



Development of a Collaborative Approach of CAD and Technical Textiles for Sustainable Healthcare Products

Jonathan R. Binder¹ , Subhadeep Paul²  Ertu Unver¹  Dipo Olaosun¹  and Parikshit Goswami¹ 

¹Huddersfield University, J.binder@hud.ac.uk

²Northumbria University, subhadeep.paul@northumbria.ac.uk

¹Huddersfield University, E.unver@hud.ac.uk

¹Huddersfield University, r.olaosun@hud.ac.uk

¹Huddersfield University, p.goswami@hud.ac.uk

Corresponding author: Jonathan R. Binder, J.binder@hud.ac.uk

Abstract. This research explores applications of CAD technologies in a multi-disciplinary approach in collaboration with researchers in medical design and technical textile engineers. New wearable medical cooling materials have been proposed to replace non-recyclable materials where testing and CAD tools enabled a collaborative approach for suitability between design, fashion, engineering, and manufacturing. Extensive literature explored the parameters for developing a new material and scalp cooling cap cover design for the prevention of chemotherapy-induced Alopecia, where medical SMEs can embed knowledge for cross-discipline development in healthcare. Extensive technical textiles testing and analysis were conducted predominantly for thermal insulation and water vapor permeability, exploring the properties of the fabrics in a comparative way in a heavily regulated design industry.

Keywords: Technical textiles, new medical product development, computer-aided design, scalp cooling.

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1 INTRODUCTION

Medical device manufacturing is a complex landscape that requires the harmonious collaboration of various disciplines [1]. Due to the complex and heavily regulated nature of medical devices, development leans on expertise from several disciplines. Particularly where the development of textiles is involved, the approach used in healthcare will significantly differ from the development of standard products such as jumpers. The developed materials must comply with ISO10993 biocompatibility testing, such as Cytotoxicity, for textiles that directly contact the skin, particularly for wearable designs. This framework utilizes a collaborative approach to the development of textiles with technical textile experts and medical designers.

In line with the UN's sustainable development goals, where responsible consumption and production are involved [2], there is an ever-growing demand for designers to integrate more

sustainable approaches to product development. However, typically in healthcare, thermosets, and non-recyclable plastics such as Silicones and Neoprene's are used, leant to their specific properties such as biocompatibility, infection control and hydrophobicity that make them so suitable [3]. Paxman have undergone an Innovate UK funded project to replace these plastics for recyclable sustainable materials.

The textile and fashion sector in United Kingdom is predominantly working towards imparting net zero and circularity [4]. To achieve a circular supply chain, industry standards are being altered and selection of eco-friendly and sustainable raw materials are being promoted. Technical textile is one area which provides value added textile products for specific and technical applications in the field of households, aerospace, automobiles, medical, geology etc. [5]. Medical textiles deal with the involvement of antibacterial textiles, scaffolds, bandages, high sorption fibres, and drug delivery devices which are needed during daily usage in healthcare [6-9]. Further usage of raw materials which are obtained from biological sources or have the potential to be fully recycled contributes towards imparting circularity in medical textile wastes.

Paxman manufactures scalp cooling caps for the prevention of Chemotherapy-Induced Alopecia. The wearable heat exchanger is worn on the head to induce vasoconstriction, limiting delivery of drugs to hair follicles without causing scalp metastases. The caps are made of an inner cooling cap and an outer cover. The outer neoprene cap cover for scalp cooling is explored, where a new material is developed to replace the existing neoprene. Technical testing is applied in an iterative design approach, where certain parameters are applied that are typically not heavily used in the textile industry such as heat extraction.

Traditionally, technical textiles tools and development CAE use software packages evidenced in this paper such as lifecycle assessment tools. CAD software is typically never used in textiles design particularly as they aren't often considered as friendly for fabric modelling, hence Clo3D and other packages are explored. This paper emphasizes as collaborative approach between technical textiles teams and designers where a combination of these CAD and software packages can be used in tandem for the development of wearable fabrics with complex applications requiring the development of bespoke engineered fabrics.

1.1 Methodology

A mixed methods approach where iterative design [10,11] is used to integrate textiles and product development to produce a new approach that could be beneficial for researchers and medical design industries. This approach required a new method for implementing test procedures with CAD tools for knowledge exchange between the disciplines for new procedures, new devices, and testing kits. These approaches are important for the successful implementation of medical regulations and suitable engineering methods for wearable soft-good medical devices. These approaches can be applied to develop new approaches for new products to improve health worldwide.

The flowchart shown in Figure 1 below highlights a framework utilized by the multidisciplinary team, where a Medical SME was able to collaborate between different departments at a university in a combined research effort. Utilizing Paxmans, extensive knowledge of medical design, regulatory approval, and network of oncologists and teams at Huddersfield University for product design, engineering, and technical textiles knowledge help an SME propose a new wearable cap cover material.

2 LITERATURE REVIEW

An extensive literature review and recyclability criteria of raw material production were used [12,13] to select an alternative material to Neoprene, which is open-cell polyester polyurethane foam as the middle layer for the cap cover. This case study utilizes a Paxman scalp cooling cap comprised of 2 main components: the wearable heat exchanger and the outer cap cover, which is currently made of neoprene. The outer cover functions as an insulative barrier against external temperatures and enables improved fit of the cap to patients' heads, which is crucial for hair retention efficacy. Open-

cell foams are readily available, low-cost, recyclable, and possess a high thermal insulation property due to their open-cell structure [14]. These types of foams are seldom used in the field of medical products.

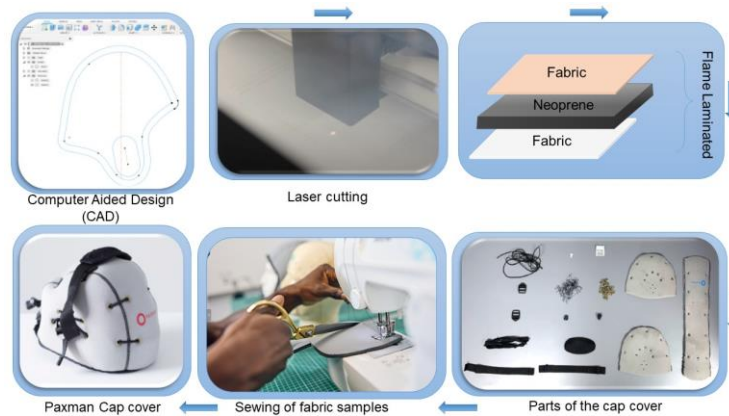


Figure 1: Flow chart representing the method of interdisciplinary prototyping.

Neoprene is a type of synthetic rubber that is synthesized by free radical polymerization of chloroprene monomers. Neoprene was used as the material to bind with other fabrics for the development of the Paxman cap cover. Neoprene is highly flexible, chemically resistant, water resistant, and possesses high thermal insulation properties. The environmental impact of neoprene is quite high as the raw materials are derived from petroleum-based sources and persist in the environment for a longer period due to the slow biodegradation rate [15]. This led to the search for an alternative raw material that would be recyclable and cause less impact on the environment in terms of the depletion of fossil fuels.

Open cell foam of thermoplastic polymers like polyester or polyurethane can provide properties like high thermal insulation [16], porous structure, less material density (compared to neoprene, which could make the cap lightweight), and allow moisture to pass through [17,18,19]. Polyester and polyurethane-based foams are recyclable and, at the same time, provide stable elastic and tensile properties (depending on the foam density and thickness and the structure of the polymer). This acts as an added advantage for the open cell foam compared to the Neoprene layer.

Direct comparison from neoprene to open-cell foam is difficult due to differing formulations. The densities, formulation, and composition of layers can bring challenges to like-for-like performance testing. The thermal insulation properties depend on the material and material design, which we will measure in later testing. For the thermal insulation range, we needed to optimize the properties of the cap cover. We looked at tensile strength and elongation properties as variable parameters. With the replacement of neoprene, ranges were provided as specifications to where we could compromise on formulation through tensile strength and elongation, but no insulation. The formulation of the new material would need to be directionally flexible, requiring fine-tuning of the tensile and elongation properties with the development of a new foam. This formulation would influence other factors, such as water vapor permeability and density influenced by the formulation of the open-cell foam. Structural considerations of components such as positioning, size, and force applied to eyelets must be supported by the new material, where multi-directional forces could compromise the material if too much force is applied. Comparative properties of Neoprene open-cell polyester and polyurethane foam are provided in Table 1.

<i>Material</i>	<i>Tensile strength (kPa)</i>	<i>Elongation at Break (%)</i>	<i>Properties</i>
Neoprene	588	400-500	4-way stretch, high thermal insulation, highly waterproof, dense
Open cell polyester and polyurethane foam	150	250	High thermal insulation, low density, porous, breathable
Nonwoven fabric (Polypropylene, polyester)	123	25-45	Low thermal conductivity, high porosity and low density
Wool woven fabric	1.7	35 (dry), 45 (wet).	High thermal insulation, light density, and less porosity

Table 1: Comparison of properties between Neoprene and open-cell polyester and polyurethane foam.

2.1 Technical Considerations

This project investigates the development of new materials to potentially replace neoprene from an outer cap cover for scalp cooling. The Paxman neoprene cap cover is used as a reference for the case study. An outer fabric layer or sleeve is typically used to develop a wearable heat exchanger on the body. The main purpose of this multi-layered structure is to insulate the heat exchanger, preventing unnecessary extraction of heat energy from the ambient environment, ensuring heat extraction is targeted at the subject, and reducing the unnecessary increase of coolant temperature caused by external heat.

Several crucial parameters are considered inputs for the new selection process. The Neoprene cap cover consisted of three layers: Neoprene at the center, polyester fabric, and Terry nylon fabric for the top and bottom layers (Figure 2). Each layer plays a specific role for the device. The outer layer is for aesthetics and infection control, the middle layer is insulative and the inner layer is biocompatible and comfortable for direct skin contact.

The new cap cover prototypes were designed using materials that followed extensive research against the parameters outlined by the existing cap. In Figure 2 below, prototypes were manufactured from a bespoke open-cell polyester polyurethane foam consisting of three layers: open-cell foam at the center, polyurethane-coated polyester fabric, and brush nylon fabric at the top and bottom layers (Figure 1). Several combinations of these three-layered fabrics were tested based on their tensile strength, elongation, stretch, raw material, and type of structure. Among them, the open-celled foam with these combinations was selected for the new working prototype depending on its performance. The thickness of the open cell foam was varied to obtain prototype cap cover samples of varied thickness, which are 8, 13, and 18 mm. All the layers of the cap cover were flame laminated together to retain sustainability and to form a composite fabric, which was used for further testing.

2.2 Technical Textiles Testing

In this paper, 2 main parameters crucial to the function of the cap are presented, thermal insulation and water permeability, even though a plethora of parameters have been evaluated. Utilizing the expertise and facilities at the Technical Textiles Research Centre at the University of Huddersfield, in collaboration with Paxman on an Innovate UK SMART project, the team was able to iteratively explore over 50 material types, blends, and grades of fabrics in over 200 prototypes, shown in Fig 2 below. An interdisciplinary approach to wearable prototype development may include generic design processes to bridge the gaps in knowledge, as shown by the taxonomic classification of visual

design representations [20]. However, 2D design still plays an important role in the fashion industry, where 2D CAD is predominantly used, though 3D CAD is still explored [21]. Testing methods for textiles and CAD are largely used, as seen in the University of Huddersfield [22], particularly in the Technical Textiles Research Centre.

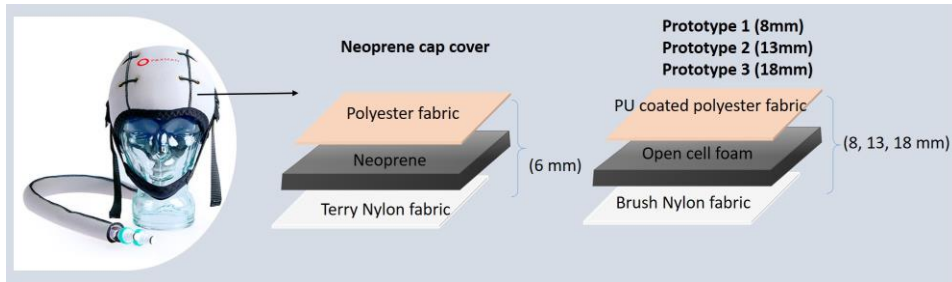


Figure 2: Proposed cap cover samples of neoprene and new prototypes.

The textile design process is a broad field, covering fashion, textiles, garments, and costumes, where various tools are used. In this application, other aspects typically explored in the fashion and textiles industry are not explored for the design of a new sustainable wearable scalp cooling cap cover. For a medical SME, there may not be all the resources or knowledge required to develop new materials or methods in other areas. Particularly for healthcare, the medical device market is heavily regulated, requiring evidence of safety and efficacy. In this project, a new cap cover material and design are explored in an Innovate UK-funded SMART grant project. The medical SME Paxman utilized existing relations in the Paxman Research and Innovation Centre at the University of Huddersfield to explore collaborations in other networks.

Evaluation of final prototypes in a commercial setting, particularly for medical devices, may require outsourced laboratory tests. This case study uses Paxman, where Paxman facilitated the evaluation of use with their current products, resources for design and development (workshop, facilities), and R&D knowledge for medical device design and development. The project focused on redesigning Paxman's current cap cover made from neoprene, and this enabled new samples to be benchmarked against a predicate device. This included multi-stakeholder collaboration, where usability testing with patients, oncologists, trainers, and users was possible. The CAD development came from In-house, where Paxman used commercially licensed software to develop designs for the samples tested. The Paxman Research Centre, an already established bridge between industry and academia, is used, where the University proposed collaboration with the technical Textiles Research Centre.



Figure 3: Thermal conductivity testing and water permeability testing machines.

2.2.1 Thermal Insulation

All the cap cover fabric samples were tested for thermal conductivity following the ASTM C518 testing standard. 20x20 cm fabric samples were used for the evaluation of thermal conductivity. The testing was conducted on a thermal conductivity instrument (TA-Instrument-Waters LLC) which represented a heat flow meter. The conductivity of the samples was calculated at a temperature range of 10-40°C. The testing sample was placed between two plates of varying temperatures (10 and 40°C), and the heat flow was directed from the bottom plate to the top plate. The instrument generated the data for thermal resistance, which was further used to assess the thermal insulation of the fabric in TOG. All the fabric samples were conditioned at 20 ± 2 °C and $65\pm 3\%$ for 24hrs.

2.2.2 Water vapor permeability

All the cap cover fabric samples were tested for water vapor permeability following the BS 7209:1990 testing standard. 9 cm circular fabric samples were used for the water vapor permeability tester (TESTEX). The samples were fixed on a disc containing water (measured by weight). The water vapor permeability index was calculated by observing the difference in weight of the amount of water that was left over after 24hrs. of the experiment. The water vapor transmission rate was calculated with respect to a reference sample according to the standard. All the fabric samples were conditioned at 20 ± 2 °C and $65\pm 3\%$ for 24hrs and the experimental conditions were also kept the same as followed by the BS 7209:1990.

3 COMPUTER-AIDED DESIGN

CAD packages were essential to developing prototypes in collaboration with textile experts to understand the composition of the materials so fabric patterns could exploit certain parameters such as directional stretch and natural compression. In this, software and CAD packages previously explored or already used by R&D teams at Paxman and Huddersfield University were explored to develop optimal cap cover designs. Textile design and pattern-cutting oriented CAD packages like Optitex and Clo 3D were analyzed [20]. For design and development, SolidWorks was used to generate DXF files for pattern cutting and technical drawings for manufacturing. Also, Blender is analyzed for educational purposes, where a more organic approach to modeling is used for rendering and animation for knowledge exchange between nondesigners.

At Paxman, there are commercial facilities capable of prototyping concepts using rapid prototyping methods. The knowledge exchange in this research between the gap in knowledge at Paxman was accommodated by the Technical Textiles Research Centre at the University of Huddersfield. At Paxman, a desktop laser cutting machine (Glowforge Pro) was used to generate samples for the technical textiles department to test in their labs based on a plethora of material samples gathered from extensive research from the Paxman Research and Development team.



Figure 4: Glowforge pro machine (Left), material samples (right).

For this project, to bridge the gap between industry and Academia in an area the SME had little experience with, the R&D teams at Paxman had to investigate several CAD packages, Optitex, Clo3D,

Illustrator, SolidWorks, and Fusion. Where samples were needed, laser cutting was the predominately used technology due to their accuracy and suitability with a plethora of various materials used. These machines used DXF files predominantly, and the chosen laser cutter was a Glowforge Pro, where the premium Glowforge software was used to cut out samples shown in Figure 5 below. In this project the team used SolidWorks to generate the CAD, and an exported DXF for use with the Glowforge Pro software for laser cutting (Figure 5). Initially, some existing CAD patterns and models were used for a rapid prototyping phase for material testing and suitability of manufacturing. Utilizing SolidWorks CAD in this phase sped up the material selection process enabled by rapid in-house prototyping.



Figure 5: Glowforge software, Laser cut samples for testing.

Following this initial scoping phase, the team used a combination of common CAD packages, SolidWorks and Fusion 360, given that the geometry of the CAD was simple flat patterns not requiring complex geometry modelling such as surfacing. The team reverse engineered these basic patterns following further rapid prototyping phases in a workshop where fabrics were sliced, drawn and scanned into the CAD packages as a sketch reference. This was conducted in the early phases, where further refinement of the geometry is cleaned up using the sketch tools in SolidWorks and Fusion 360. Example of this can be seen in Figure 6 below.

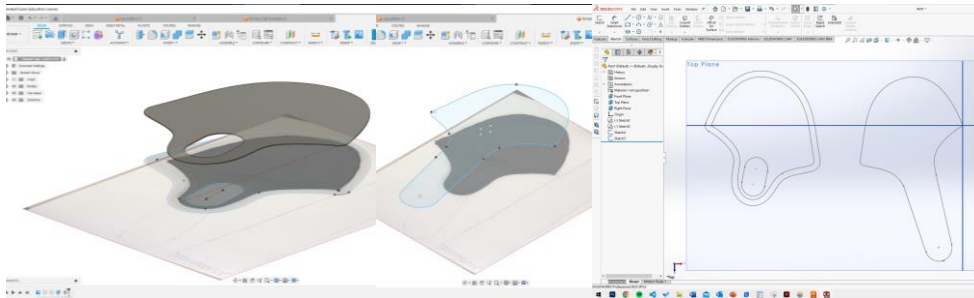


Figure 6: Fusion 360 and SolidWorks flat pattern CAD geometry modelling.

Using these rapid CAD and Prototyping techniques, the team utilized an iterative approach for the preparation of samples for technical textiles testing in a lab at the University of Huddersfield. Over 200 prototypes were generated in this process (Figure 7), where progressive refinement and optimization was achieved for developing a new cap cover design. This multi-disciplinary research deployed enabled and streamlined through CAD allowed exploration of the various CAD packages that were most efficient for medical SMEs.

Life cycle assessment (LCA) is a tool to analyse and calculate the impact of a product from its raw material to its disposal stage. This can be used to compare the environmental impact of the Neoprene and the open cell foam-based cap cover and further optimize the impact assessment of

both these caps. Using the SimaPro software we can identify the input resources, raw material, the energy inputs, and parameters which can lead to further comparative assessment of the cover materials. The data opt-in analysis can give us an alternative approach recommendation on the design of the material and the impact of changes. Even changing the type of sewing method can impact the LCA.



Figure 7: Various cap cover prototypes explored with new materials and CAD.

4 DISCUSSION

Over the years huge progress has been made in the field of medical textiles considering the demand for such material and the complexities involved in designing them. The testing phase related to medical textile involves the evaluation of specific properties including, sorption behavior, wicking properties, thermal resistance, material strength and extensibility and biocompatibility [21,22]. This article provides how CAD can be utilized to design a bio-compatible and eco-friendly medical textile that can be used for scalp cooling during chemotherapy treatment.

All the cap cover fabric samples were conditioned at 20±2°C and 65% relative humidity for 24hrs. before the testing. All the prototypes showed higher mean thermal insulation value compared to Neoprene fabric samples (Figure 7). The foams used in the prototypes are open celled which has hollow cavities in their internal structure. These cavities create air pockets which improves the insulation property of the material [23]. From Prototype 1 to 3 a gradual increase in mean thermal insulation with the increase in thickness of the samples were observed (Figure 8). Thus, it can be confirmed that thermal insulation of the open cell foam prototypes is dependent on the thickness of the material. Therefore, the open celled foam can be used as a possible replacement for Neoprene.

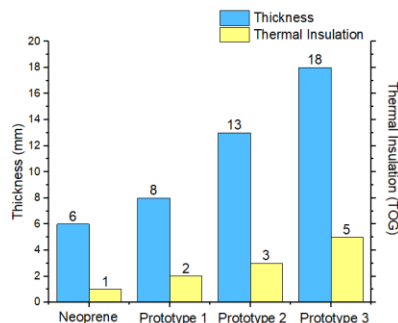


Figure 8: Colum plots for thickness and thermal insulation value of the fabric samples.

All the prototypes show higher water vapor permeability compared to Neoprene fabric samples (Figure 9). As the thickness of the open-cell foam prototypes increased, the water vapor permeability also increased. This could suggest that if condensation occurs, the transfer of moisture through the fabric will be quicker for a thicker fabric. This suggests the presence of micropores within the open-cell foam, which can aid in the diffusion of moisture vapor through the fabric [24]. Also, if the surface layer of the fabric has lower surface energy (less attractive to water molecules), it could increase the diffusion of moisture through the structure of the foam [25]. Thus, it can be said that the WVP of Prototype 1 is closer to the WVP of the Neoprene fabric sample, which did not show any condensation during the (3hrs per cycle) chemotherapy treatment.

Due to the higher thermal insulation of Prototype 1, it has a higher tendency to maintain the temperature of the micro-climate of the wearer compared to the Neoprene cap cover. At the same time, the presence of micro-pores inside the open cell foams will make the material breathable, and the wearer will not feel any discomfort if condensation takes place. Thus, among the samples tested, Prototype 1 could be accepted as an optimized sample in terms of thermal insulation and WVP.

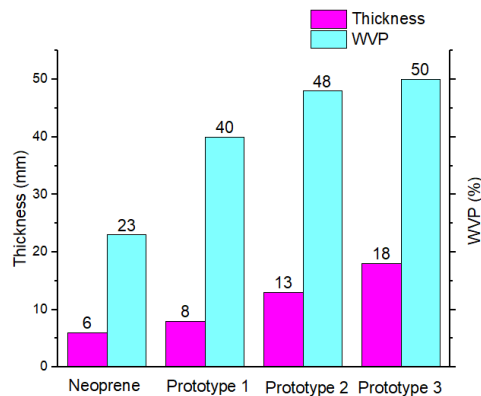


Figure 9: Column plots for thickness and water vapor permeability value of the fabric samples.

5 CONCLUSIONS

Following a successful collaboration with the technical textiles department in an innovative UK-funded project, the teams have successfully developed a new open-cell material for use in a cap cover for chemotherapy-induced alopecia wearable cooling devices. A new design has been proposed, and 2 patents have been filed for the new cap and cover. Utilizing CAD packages enabled the iterative design and development processes, including technical testing and streamlining of development within a medical SME between several academic disciplines to achieve a manufacturable device following a regulatory testing phase. Regulatory compliance is a long and expensive process, and the framework deployed in this project provides a lower risk and increased evidence for the successful implementation of new innovations in an international market.

Paxman R&D teams understand the importance of multidisciplinary collaboration in the development of medical devices. For SMEs, it can often be difficult to justify investment into completely new areas or new CAD technologies and equipment for testing when it can be outsourced to academic institutions. Collaborations with academia are seen as essential, where you get access to state-of-the-art facilities and equipment as well as skilled people and knowledge that are constantly being explored. In this project, the R&D teams at the University of Huddersfield and Paxman have collaborated with the technical textiles research Centre to successfully develop an alternative 3-layer solution to the existing Paxman scalp cooling cap cover. With this, extensive testing using various software and CAD packages outlined above not only streamlined the

development process of materials but also the design process, enabling the design teams to exploit the properties of the materials explored and developed fully. From this, it has been possible to optimize designs in other areas by reducing parts through self-compressive properties, which improve the efficacy and sustainability of the cap.

Further collaboration with the Technical Textiles Research Centre will be used to investigate the Life Cycle Analysis of the existing (Neoprene) and prototype cap covers using the SimaPro software. This will provide a detailed comparative study of the environmental impact assessment of the cap covers and allow the R&D design team at Paxman to investigate various raw material, manufacturing, designing and process aspects to reduce the environmental impact of the cap covers thus opting for a sustainable and eco-friendly supply chain.

Jonathan R. Binder, <https://orcid.org/0000-0001-9413-2466>

Subhadeep Paul, <https://orcid.org/0009-0007-6648-1723>

Ertu Unver, <https://orcid.org/0000-0002-9031-6353>

Rilwan Olaosun, <https://orcid.org/0009-0001-4966-8787>

Parikshit Goswami, <https://orcid.org/0000-0003-1488-409X>

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