add something to/inside the subject or object,” and “1.3 Use the environment,” which seems too general and not practically helpful. Also, some definition of the class seems debatable. For example, to “Eliminate, trim out the harm” occupies six solutions, and to “stop, block the harm” occupies another 11. The two classifications however describe the same Harm-elimination process, just in different level or degree. Eliminating harm means fully stopping and partially stopping means eliminating. Further concern is regarding Field and Action. In TRIZ, action is a by-product resulted from the reaction of F, S1 and S2, basically the consequence of elements or process generated by elements. Field and Action are not the “phenomenon” in one level. Field can contain an action, but not action itself. Additionally, the congruity could also be a concern. For example, the first two solution classes of Oxford Creativity, namely Harm and Insufficiency, are based on functions between field F and Substances S1, S2, while the third one, namely measurement, is based on requirements by researchers on the product level or on the function level of product. For another example, for the Measurement, there includes two Functions as well, harmful means of measurement or insufficient means measurement, then solutions given in Measurement category seem as repetitive with solutions given in first two categories. In practical use, this might cause repetitiveness in solution-searching [29]. Some standard solutions are partly repetitive with 40 principles. Therefore, rapid solution-searching while maintaining the general

| Class No. | Description                                      | Notes                  | 3DPVS Applicability |
|-----------|--------------------------------------------------|------------------------|---------------------|
| 1         | Improving the system with no or little change     | 13 Standard Solutions  | Yes, high           |
| 2         | Improving the system by changing the system       | 23 Standard Solutions  | Yes, high           |
| 3         | System transitions                               | 6 Standard Solutions   | Yes, high           |
| 4         | Detection and measurement                        | 17 Standard Solutions  | Yes, low            |
| 5         | Strategies for simplification and improvement     | 17 Standard Solutions  | Yes, low            |

vs.

| Class No. | Description | Notes                  | 3DPVS Applicability |
|-----------|-------------|------------------------|---------------------|
| 1         | Harm        | 24 Solutions with 4 Sub-class | Yes, high          |
| 2         | Insufficiency | 35 Solutions with 3 Sub-class | Yes, high         |
| 3         | Measurement | 17 Solutions with 3 Sub-class | Yes, low          |

Table 8. (a) Innovation standard solutions by traditional TRIZ vs. (b) Adjusted innovation principles by Oxford creativity.
congruity is needed. These concerns might need to be addressed, to a certain extent, in the ISS established for 3DPVS design.

6.2 Restructuring ISS for tailored 3DPVS design context

To assist with the four-route methodology established by this research for the novel development of 3DPVS, we attempt to adapt and restructure the Innovation Standard Solutions (ISS) based on Altshuller’s 76 Standard Solutions and the simplified version of Oxford Creativity.

As early introduced, the essence of 3DPVS development is a cross-domain scientific design covering realms of scaffold engineering, vibration science, mechanical science, 3DP, and so forth. Therefore, standard solutions or principles need to be tailored, or at least compatible for these realms, to ensure with design proficiency and convenience. The proposed ISS contains most of the original standard solutions in both traditional TRIZ and Oxford Creativity, with new extensions and modifications; that is, part of the TRIZ and Oxford solutions have been simplified to make it more scientifically specific and accurate, part have been modified to be general and applicable for wider context, and several derived new solutions have been added covering novel cross-domain innovation aspects. In brief, ISS for innovation of 3DPVS, as well other similar bio-product design, is proposed to make best of both worlds of traditional TRIZ and Oxford Creativity while addressing some limitations they potentially have on 3DPVS context. Traits of ISS include but not limited to following aspects: first it can be directly anchored with the 40 Innovation Principles for solving 3DPVS System Contradiction; second, it potentially provides with more effectiveness, clarity, and integrity when cooperating ISS with SFMA methods; and third, new formula of most solutions has been uniformed: “what action” + “how to act” + “where/when is the context”; this makes each solution be understandable, specific, and accurate. In this connection, four classifications with be established, with the philosophy and focus as follows.

Contradiction-solving-based. In this category, five Solutions revolve around solving concerns related with consciousness and contradiction-solving. Consciousness from one engineering realm toward others, especially cross-domain ones, seems always challenging and understanding, addressing this is thus necessary for every designer. Since contradiction is the core of problem-solving in TRIZ, better understanding and analysis on contradiction and make it applicable, become another vital issue. It is also worth noting that before analyzing the solutions of usefulness, or harm, which will be discussed later, the system model itself needs to be established properly in accurate way; otherwise the following analysis to tackle “harm” or strengthen “usefulness” will be ineffective or even faulty. The process of establishing a proper SFMA is predominant, and it can be considered as “Neutral” in terms of the desired or undesired functioning of reality system, which is represented by “usefulness” and “harm” respectively.

Usefulness-based standard solutions. In this category, eight Solutions concern with Useful Action, function, or Activity that is needed by system while seems lacking, incomplete, or inadequate. First, four solutions will be about “Creation of SFM from incomplete model”; second, two solutions are regarding the “Delete excessive elements of SFM, and making it simplified”; third, one solution focuses on “Transform traditional SFM into NSFM which contains the analysis of Three Forces.”

Harm-based standard solutions. As the opposite of “usefulness,” “harm” needs to be mitigated, decreased during design process. This category contains 26 elementary
solutions with two basic strategies in problem-solving. First, 18 solutions would deal with “Eliminate the Harm or Decrease its Degree” and secondly, eight solutions focus on “Transform harmful functions, activities or objects into positive.”

Similar as Usefulness-based solutions, “harm”-based solutions could potentially be applied not only on technical engineering aspects for 3DPVS but also useful to solve other harmful actions or functions as it represents the very H force in Law of Three. These solutions could potentially be the universally standard solutions to the engineering, scientific, and philosophic world, which deals with “Harm” and “Usefulness.”

**Insufficiency-based elements.** Two basic strategies composing 37 solutions are included in this category, which aims to help improve, change, or enhance definite functions by changing the Substances (S1 or S2), or the action/field (F), which acts between them. Nineteen solutions deal with the “Change, evolve the system” components or add new elements to them. Eighteen solutions focus on “Enhance, strength or improve the Action focusing on Insufficient or Missing Field.” In this category, to find the right F when there is an object (S2), which needs to provide some extra functions or change, a subject or tool (S1) with a field (F) to deliver/complete such function, becomes the key. This group of standard solutions also helps find a solution, particularly when cooperating with Scientific Effects Analysis.

To conclude, ISS established inside TRIZ-based methodology could increase the speed of generating innovative ideas and creating novel but practical concepts, which is especially necessary in the 3DPVS conceptual developing scenario. ISS could not only be used for Route 3 and 4 where no easy identification on System Contradiction or Physical Contradiction of definite design question can be obtained, but also as general innovation standards for much wider multi-cross domain designs and innovations.

7. **Concluding remarks**

In this study, TRIZ methods have been reviewed systematically and exploring them for the concept design of 3DPVS has been illustrated and discussed. Following this study, a proper methodology derived from TRIZ could be created. Considering the possible limitations of traditional design approaches on scaffold engineering and the limitations on TRIZ, we tailored and transferred traditional TRIZ-based principles into the new context that can be directly applicable by concept generation of 3DPVS. For several key information, for example, the generated concept criteria, rank scores, and selected optimal concept, readers can refer to author’s another paper [31] for more details.

Further connected, this study aims to provide a useful, effective, and accurate cross-domain aspects of TRIZ for the innovation and design for novel scaffold. In this connection, 39 Parameters TRIZ Matrix and 40 Innovative Principle for system contradiction could be attempted with core elements transferred into scaffold contents especially tailoring for 3DPVS conceptual design. This means that, original explanation of TRIZ principles and parameters, their possible and extended indication, as well as the application on 3DPVS could be analyzed comprehensively. SFM and SFMA have been studied and proposed with their potential new functions, with the Three Forces embedded. Next to this, from traditional TRIZ-based ISS and the newly brought ones, a same-essence but restructured format can be generated, conveniently dealing with the comprehensive aspects appearing on innovating 3DPVS. The ISS for 3DPVS coming from the Innovation principles, making SFM process more easily addressable.
This study has established a ready-to-use knowledge base, which could connect TRIZ innovators and those who focus on novel 3DPVS designs but do not know how to use TRIZ. Utilizing TRIZ-based method, it is expected that the conceptual design, especially the concept generation, will take place more efficiency. Thus the study can fill a gap in the scaffold design and TRIZ literature, which are preliminary to preparing future works of establishing formal TRIZ-based methodology for scaffold innovation.

In terms of the future work following this study, it may include a validating part on the Expert Survey, which can be conducted on experienced experts in relevant but cross-domain academic realms. Analyzing experts’ feedback, we might draw a preliminary conclusion about the basic relevance, usefulness, and practicality of TRIZ-based methods on 3DPVS conceptual design.

Compliance with ethical standards

Conflict of interest

The authors declare no conflict of interest.

Ethical approval

This study does not contain any studies with human or animal subjects performed by any of the authors.

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