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PRODUCTION & MANUFACTURING | RESEARCH ARTICLE

Design for reusability of medical equipment for optimal modularization using an endoscope as case study

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Abstract: The reprocessing of reusable medical equipment (RME) is complex due to the difficulty of eliminating infections. Healthcare providers have expressed dissatisfaction with the difficulty faced in cleaning and disinfecting medical equipment after use. Reprocessed RMEs include endoscopes, valves, adapters etc. This research aims to increase the ease of reprocessing and decrease the risk of infection using a collaborative modular architecture framework. The methodology is divided into four steps. First, we identify and define the product's functional and physical decompositions. Secondly, based on stakeholders' input, parameters such as design, human factors, and cost were identified to be the main factors affecting the reprocessing of an endoscope. The parameters' subsequent metrics are selected for performance requirements. Thirdly, surveys are developed to collect data about the performance of different endoscope models. Fourthly, we utilize a linear multi-objective optimization model which aims at generating representative solutions on the true Pareto front of the problem that maximizes the similarity among module members in terms of the factors. Finally, we combine the module information with efficiency feedback to derive recommendations for the users. A case study is presented using hospital data. The results indicate that there is a high risk

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The need to reduce infection rates due to improper cleaning of medical devices has been emphasized in literature and hospitals today. This research work aims to identify and distinguish medical devices that are safe and easy to reprocess after use.

PUBLIC INTEREST STATEMENT

A reusable medical device is a piece of equipment that healthcare providers can reuse to treat multiple patients. Endoscopes, surgical forceps, brushes, and stethoscopes are some examples of reusable medical equipment. Many hospitals are not carefully cleaning these devices, a dangerous practice that sometimes leads to infections or even device failure. This research studies the various groups of medical equipment, parameters that affect their cleaning based on stakeholders' input and analyze these parameters using a mathematical model to derive a cluster of devices with high-risk of infection if not properly cleaned.

of infection caused by human errors during reprocessing for endoscopes clustered in *Module 1* compared to *Module 2* and *3*. To ensure that the safety and quality of medical care rendered to patients are not compromised, we recommend that healthcare providers utilize endoscopes in *Modules 2* and *3* as they are safe and easy to reprocess.

Subjects: Industrial Design; Quality Control & Reliability; Manufacturing & Processing; Production Systems & Automation

Keywords: Reusable medical equipment; patient care; analytic hierarchy process; endoscope; clustering; multi-objective optimization; product modularization

1. Introduction

The endoscope is a complex but durable instrument and is safe for use in thousands of medical imaging procedures. It consists of a flexible tube with a miniature camera inserted into the digestive tract of a human body, as well as control knobs connected to cables that allow the tip of the flexible tube to precisely maneuver for a video image (Figure 1). Also, in the tube are channels that allow the device to sample tissue, stop bleeding, or remove polyps. In all areas of medicine and surgery, sophisticated medical devices such as endoscopes are generally not discarded after use in one patient but instead reused in subsequent patients. This practice is very safe, provided that the equipment is cleaned thoroughly and disinfected. Endoscope reprocessing has three main steps (Muscarella, 2006):

(1) Pre-processing: Cleaning the endoscope and its detachable components using a detergent solution and brushes.

(2) High-level disinfection: Using a liquid chemical germicide (LCG) followed by thorough water rinsing to remove residual LCG from the instrument. The US Food and Drug Administration (FDA) has approved and authorized the use of this process.

(3) Post-processing: Proper handling and storage of the endoscope. This final step also includes drying the endoscope and its internal channels after terminal water rinsing.

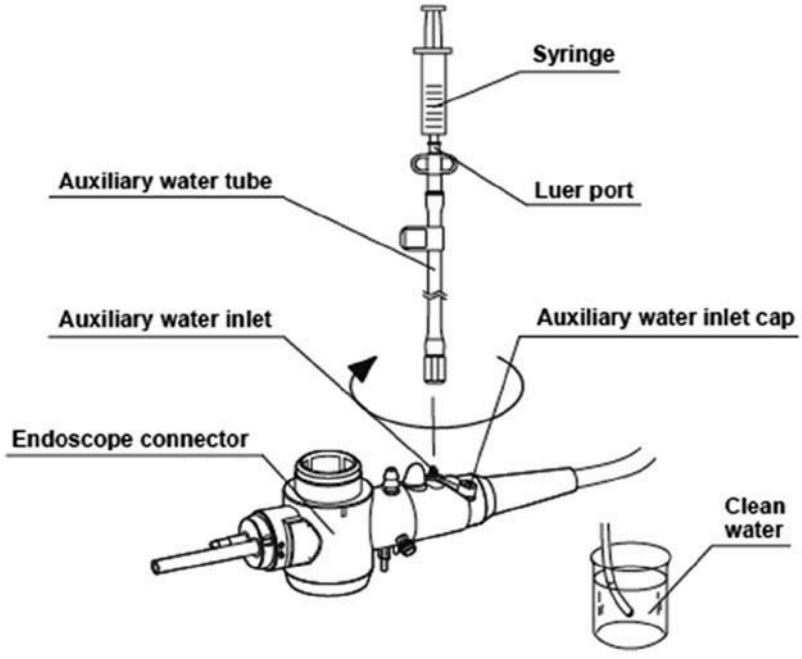

Figure 1. Olympus endoscope (Source: Olympus—Evis exera type 160 reprocessing manual, p. 25).

Although the risk of endoscopy-related infection is statistically low, contaminated endoscopes are most times the cause of healthcare-associated infection than any other medical device (Rutala & Weber, 2010; Seoane-Vazquez & Rodrigues-Monguio, 2008). The completion of twelve steps recommended by the Society of Gastroenterology Nurses and Associates (SGNA), Center for Disease Control (CDC), and Multi-Society Guidelines defined the compliance with endoscope reprocessing guidelines (Nelson et al., 2003). However, current endoscope reprocessing practice depends on vendor manuals (Desilets et al., 2010) that detail more than thirty steps, which differs for each endoscope model. A recent study (Ofstead, Wetzler, Snyder, & Horton, 2010) indicates that guideline adherence resulted in 1.4% of endoscopes being reprocessed using manual cleaning methods. Also, failure to properly reprocess a medical device can result in the transmission of infectious viruses, including Hepatitis B, Hepatitis C, HIV, and other blood-borne pathogens (Authority, 2010; Nelson, 2002; Rutala & Weber, 2001). According to the ECRI Institute, inadequate reprocessing of endoscopic devices and surgical instruments was one of the "Top 10 Health Technology Hazards" in 2013 (Institute, 2013).

The motivation of this research stems from the high contamination rates and cost of replacing endoscopes due to poor reprocessing practices observed in hospitals which compromises the quality of medical care rendered to patients. Studies have shown that in the United States, 15 million procedures involving flexible endoscopes are performed annually (Muscarella, 2006). Continued efforts are needed to ensure that quality is maintained during endoscope reprocessing to reduce the number of endoscopy-related infections (Seoane-Vazquez, Rodriguez-Monguio, Visaria, & Carlson, 2007).

Modularization is used to organize products into modules, which is a critical concept in Design for Reusability, as well as a precondition for an efficient product configuration process (Muscarella, 2006). The main idea behind this study is to apply modularization logic to simplify existing complex reprocessing procedures. In doing so, we consider multiple aspects of endoscopes and reprocessing that are generally independent of each other. We propose a scheme that can be used to group existing endoscope set of a hospital by exploring design, cost, and human factors that have direct effects on reprocessing procedures. Then, we evaluate the resultant groups (modules) separately, and standard procedures developed for each module of endoscopes.

The advantage of the current approach is twofold. First, since we supply a multi-objective procedure while optimizing similarities among each module, the user does not have to worry about selecting only one among equally important contributing factors, nor bother with deriving constraint values for the remaining factors he wants to include in the set. Secondly, with the application of multi-objective optimization methodology, the user comes up with multiple optima, i.e., representative optimal solutions, that can be used to determine the final modularization. At this stage, we propose an analytic hierarchy process (AHP) to reevaluate and reduce the representative Pareto set into a single one that contains flexibility as well, especially while choosing the assessment measures.

The rest of this article is organized as follows. In Section 2, we present the relevant existing literature with different methodologies focused on reprocessing of medical devices. Section 3 describes the details of the methodology as well as the results obtained for the case study. Specifically, we explain details about flexible endoscopes, performance measure identification, data collection, representative multi-objective optimization algorithms, and mathematical models before presenting our results and recommendations. We conclude with Section 4 and suggest possible directions for future investigations into this topic.

2. Literature review

The research by Rutala and Weber (Rutala & Weber, 2004) is one of the first and broadest endoscope reprocessing studies, which resulted in a list of forty-one cleaning rules. These rules, based on a broad literature search, involved recommendations on every step of manual and automated reprocessing. (Ofstead et al., 2010) analyzed the impacts of human factors and automating endoscope reprocessing. As a result of the analysis, which consisted of interviews,

surveys, and direct observations, the authors concluded that automation supported by enhanced training would improve guideline adherence.

(Hildebrand et al., 2010) conducted a heuristic evaluation of the endoscope multiple product designs with the reprocessing procedure. Multiple product design problems were found to disrupt users' capacities for memory, vision, and feedback. (Jolly et al., 2012) further validated these initial findings in a usability study examining the challenges that novice technicians face in completing the reprocessing procedure. This study also indicated that high memory demand, lack of visibility, and poor feedback are the leading causes of error during reprocessing. Most of the literature reviewed emphasizes that the reprocessing technician is the primary source of error (Authority, 2010). However, multiple studies underline the fact that, even if the technician follows the instructions carefully, the endoscope may remain contaminated (Seoane-Vazquez et al., 2007).

The study completed by (Hildebrand et al., 2010) :explores in detail the human factors in endoscope cleaning. The study emphasized the importance of human memory in the reprocessing procedure, the design of the endoscope, and the technician's lack of knowledge of proper reprocessing. Also, training, environment, visibility of parts, and feedback are other factors that contribute to human errors. Particularly for gastrointestinal endoscopes, improvements in cleaning devices and techniques are highly critical. (Petersen et al., 2011) developed a Multi-Society Guideline for reprocessing flexible GI Endoscopes. (Forte & Shum, 2011) developed an automated approach called EVOTECH® Endoscope Cleaner and Reprocessor (Institute, 2013), which was the first system to receive United States Food and Drugs Administration (FDA) approval to eliminate manual pre-cleaning of the endoscope before its automated high-level disinfection processing.

A reprocessing protocol has been developed by (Spaun et al., 2010), which utilizes scoring to rank the available sterilization options. This protocol involves mechanical cleaning and high-level disinfection per Multi-Society Guidelines, with subsequent terminal sterilization using a validated peracetic acid protocol. The difference between sterilization and disinfection motivated this study. (Suh, 1995) investigated the axiomatic approach to design in order to facilitate decisions made during the design stage of product and process development and their effects on product quality and process productivity. According to (Kuo, Huang, & Zhang, 2001), there are environmental concerns that mandate review of disassembly and recycling factors during the design stages. They also demonstrated that a design structure matrix (DSM) could be used to address the interdependency (feedback and iteration) of complex product development processes.

Extensive research has been done to understand the human factors in endoscope cleaning and the errors in the reprocessing of endoscopes. Several guidelines for endoscope reprocessing have been developed. However, to address the issue of reducing the risk of infection in reusable medical equipment (RME), a multi-objective approximation algorithm is preferable (Steuer & Choo, 1983; Vazirani, 2013). The model studied is a multi-objective integer programming (MOIP) problem. For this purpose, (Aguwa, Monplaisir, Sylajakumari, & Muni, 2010) used a goal programming method for modularization in a different context. However, this procedure requires rerunning the entire model by setting new goals at every iteration in order to generate alternative solutions on the Pareto surface. The algorithm we have proposed (Özlen & Azizoğlu, 2009) can generate a whole Pareto surface for MOIP problems. Our contribution to knowledge via this research is by utilizing the algorithm to generate a representative set instead of using it to get the complete Pareto set since the entire Pareto set is not necessary for the analysis. Hence, the total time requirement of the proposed procedure is reduced significantly (Aguwa et al., 2010).

3. Methodology

Clustering based on similar properties and mass customization has several advantages, as in the case of steam turbines resulting in shorter lead times and reducing production costs (Yang, Qi, & Lu et al., 2007). For a typical architecture, it is important to partition the products into useful and practical modules (Aguwa et al., 2010). Based on the reprocessing properties of endoscopes, we cluster it into

several modules. The steps outlined in this study are generic and can be modified to any number of endoscopes. Figure 2 shows the scheme which summarizes the steps used during the project.

3.1. Step 1: product description

In this step, the physical and functional decomposition of the products, process, or services is performed. Since the physical and functional parameters are closely related to reprocessing requirements, understanding the properties of an endoscope from both aspects is necessary in order to build a reliable evaluation architecture. Table 1 shows the models currently in use in a Veterans Affairs (VA) medical facility and the corresponding properties of the models.

3.2. Step 2: performance requirement

3.2.1. Identification of performance parameters and corresponding metrics

Three important parameters identified to evaluate the endoscope modules were developed with the help of subject matter experts (SME): they are design, human factors, and cost. These were analyzed and prioritized using analytic hierarchy process (AHP), which is a decision-making tool (Saaty, 2008). The parameters are used as the three objectives of the multi-objective optimization algorithm. Using these parameters as general procedures, we identify more detailed metrics which affects the reprocessing procedure of the devices. These metrics are used in order to make a more detailed comparison among endoscope models. The identified parameters and metrics are summarized below:

Design: A product that fulfills its functions as intended has appropriate geometrical and material properties in terms of reprocessing and has a high design efficiency. Based on this general definition, the corresponding metrics used to evaluate the efficiency of the design are as follows:

(1) The depth of distal end insertion during the procedure *(Insert)*: The longer the part is in usage, the more effort and cleaning material used to clean the effective part.

(2) Length of flexible material at the distal end *(Flex)*: The procedures to clean the flexible and the rigid part of the endoscope are different.

(3) The number of parts *(Parts)*: As the number of parts increases, the time and the effort necessary to clean the device increases.

(4) The number of mounts *(Mount)*: This property also changes the cleaning procedure of the device.

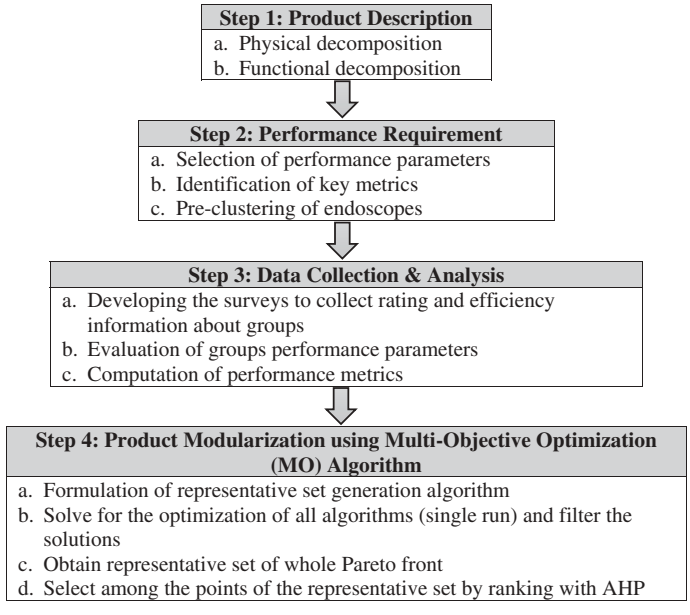

Figure 2. Proposed methodology flowchart.

Table 1. Functional properties of an endoscope

Functional Type	Procedure Type	Insertion Point	Use Frequency (per year)	# Scopes in Inventory	Brand Name & Size
Sigmoidovideoscope	Last part of the colon (0.61 m)	Rectum	4	1	Olympus 730
Sigmoidovideoscope	Last part of the colon (0.61 m)	Rectum	50	4	Olympus 730
Colonovideoscope	Whole colon (1.22 m—1.52 m)	Rectum	0	1	Olympus 1330/1680
Colonovideoscope	Whole colon (1.22m—1.52m)	Rectum	1152	4	Olympus 1330/1681
Colonovideoscope	Whole colon (1.22 m—1.52 m)	Rectum	146	12	Olympus 1330/1682
Gastrointestinal	From mouth to duodenum	Mouth	2	1	Olympus 1030
Gastrointestinal	From mouth to duodenum	Mouth	3	1	Olympus 1030
Gastrointestinal	From mouth to duodenum	Mouth	36	1	Olympus 1030
Gastrointestinal	From mouth to duodenum	Mouth	871	8	Olympus 1030
Small Intestinal Videoscope	From mouth to S.I.	Mouth	0	1	Olympus 1030
Duodenovideoscope	Duodenum	Mouth	12	2	Olympus 1030
Duodenovideoscope	Duodenum	Mouth	53	3	Olympus 1030

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Human factors: Best fit among people, tools, and environment that enhances performance, user satisfaction, and patients' safety. According to this definition, the metrics used to evaluate the efficiency of human factors are as follows:

(1) The number of steps in the standard operating procedure: As the number of steps in a standard operating procedure increases, it becomes harder to memorize the details of the procedure; also, this increases the time required for reprocessing.
(2) Visibility/reachability to the entire surface *(Visible)*: As the visibility of the deep parts increases, it becomes easier to detect particles to be removed. Also, if the reachability is easy, the reprocessing becomes easy and safe.

Cost: The monetary expense involved in the reprocessing of the product; and the costs of infection risk that may be caused by its reprocessing procedure. Based on this general definition, corresponding metrics used to evaluate the efficiency of design are as follows:

(1) Cost of reprocessing *(Cost)*: As the cost of material necessary to reprocess the device increases, the cost efficiency decreases.
(2) Cost causing infection from errors in reprocessing *(Infection Risk)*: As the risk due to reprocessing increases, the cost efficiency of the model decreases. Insertion point and the effective region of the models are used to make comparisons among models measuring this metric. Data from the Joint Commission (Lagu, Goff, Hannon, Shatz, & Lindenauer, 2013) suggests that 36% of accredited hospitals surveyed in 2011 were noncompliant with its standards to reduce the risk of infection associated with medical equipment, devices, and supplies. At the minimum, endoscope reprocessing problems can create anxiety amongst patients when notified of exposure to a contaminated endoscope. At worst, they can lead to life-threatening infections. In either case, such incidents can alter a facility's reputation (Institute, 2013).

3.2.2. Pre-clustering of endoscopes

The necessity of reducing the number of comparisons completed by SMEs drives the effort to pre-cluster endoscopes. As the number of comparisons increases, the attention and time requirement to fulfill the input sample study increases; this may result in questionable outputs and may further compromise the project. The clustering has to be carried out in such a manner that it would not shield the essential distinctions between models; that is, the models in a pre-cluster should have significant commonalities especially in terms of preprocessing. There are three different equipment clusters used to clean the existing set of endoscopes (see Table 2). Table 3 presents the number of equipment groups used for each endoscope models.

Additionally, functional types of the models should be the same since the output may be used to eliminate some models from the current set of devices, which means that functional distinctions

Table 2. Pre-clusters names and their models

Code of Groups	Functional Groups	Models
SIG1	Sigmoidovideoscope	CF 140S
SIG2	Sigmoidovideoscope	CF Q160S
SM INT	Small Intestinal Videoscope	SIF Q140
COL1	Colonovideoscope	CF 2T160L/I
COL2	Colonovideoscope	CF Q180AL/I, CF Q180AL/I
DUOD	Duodenovideoscope	TJF 160F
GAST1	Gastrointestinal Scope	GIF 160, 1TQ160, Q160, XP 160
GAST2	Gastrointestinal Scope	GIF Q180

Table 3. Reprocessing equipment groups

Endoscope Model 1	Endoscope Model 2	Endoscope Model 3
1. ENDOZIME SOLUTION	**1**. ENDOZIME SOLUTION	**1**. ENDOZIME SOLUTION
2. ENDOZIME SPONGE OR 4 X 4 SPONGE GAUZE	**2**. ENDOZIME SPONGE OR 4 X 4 SPONGE GAUZE	**2**. ENDOZIME SPONGE OR 4 X 4 SPONGE GAUZE
3. DISPOSABLE BRUSH KIT BW-201T.B, MAJ-1339	**3**. DISPOSABLE BRUSH KIT BW-201T.B, MAJ-1339	**3**. DISPOSABLE BRUSH KIT BW-201T.B, MAJ-1339
4. REUSABLE BRUSHES BW20T, MAJ-507	**4**. REUSABLE BRUSHES BW20T, MAJ-507	**4**. REUSABLE BRUSHES BW20T, MAJ-507
5. TRANSPORT CONTAINER	**5**. TRANSPORT CONTAINER	**5**. TRANSPORT CONTAINER
6. STERILE TOWEL	**6**. STERILE TOWEL	**6**. STERILE TOWEL
7. 70% ALCOHOL	**7**. 70% ALCOHOL	**7**. 70% ALCOHOL
8. 30 CC SYRINGE	**8**. 30 CC SYRINGE	**8**. 30 CC SYRINGE
9. LEAK TESTER	**9**. LEAK TESTER	**9**. LEAK TESTER
10. LEAK TESTER TUBE	**10**. LEAK TESTER TUBE	**10**. LEAK TESTER TUBE
11. CHANNEL PLUG MH-944	**11**. CHANNEL PLUG MH-944	**11**. CHANNEL PLUG MH-944
12. ENDO FLUSH MACHINE EFP250	**12**. ENDO FLUSH MACHINE EFP250	**12**. ENDO FLUSH MACHINE EFP250
13. INJECTION TUBE MH-946	**13**. INJECTION TUBE MH-946	**13**. INJECTION TUBE MH-946
14. PORTABLE SUCTION MACHINE	**14**. PORTABLE SUCTION MACHINE	**14**. PORTABLE SUCTION PUMP
15. SUCTION CLEANING ADAPTER MH-856	**15**. SUCTION CLEANING ADAPTER MH-856	**15**. SUCTION CLEANING ADAPTER MH-856
16. STERILE SUCTION TUBES	**16**. WASHING TUBE MH-974	**16**. WASHER TUBE MH-974
17. WASHING TUBE MH-974	**17**. STERILE SUCTION TUBES	**17**. STERILE SUCTION TUBES
18. AW CHANNEL CLEANING ADAPTER MH-948	**18**. CHANNEL CONNECTION TUBE MAJ-420	**18**. WATER-RESISTANT CAP, MH-553
19. WATER-RESISTANT CAP, MH-553	**19**. AW CHANNEL CLEANING ADAPTER MH-948	
	20. WATER-RESISTANT CAP, MH-553	

must remain obvious while making comparisons. Based on this evaluation and the discussions, the pre-clustering scheme used in this project has two levels: functional groups and equipment clusters used during the reprocessing procedure. Figure 3 presents the resultant breakdown scheme and the depiction of the general clustering idea. As a result of this pre-clustering, thirteen models in use are grouped under eight clusters, and the SMEs performed 28 pairwise comparisons ($^{8}C_{2}$), instead of making 78 ($^{13}C_{2}$) pairwise comparisons.

3.3. Step 3: data collection and analysis

3.3.1. Design review

As mentioned above, three different types of data collection techniques were designed to collect the necessary inputs and opinions from SMEs. The techniques consist of:

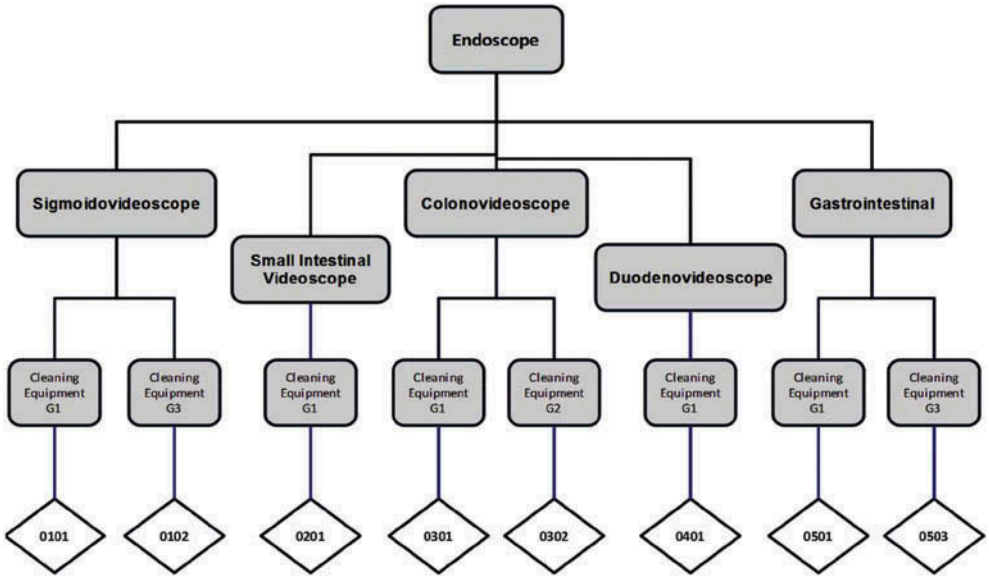
(1) Veterans Affairs (VA) RME comparison study

(2) VA RME parameter rating

(3) Analytic Hierarchy Process (AHP)

VA RME comparison study: The information in this study is used as a direct input to the optimization procedure in the next step. It contains the core information that shapes the outcome. This survey includes the introduction, pairwise comparison explanation with a basic example,

Figure 3. Pre-cluster breakdown and corresponding codes.



parameter and metric explanations, pre-clusters with their contents, and finally the comparison table. This table contains pre-cluster pairs on the first column and metrics for each parameter on the first row. Therefore, the comparison rating of each pairwise comparison in terms of the corresponding metric is given on the intersection cell. The rating scale used in this study is 1 to 10, where 10 represents a complete similarity between the models of the compared clusters, while 1 represents a complete distinction between the models of the compared clusters.

VA RME Parameter Rating: The primary purpose of this parameter rating is to obtain the necessary weights to make the final decision after generating the Pareto solutions. During the multi-objective optimization, the resemblance within each module is maximized from the point of cost, design, and human factors; the efficiency of these modules is ignored. The outputs of the multi-objective optimization phase are evaluated using the information obtained from this survey. Hence, the final decision contains the information on efficiency from different aspects as well as the commonality of the items within each module. This is constructed by rating the efficiency of pre-clusters according to design, human factors, and cost. The first parts are similar to those in the comparison study, while the data entry table is much simpler than in the previous study (Deb, Miettinen, & Sharma, 2009). On the first column, the names of the pre-clusters exist, while three parameters appear on the first column. Therefore, the corresponding efficiency rating for each pre-cluster is inputted on the intersection cell. The rating scale used in this method has three levels: low, medium, and high.

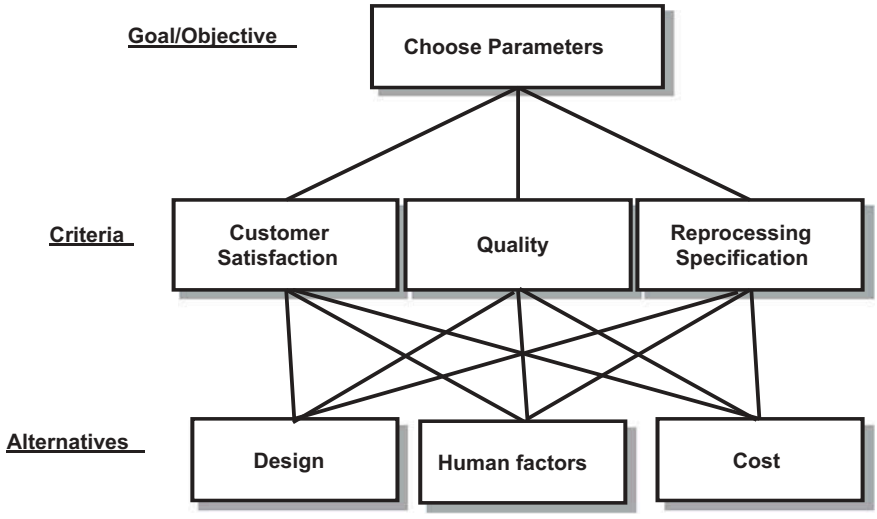
Analytic Hierarchy Process: This process is used to rank the candidate solutions and understand the importance of each parameter used in this project as input from the client. The criteria used to evaluate each parameter, i.e., design, human factors, and cost, are patient satisfaction, quality, and reprocessing specifications (see Figure 4).

The relative importance of each parameter is obtained, making pairwise comparisons between parameters on a scale of 1 to 10.

3.3.2. Data collection methodology

Questionnaires and interviews were the methods adopted for data collection from two focus groups (consisting of 15 personnel) formed with the help of the hospital department in charge of the Endoscope equipment. Each group included a variety of SMEs from Sterile Processing Service and the Biomedical Service, which completed the comparison study. After the group's discussion,

Figure 4. AHP architecture.



a common idea was agreed as a result. Since AHP is a decision support tool, managerial insight is necessary; therefore, this was completed after enlisting opinions of personnel who are in managerial positions at the hospital. Similarly, the parameter rating was filled based on the opinion of technicians who see the endoscope usage and reprocessing from a broader aspect.

3.4. Step 4: product modularization using multi-objective (mo) algorithm

This area of multiple criteria decision making involves optimizing the multiple objective functions of design, human factors, and cost simultaneously. The focus is on finding optimal modules and performing modular analysis with different design parameters. This section defines the MO algorithm, reviews the mathematical model used, and the procedures for ranking and evaluating results.

3.4.1. Multi-objective optimization (MOP) algorithm

In multi-objective optimization, Pareto optimality is an important concept (Mattson, Mullur, & Messac, 2004). From the definition of MOP, the result of multi-objective optimization is generally a set of solutions, rather than a single solution, which is called the Pareto set. There are methodologies which aim to obtain a single solution from this set which may seem desirable from a practical standpoint since, in the end, only a single solution can be applied. Although there are multiple criteria involved in optimization procedures, a mathematical program cannot account for all real-life parameters. Based on this observation, the algorithm used in this project aims to generate a representative set of the whole Pareto set. The current approach has two benefits; first, the user does not have to define right-hand-side values to constrain objectives, which is the case in goal programming or constrained programming; second, generating a representative set of Pareto solutions supplies more alternative solutions, which in turn supplies flexibility while identifying the most practical modular design. Figure 5 presents a general Pareto set, and the representative solution points obtained in this set on a sample case with three objectives.

An AHP-based ranking procedure which can be used to rank the candidate, i.e., Pareto optimal solutions, is also given. This step is proposed as an extension to deduce a single solution for the analysis. At this point, it is worth emphasizing that the solutions obtained at the end of the MO procedure are equally optimal and preferable. By changing the AHP factors used, we obtain a different ranking with the guarantee that a final solution is still optimal based on the main objectives of MO procedure. The following section presents the details of the mathematical model and the steps for the algorithm.

3.4.2. Steps of the algorithm

Step 0: Best points for each of the objective k are found in the feasible region, k = 1, ..., N, by optimizing one objective at a time. These points called anchor points, z_k^A. Nadir point, z^N, is calculated by finding

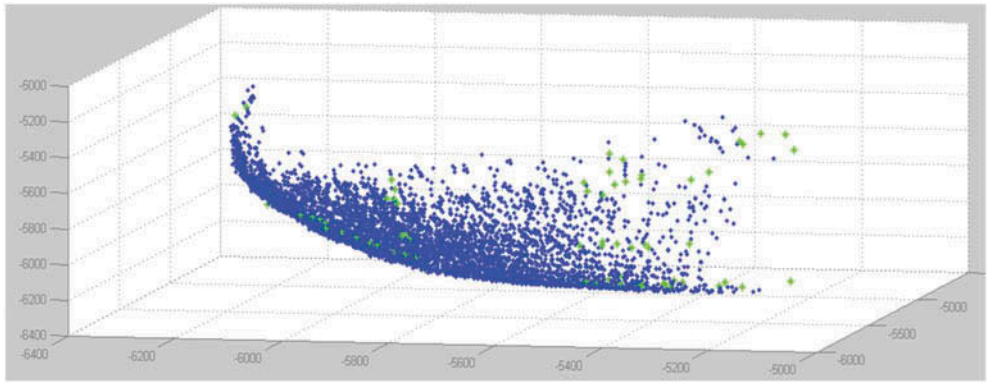


Figure 5. General Pareto Set and Solutions—The entire Pareto set consists of multiple solutions. Representative solutions generated by the algorithm are green points in this set.

the worst value of all objectives (Deb et al., 2009). Using the coordinates of these points on the objective space-relevant search region in N-dimensional objective space is determined. Then, the objective space is divided into equal regions on N-1 dimensions while leaving one dimension out at a time (e.g., k = 1,.,t-1,t + 1 ..., N; all but tth objective), to form the "grids". The user determines the number of grids (i.e., according to the approximate amount of solutions desired by the user, the number of grids can be changed, following the simple rule that increasing the number of grids will lead to more alternatives). Based on this observation, we deduce that, when the number of grids goes to infinity, the algorithm is supposed to generate the whole Pareto front. If we decide to divide each axis into i equal parts, we will obtain $N{\cdot}I^{N-1}$ grids in total. Set grid count: t = 0.

Step 1: Set t = t + 1. If t > N, stop; else gridcount = 1; set both the lower bound, lb^k, and the upper bound, $ub^k$of the grid to its minimum value (i.e., anchor value, z_k^A) on each objective *k*.

Step 2: Set gridcount = gridcount + 1; Calculate the boundaries of the new grid for each dimension k = {1 ... t-1,t + 1, ..., N} as follows: $lb^k_{gridcount} = ub^k_{gridcount-1}$ and $ub^k_{gridcount} = lb^k_{gridcount} + \frac{z_k^N - z_k^A}{I}$.

Step 3: Within each grid, the tth objective is optimized. Using this resultant point and the farthest coordinates of the grid, we determine two reference points, r_k, in each grid.

(a) The weights, λ_k, are determined again based on the nadir point and the reference points.

(b) ρ is assigned a value ranging from $0<\rho \ll 1$.

Step 4: Solve the scalarization model (Ehrgott, 2006) for each reference point on each grid. Record the resultant point. If grid count is equal to l^{N-1}, return to step 1; if not, return to step 2. See Figure 6 for the flowchart of the steps utilized in the algorithm.

3.4.3. Mathematical model

Scalarization is a single objective related to a MO problem with additional variables or parameters. It is usually solved repeatedly to find some subset of efficient solutions of the MO problem (Ehrgott, 2006). Ehrgott (Ehrgott, 2006) discussed all relevant aspects of the main scalarization techniques specifically for linear MO problems. The most general form of the achievement scalarization function is:

$$\min_{x\in X} \max_{k=1\ldots N} \lambda_k(c_k x - r_k) + \rho \sum_{k=1}^{N}(c_k x - r_k), \tag{1}$$

Where:

r_k is the reference point for objective k, $\lambda>0$ is a vector of weights, and ρ is a nonnegative scalar < 1 which is the coefficient of "augmentation part"; *X* is the feasible solution set. In (Wierzbicki, Makowski,

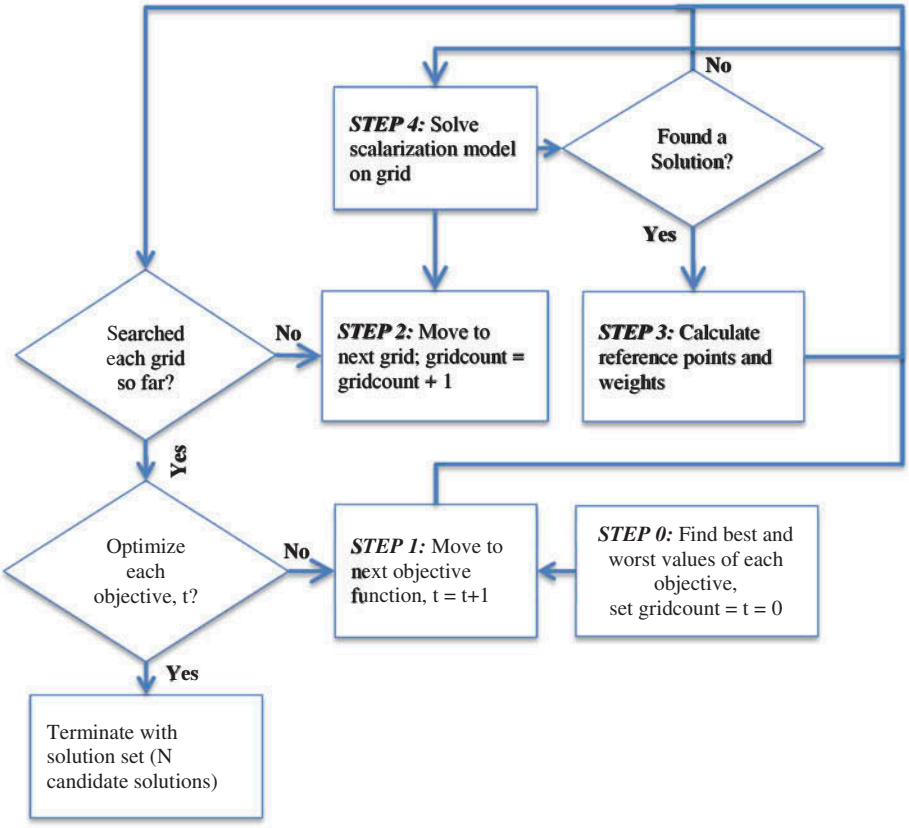


Figure 6. Multi-objective optimization algorithm flowchart.

& Wessels, 2000), this function has been called a "prototype" achievement scalarizing function. To linearize the nonlinear expression in Equation (1), the first term in the summation is replaced with the α variable in the version below and added as an additional constraint to the formulation (i.e. Equation 3).

$$\text{P1}: \min\ \alpha - \rho\left(\sum_{k=1}^{3} \lambda_k \left\{c_{ij}^k X_{ij} - r_k\right\}\right) \qquad \forall i, \forall j \in 1 \ldots n \tag{2}$$

s.t.

$$\lambda_k \left\{c_{ij}^k X_{ij} - r_k\right\} \leq \alpha \qquad \forall k \in \{1, 2, 3\} \tag{3}$$

$$\sum_{j}^{n} X_{ij} = 1 \qquad \forall i \in 1 \ldots n \tag{4}$$

$$X_{ij} \leq X_{ii} + X_{jj} \qquad \forall i, \forall j \in 1 \ldots n \tag{5}$$

$$\sum_{i}^{n} Xij \geq M \qquad \forall j \in 1 \ldots n \tag{6}$$

$$X_{ij} \in \{0, 1\}$$

Where:

c_{ij}^1 *is for design*, c_{ij}^2 *is for human factors*, and c_{ij}^3 *is for cost*.

k: Indices for the objectives (k = 1: design, k = 2: quality, k = 3: cost)

N: Total number of objectives (3)

M: Lower bound for the number of modules (1–3)

i, j: Indices representing each endoscope pre-cluster

n: The total number of endoscope models included in the model

X_{ij}: Binary decision variable; 1 if pre-cluster I and j are put into the same module; 0 otherwise. For any $X_{ij} = 1,$ based on the ordering preference of i and j in Equations 4 and 6, j indicates the pre-cluster that represents the module under which the grouping occurs; i.e., $X_{ij} = 1 \rightarrow X_{jj} = 1$.

α: Variable added to the model which holds the maximum distance from the reference point

$r_k,\ \lambda_k$ *and* ρ are the parameters that are determined by the algorithm

r_k: The reference point is a point on the objective space determined by the algorithm before the optimization starts

λ_k: Weights of the distance between the objective value of the current solution and the reference point

Ruiz, Luque, and Cabell (2009) studied the weighting schemes. This study utilized the GUESS scheme, following the rule that the total weights of all objectives should be equal to 1.

$$\lambda_k = \frac{1}{\sum_{k=1}^{N} \frac{1}{\bar{z}_k^U - r_k}} \left(\frac{1}{\bar{z}_k^U - r_k} \right) \tag{7}$$

Where $\bar{z}_k^U = z_k^N + 0.0001$ and z^N denote the nadir point.

ρ: Coefficient which guarantees that not only the maximum distance but also all the distances in all coordinates (objectives) are taken into consideration while performing the minimization. It is a value $0 < \rho \ll 1$.

α: Decision variable added in order to carry the value of the maximum distance of the solution to the reference point, from all of the objectives' perspectives

Equation (2): The objective function which minimizes the distance between reference point r_k and the solution point in terms of all criteria (design, quality, cost).

Equation (3): The term on the right-hand side controls the maximum distance between the reference point r_k and the solution point.

Equation (4): Guarantees that each model is placed only in one module.

Equation (5): Guarantees that if a model is selected in a module ($X_{ij} > 0$), the variable of that module should also be more than one.

Equation (6): A lower bound is set for the number of modules.

3.4.4. Ranking procedure

As explained above, weights for each parameter is obtained as the result of AHP procedure, represented by w_d, w_{hm}, w_c. The inputs of the AHP procedure are evaluated using Expert Choice

Software. As a result of the optimization algorithm, multiple candidate solutions were derived. We represent the number of each candidate solution with *i*, i = 1, ..., N. Then, each solution has a design, human factor, and cost value: DS_i, HFS_i, CS_i. These values represent the relative resemblance within each module scheme proposed by solution *i* for design, human factors, and cost, respectively. Multiplying these values by each parameter's weight obtained from the AHP procedure, the overall resemblance achievement value obtained is:

$$WSE_i = w_D DS_i + w_{HM} HFS_i + w_C CS_i \quad (8)$$

Note: This WSE_i value can be used to rank the candidate solutions.

3.4.5. Evaluation of results

At this point, it is essential to highlight that the WSE_i values represent the overall resemblance score obtained by solution *i*. However, if we want to produce a more detailed solution on the efficiencies of each module proposed by solution *i*, we need to know the efficiency of the models in a module. In order to achieve this goal, the results of "parameter rating" are used. The results are in verbal scale, however, and is easily converted into ordinal numbers. That is, using L = 1, M = 2, and H = 3, the average design, human factors, and cost efficiency within a module are calculated. For example, if a module in solution *i* have models whose design efficiency are all "H", then the average DE_i will be 3 for this solution. Similarly, HFE_i and CE_i are computed, and evaluation of the resultant modules can be made based on these values.

3.5. Results

3.5.1. Optimization results

As observed in the mathematical program, one of the constraints, Equation (6), restricts the number of modules in the final solutions. By changing this constraint to two different values, two different solution sets are obtained.

3.5.1.1. Results with 2-modules. The first candidate solution from the analysis yielded 27 results and three optimal solutions. The solution sets optimizing eight pre-clusters are outlined in Table 4 (a–c). The shaded cells (along the diagonal) containing the number 1 along with the cells within the same column containing the number 1 indicates pre-clusters that are in the same group. This grouping is summarized on the right side of each table by Module 1 and Module 2.

3.5.1.2. Results with 3-modules. The second candidate solution from the analysis yielded 180 results and two optimal solutions. The solution sets optimizing eight pre-clusters are outlined in Table 5(a,b). The shaded cells (along the diagonal) containing the number 1 along with the cells within the same column containing the number 1 indicates pre-clusters in the same group. This grouping is summarized on the right side of each table by Module 1, Module 2, and Module 3.

3.6. Ranking results

3.6.1. AHP results

The AHP results for cost, design, and human factors parameters (see Figure 7 and Table 6). The objective values of each candidate solution *i* are called similarity achievements in design, human factors, and cost, and represented by DS_i, HFS_i, and CS_i. These values are multiplied by weights 0.484, 0.324, and 0.192, as explained in the methodology section. Each similarity achievement value and the corresponding overall score for each candidate solution is in Table 7.

3.7. Recommendation

From Table 7, we observe that Three Module Solution Code 1 offers higher similarity values than Solution Code 2 when multiplied with the weights of the parameters. The Design factors and the

Table 4. (a) Solution 1 with 2-modules

1	SIG1	SIG2	SM INT	COL1	COL2	DUOD	GAST1	GAST2	Module 1	Module 2
SIG1	0	0	0	1	0	0	0	0	COL 1	GAST2
SIG2	0	0	0	0	0	0	0	1	SIG1	SIG2
SM INT	0	0	0	1	0	0	0	0	SM INT	DUOD
COL1	0	0	0	1	0	0	0	0	COL 2	GAST1
COL2	0	0	0	1	0	0	0	0		
DUOD	0	0	0	0	0	0	0	1		
GAST1	0	0	0	0	0	0	0	1		
GAST2	0	0	0	0	0	0	0	1		

(b) Solution 2 with 2-Modules

2	SIG1	SIG2	SM INT	COL1	COL2	DUOD	GAST1	GAST2	Module 1	Module 2
SIG1	0	0	0	1	0	0	0	0	COL 1	GAST2
SIG2	0	0	0	1	0	0	0	0	SIG1	COL 2
SM INT	0	0	0	1	0	0	0	0	SIG2	DUOD
COL1	0	0	0	1	0	0	0	0	SM INT	GAST1
COL2	0	0	0	0	0	0	0	1		
DUOD	0	0	0	0	0	0	0	1		
GAST1	0	0	0	0	0	0	0	1		
GAST2	0	0	0	0	0	0	0	1		

(c) Solution 3 with 2-Modules

3	SIG1	SIG2	SM INT	COL1	COL2	DUOD	GAST1	GAST2	Module 1	Module 2
SIG1	0	0	0	1	0	0	0	0	COL 1	GAST2
SIG2	0	0	0	0	0	0	0	1	SIG1	SIG2
SM INT	0	0	0	1	0	0	0	0	SM INT	DUOD
COL1	0	0	0	1	0	0	0	0		GAST1
COL2	0	0	0	0	0	0	0	1		COL 2

(*Continued*)

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Table 4. (*Continued*)

(c) Solution 3 with 2-Modules

3	SIG1	SIG2	SM INT	COL1	COL2	DUOD	GAST1	GAST2	Module 1	Module 2
DUOD	0	0	0	0	0	0	0	1		
GAST1	0	0	0	0	0	0	0	1		
GAST2	0	0	0	0	0	0	0	1		

Table 5. (a) Solution 1 with 3-modules

1	SIG1	SIG2	SM INT	COL1	COL2	DUOD	GAST1	GAST2	Module1	Module2	Module3
SIG1	0	0	0	1	0	0	0	0	SIG2	COL1	GAST1
SIG2	0	1	0	0	0	0	0	0	COL2	SIG1	GAST2
SM INT	0	0	0	1	0	0	0	0		SM INT	DUOD
COL1	0	0	0	1	0	0	0	0			
COL2	0	1	0	0	0	0	0	0			
DUOD	0	0	0	0	0	0	1	0			
GAST1	0	0	0	0	0	0	1	0			
GAST2	0	0	0	0	0	0	1	0			

(b) Solution 2 with 3-modules

2	SIG1	SIG2	SM INT	COL1	COL2	DUOD	GAST1	GAST2	Module1	Module2	Module3
SIG1	0	0	1	0	0	0	0	0	SIG2	SM INT	GAST1
SIG2	0	1	0	0	0	0	0	0	COL2	SIG1	GAST2
SM INT	0	0	1	0	0	0	0	0		COL1	
COL1	0	0	1	0	0	0	0	0		DUOD	
COL2	0	1	0	0	0	0	0	0			
DUOD	0	0	1	0	0	0	0	0			
GAST1	0	0	0	0	0	0	1	0			
GAST2	0	0	0	0	0	0	1	0			

Figure 7. AHP results.

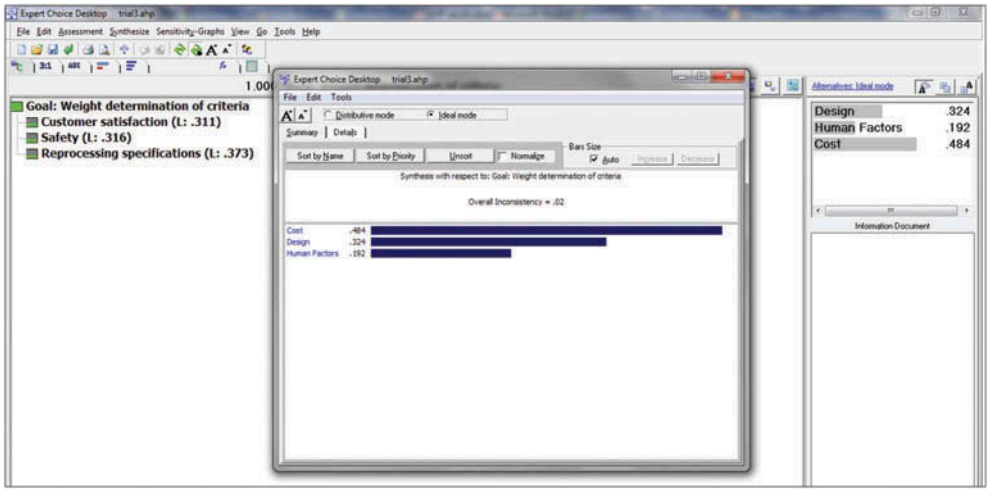

Table 6. AHP results & ranking

Alternative rankings with structure	Result	Rank
Cost	0.484	1
Design	0.324	2
Human factors	0.192	3

Overall Inconsistency = 0.02 ≤ 0.1.

Table 7. Candidate solutions

2 Module Solutions				
Solution code	**DS**	**HMS**	**CS**	**Similarity**
1	53.01	54.02	47.5	50.54
2	50	54.35	48	49.87
3	49.34	56.35	47.5	49.8
3 Module Solutions				
Solution code	**DS**	**HMS**	**CS**	**Similarity**
1	43.67	46.35	44.5	44.59
2	41.34	48.35	44	43.97

Cost factors of Three Module Solution Code 1 are higher than those of Three Module Solution Code 2. Evaluations based on efficiency tell us that Code 1 (44.59) has a higher similarity value than Code 2 (43.97). We conclude that the Three Module Solution Code 1 is the best solution.

Also, we observe from our evaluation that the first module consists of Colonovideoscope and Sigmoidovideoscope. From this observation, we recommend extra care and attention in reprocessing these models as they contain higher risks of contamination than the other groups. It is better to minimize or eliminate the usage of these models to reduce the risk. It is more advisable to use similar models with the same functionality in Modules 2 and Modules 3, to minimize further risks. Additionally, the results can be used to develop standard reprocessing procedures for the models within a group (see Table 8).

Table 8. Reprocessing recommendations

#	Modules	Groups	Endoscopes	Type	SOP	Reprocessing Comments
1	**1**	COL2	CF Q180AL/I	Colonovideoscope	GE8391 03	***Reprocessing needs extra attention; and contains more risk than other modules.*** The groups have *good* **design** efficiency properties (DE:2.34); are the *least efficient* in terms of **human factor** properties (HFE:2.00); are the *least efficient* in terms of **cost** properties (CE:2.00).
2			CF Q180AL/I	Colonovideoscope	GE8391 03	
3		SIG2	CF Q160S	Sigmoidovideoscope	GE1016 06	
4	**2**	SIG1	CF 140S	Sigmoidovideoscope	GR7237 09	***Reprocessing needs some attention since groups/scopes in this module contain some risks; however it has the most convenient groups in terms of human factors efficiency.*** has *good* **design** efficiency properties (DE:2.34); are the *most efficient* in terms of **human factor** properties (HFE:3.00); has *good* **cost** efficiency properties (CE:2.34).
5		COL1	CF 2T160L/I	Colonovideoscope	GR7387 17	
6		SM INT	SIF Q140	Small Intestinal Videoscope	GR7237 09	
7	**3**	DUOD	TJF 160F	Duodenovideoscope	GR5233 21	***Reprocessing is safer and easier for the groups/scopes in this module***: are the *most efficient* in terms of **design** properties (DE:3.00); *good* **human factors** efficiency properties (HFE:2.28); are the *most efficient* in terms of **cost** properties (CE:3.00).
8			TJF 160VF	Duodenovideoscope	GE1675 12	
9		GAST2	GIF Q180	Gastrointestinal	GE8391 03	
10		GAST1	GIF 160	Gastrointestinal	GE1016 06	
11			1TQ160	Gastrointestinal	GE1016 06	
12			XP 160	Gastrointestinal	GE1016 06	
13			Q160	Gastrointestinal	GE1016 06	

4. Conclusion and future research directions

In this study, we presented a generic methodology to modularize endoscopes for reusability and reduce the risk of infection due to poor cleaning and reprocessing. This methodology utilizes simplification and generalizing cleaning steps for modules. It further involves data collection, which includes product description, identification of key metrics, pre-clustering, and data analysis steps. Based on formal communication and observation of the SMEs, parameters such as design, human factors, and cost where identified to be the main factors affecting the reprocessing of an endoscope. Since data collection and product description rely heavily on the feedback of SMEs, three different surveys were developed to collect the necessary data. The first one compares RME models in terms of similarity on these three main factors; the second collects the efficiency of each RME model from the design, human factors, and cost perspective; and the last assesses the relative importance among the three main factors. In the second phase, we propose a linear multi-objective optimization model which aims at generating representative solutions on the true Pareto front of the problem that maximizes the similarity among module members in terms of the three main factors. We present the resultant set as the outcome of two and three-module runs. Then, we showed how the relative importance feedback is used in the AHP procedure to make selections between these Pareto optimal results. Finally, we combine the module information with efficiency feedback to derive recommendations for the user based on the general efficiency levels of design, human factors, and cost. We used data from the VA hospital in Michigan, USA to verify the proposed methodology. The results show, the clustering of endoscope models into two and three modules at different solution codes respectively. Based on this clustering, we are able to identify the types of RMEs with high-risk infections due to human errors in reprocessing as seen in Table 8. Furthermore, to ensure that the quality of medical care rendered to patients is not compromise, we recommend that the hospital utilize endoscopes in modules two and three as they are safe and easy to reprocess compared to similar models in module one.

Advantages of the proposed methodology are mainly related to flexibility, especially at the identification of key metrics, pre-clustering, and optimization steps. With slight modifications, users can change the parameters to solve similar problems occurring in a different context. Future research work will aim at analyzing the efficiency of the feedback and utilizing it in the optimization model as a new objective; hence, a reduction in inefficient modules. Also, we consider evaluating the cleaning error cost of the equipment and a comparison of the disposable equipment replacement of RMEs.

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