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Josue R. Crespo-Varela, The Pennsylvania State University
Gül E. Okudan-Kremer, The Pennsylvania State University
Conrad Tucker, The Pennsylvania State University
Lourdes A. Medina, University of Puerto Rico, Mayaguez
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AN ANALYSIS OF COMPLEXITY MEASURES FOR PRODUCT DESIGN AND DEVELOPMENT

Josue R. Crespo-Varela
Industrial Engineering
The Pennsylvania State University
State College, Pennsylvania 16802
Email: jrc405@psu.edu

Gül E. Okudan Kremer
Industrial Engineering and Engineering Design
The Pennsylvania State University
State College, Pennsylvania 16802
Email: gek3@engr.psu.edu

Conrad S. Tucker
Industrial Engineering and Engineering Design
The Pennsylvania State University
State College, Pennsylvania 16802
Email: ctucker4@psu.edu

Lourdes A. Medina
Industrial Engineering
University of Puerto Rico at Mayaguez
PR-65, Mayagüez, 00680, Puerto Rico
Email: lourdes.medina@gmail.com

ABSTRACT

Complexity metrics have been developed for multiple applications such as consumer products, software, trajectory selection and assembly systems. Although existing complexity metrics were developed to reduce product design and development costs, their lack of simplicity in formulation and robustness has limited their applicability. This paper proposes a standard methodology for comparing and evaluating these metrics and introduces dimensions of complexity that should be considered towards the goal of developing a generalizable product complexity measure. To this end, this paper introduces variables that integrate multiple facets of complexity into a single metric.

A medical device case study is used to compare the efficiency and robustness of existing complexity measures. The medical device case study also serves as the motivation for the proposed complexity metric due to the complexity of the domain itself and the increasing importance of mitigating healthcare costs. Overall, product complexity metrics can aid medical device development by increasing the understanding about the design and its implications regarding development time and FDA approvals.

1. INTRODUCTION

Complexity is a common topic of concern in many domains. The definition of this term is “complex” itself. The literature has paid particular attention to the complexity of systems and products, and how to define and solve complexity problems. The ability to handle complex systems and products depends on the level of experience, knowledge and ability to learn [1]. For the development of new innovative products, designers must acquire the knowledge and skills necessary for the particular development. As a result, the duration of the design process is affected by the design team’s learning curve in relation to complex product designs [2]. The greater the complexity of a product, the greater the magnitude of domain knowledge needed to understand and develop it, and thereby potentially increasing its development time. For example, evidence shows that the time-to-market is affected by the experience level of the development team for the particular case of medical devices [2].

In this paper, a detailed review of complexity metrics is presented, followed by a standardized evaluation approach that compares different complexity metrics based on their correlations for a selected set of medical devices. The complexity in this domain has never been studied in detail. According to Hiller [3], medical device domain represents revenues of more than 300 billion per year, and plays a significant role in the health and well-being of society. Although a complexity metric definition specific to this domain does not exist, complexity is defined as the difficulty to understand the functionality requirements of a medical device product and the
interconnection of its components. Complexity metrics are used to quantify the complexity of products and systems across different fields; however, medical devices are specifically considered as the domain of study due to the increasing challenges in this domain. Meanwhile, the literature to date does not provide the development or implementation of complete or proper complexity metrics for medical devices [4].

While complex products tend to be more expensive, given the design and manufacturing challenges [5], their costs are also impacted by the development environment. This might be the result of patents that cost between $5,000 and $15,000, depending on the complexity of the product [6]. For example, patenting an extremely simple product, e.g., paper clip, costs between $5K and $7K, while patenting a highly complex product, e.g., MRI scanner, can cost more than $15K [6]. Meanwhile, a greater impact of product complexity is observed in the development environment of highly regulated products [7]. Currently, the complexity of medical devices is a big concern due to the increasing number of patents filings and reviews. For example, in 2003 alone, there were more than 9,000 medically related patents issued by the United States Patent and Trademark Office. Therefore, domain of application is specifically chosen to be medical devices so that the impact of complexity on device approval can be studied.

The assessment of product complexity is expected to improve the development of medical devices by establishing better goals and expectations throughout the development process. Regulatory agencies may use this measure to improve their procedures such as evaluating their current classifications of risks. Likewise, unnecessary complexities can be eliminated from the design [8] (i.e., redundancy in unnecessary components). Decreasing the complexity of medical devices is expected to help make design upgrades easier, reduce the development time and cost, and increase the efficiency and safety of designs. Accordingly, this work investigates the complexity of medical devices with the use of existing metrics published in the literature for different products.

The paper is organized as follows. Section 2 reviews the relevant literature on complexity, with a focus on the design metrics. This review includes a discussion of the definitions for complexity from multiple sources. In this section, we explain the different complexity metrics that have been developed along with their algorithms, variables and equations. Section 3 describes the methodology to understand and analyze the product complexity for medical devices. Complexity metrics identified from the literature are compared in detail in order to identify the most appropriate metric(s) for medical devices. Section 4 shows a case study of the selected metrics using hip devices products. The metric results are analyzed and discussed in section 5, where dimensions for a generalizable complexity metric are formally introduced to address some of the limitations of existing complexity metrics. Finally, Section 6 concludes the paper and provides directions of future work relating to complexity in medical devices.

2. LITERATURE REVIEW

The word “complex” originates from the Latin word *complexus*, which is defined as entwined, twisted together, or an aggregate of parts [5]. Complexity as a term is usually explained with very diverse definitions that are applied depending on the context of the problem under study [7]. For example, Rodriguez-Toro et al. propose five different definitions for potential different applications [8]. These definitions are: (1) *Arithmetic*, which is related to the number of arithmetic operations required for the mathematical computation; (2) *Entropy* is defined as the rate at the predictability disappears; (3) *Games* is based on the detailed information needed to develop a game strategy; (4) *Information* is defined as the complexity of a collection of patterns by using an information algorithm; and (5) *Software* is related to the gap in the planning process related to the highest level of the software tool used by the designer.

Researchers are continuously developing methods to address the complexities of product designs. Metrics, theorems and new methodologies are proposed with the aim of reducing product complexity and managing complexities during the design process. For instance, Suh uses Axiomatic Design to minimize the complexity of processes [9]. The analysis of design complexity (DC) also depends on the type of applications being evaluated; the DC literature mostly focuses on the study of complexity for products or software applications.

Researchers have developed different types of metrics with the objective of minimizing the complexity of designs and systems. For example, Mathieson classifies the complexity metrics in four groups: 1) size, 2) interconnection, 3) centrality, and 4) decomposition [10]. These different types of metrics have been developed for various design applications involving software, products and path decisions. Table 1 summarizes the metrics found in the literature based on their application in the different design phases and the type of application.

Complexity metrics are developed with the use of equations, diagrams and algorithms that measure different aspects of the design. Some of these metrics only focus on measuring the size of the system and do not consider the complexity generated due to the interactions between components. For instance, they deem the complexity aspect of assemblies to be negligible. Metrics are also developed with the sole focus on the interconnections between components (e.g., [11, 12]). In general, the application of most of these metrics requires constructing a network diagram as a representation of the interconnections.

Researchers have also combined considerations of the components’ size and interactions in the development of complexity metrics for different applications, where network
diagrams are used to represent the different components and levels (e.g., [13-15]). The metrics that use various aspects of complexity are expected to be more comprehensive. However, no comparison or validation of this fact was found in the published literature. Accordingly, we implement and compare a set of complexity metrics to shed light on their pros and cons.

3. COMPLEXITY METRIC SELECTION FOR ANALYSIS

This section explains the method followed for the selection, implementation and validation of these metrics. The complexity metrics to implement are narrowed down from the literature. These metrics are divided into three groups that explain the filtering process (Figure 1).

![Figure 1. FILTERING PROCESS.](image)

The initial review of fourteen metrics (top group in Figure 1) reduced the metrics set by elimination of metrics that do not provide a formal mathematical formulation (e.g., [15-16]). Also, the complexity metrics developed for software are not used due to a lack of applicability of their parameters in the product design space (e.g., [17-18]). Likewise, Hong et al.’s complexity metric does not apply given it is very specific to the performance of buffers and registers. Although Ameri et al. [20] developed a metric for products; their metric includes probability values instead of a numerical solution and is therefore outside of the scope of this paper. On the other hand, Rodriguez-Toro et al. [8] used a hierarchical approach as an initial mapping to understand the components and their interactions. They developed a weighting method to differentiate the complexity between interfaces. However, this metric presents a “rough” and generalized mathematical representation” that requires further development.

As a result of analyzing the second group, three metrics are selected for analysis. These metrics, summarized in Table 1, provide a broad consideration of complexity aspects. Most of the metrics shown in Table 1 address the complexity based on the product size. However, Bashir and Thompson [21]’s metric is based on the functionality of the device. They developed a complexity metric using a hierarchical approach. This requires the decomposition of all product functions, starting from the most basic to the most advance. The impact of functions has a linear relationship with the levels, where functions at higher levels have more impact than those at basic levels. Although, Bashir and Thompson [21] improved the complexity metric with the consideration of weighted product functionalities, they neglected to consider the number of parts and assemblies.

![Table 1. METRICS EVALUATION.](image)

Roy et al. [22] developed a complexity metric to address product variants and demand. This metric was inspired by Galsworth’s [23] work, which measured the complexity as the sum of product variants and the product parts. Even though Roy et al. [22] had an innovative point of view, this metric (demand ratio) can only be implemented by a company developing the given product to have variants and relevant demand data. The design ratio, a component of the proposed metric, is by definition a measure of commonality for each part variant. A low design ratio is interpreted as an increase in complexity, meaning that there is less commonality and therefore more variation. This metric is implemented by calculating the design ratio for each part variant. Accordingly, this paper implements the design ratio for hip replacements based on data found in relevant bill of materials (BOM).

Keating [13] quantified the complexity based on the number of modules and interactions. Modules are generated to diminish the impact of the coupling. The motivation of Keating [13] was to quantify the complexity of electronics chips in order to improve the design quality in the early development stages. The first step to use this metric is to create a mapping of the modules and their interactions.

4. METHODOLOGY

This section demonstrates the implementation and assessment of complexity metrics for 21 hip replacement devices. These devices were selected based on Medina et al.’s [24, 25] work, who studied the influence of various factors in medical device development. While complexity metrics can be
employed in different applications such as software, robots and airplanes, this paper compares the selected metrics using similar medical products (hip replacements) in order to investigate their sensitivity, that is – can the metrics show the complexity differences across similar devices? The metrics implemented include the set of three by Bashir and Thompson [21], Roy et al. [22], and Keating [13]. In the following sections, we first explain how these metrics are implemented and then present the comparison and validation analyses.

4.1 Bashir and Thompson’s Metric

Bashir and Thompson’s [21] metric was developed to quantify complexity focusing on product functions with the analysis of their hierarchical decomposition. This can be mathematically represented as:

$$PC = \sum_{j=1}^{l} F_j k_j$$

(1)

where,

- PC is the product complexity
- $F_j$ is the number of functions at level j
- $l$ is the number of levels
- $k_j$ is the weight for level j, where $k_1 = 1$, $k_2 = 2$, etc.

While implementing Equation 1 for this study, this complexity metric is slightly modified. According to the functional decomposition steps provided in Figure 2, functions that can be matched with an existing component should not be included in the function tree diagram. However, components are the major differentiating factor between hip replacement systems. The components of these devices have a direct impact on functionality with a one-to-one relationship between functions and components. For instance, an important function of most hip replacement devices is to replace the femoral head due to bone damage. This function would be satisfied with the implementation of one of the part/component variants of the Trial Bipolar Head shown in Table 3.

Bashir and Thompson’s [21] PC metric is implemented through the evaluation of components and their functionality as they relate to the anatomic functions of the hip joint. As a result, a Function Tree diagram (Figure 5) of all the possible functions for the most complex scenario is developed. For instance, if a device does not include a particular component, then the related functions in Figure 3 should not be included for the particular device. If the device does not include the femoral stem, then the bone fixation function in Figure 3 would not apply, and thus it is removed along with its sub-functions (e.g., bone alignment, support weight and body stability).
The implementation of PC for Medacta’s Bipolar Head is described by the following steps with the development of the function tree in Figure 4:

Step 1: Generate the first level (j = 1) of the tree diagram based on the base function, which is the main purpose of the product. In Bashir and Thompson’s [21] example the base function of the power supply (product) is to supply the DC power. For Medacta’s Bipolar Head the base function is to replace the joint.

Step 2: Decompose the base function into sub-functions for the second level (j = 2). In Bashir and Thompson’s [21] example, the sub-functions of the base function (supply DC power) are: (1) assemble components, (2) protect device, (3) convert power and (4) provide interface. For Medacta’s Bipolar Head the sub-functions of replacing the joint are: (1) assemble components, (2) replace femoral head and (3) connect the femur with the femoral head.

Step 3: Decompose the sub-functions identified in the prior step into further sub-functions. Repeat until no more functions can be generated.

Step 4: Calculate the product complexity with Equation 2. For Medacta’s Bipolar Head, this calculation is shown by Equation 3. The first term represents the number of functions for the particular level. According to the functional decomposition diagram shown in Figure 4, the first level (j = 1) has only one function, which generates the term 1*1. The second level (j = 2) consists of three sub-functions from the first level for which the second term of the equation is 3*2. Meanwhile, the third level (j = 3) has two sub-functions, which result in the term 2*3. The summation of these terms provides a PC value of 13.

\[
PC = \sum_{j=1}^{l} F_j k_j
\]

\[
PC = (1)(1) + (3)(2) + (2)(3) = 1 + 6 + 6 = 13
\]

4.2 Roy et al.’s Complexity Metric

Roy et al. [22] propose the design ratio as a metric that can be used as an indicator of complexity based on part variants. As a result, this metric does not provide a single design ratio per product but instead a value per product variant. This is better explained by Equations 4 and 5, which show that design ratio is related to the number of product and part variants. Mathematically, this is represented as:

Design ratio (i) = \( \frac{n_i}{n} \)  

where,  
\( n_i \) = number of product variants that use part variant \( i \)  
\( n \) = total number of product variants

Demand ratio (“Off take”) = \( \frac{d_i}{d} \)  

where,  
\( d_i \) = demand for all product variants that use part variant \( i \)  
\( d \) = total demand for all product variants

The number of product variants, \( n \), explains how many part combinations can be converted into final products. Meanwhile, the number of product variants that use part variant \( i \) (\( n_i \)) refers to how many final products that can be generated from the particular part variant. The implementation of this metric includes the calculation of the number of possible product combinations.

Given that this metric provides a design ratio for each part variant \( i \), the design ratio is calculated for the case to convey the highest complexity in the product. In other words, the lowest design ratio (lowest commonality) is selected as an indicator of
Given the inversely proportional relationship between design ratio and complexity, an adjustment can be made to make the interpretation easier. Given that the maximum design ratio is one, the design ratio value is subtracted from 1 to represent complexity.

To implement this metric, the information is gathered from the BOMs of relevant devices (Table 3) in order to be consistent in the assessment of different metrics. Table 8 shows the design ratio results for each part variant based on the BOM. The steps describing how these results were generated are described below:

Step 1: Quantify the total number of variants \(n\), which is calculated using the BOM of the product.

Step 2: For each part variant \(i\), calculate the number of product variants that use part variant \(i\) \(n_i\).

Step 3: Calculate the design ratio using Equation 8 for each part variant \(i\).

Step 4: Determine the design ratio for the product by selecting the minimum value from the design ratios among all the part variants.

Step 5: Subtract the design ratio calculated for the product from one.

From Table 3, it is observed that there are two part types with multiple variations. These components are the Trial Bipolar Head and the Femoral Head Sizer with 10 and 3 variations, respectively. This means that there are 30 product combinations \(n\). In comparison with the previous metric there were only five functions. In terms of the number of product variants used by each part variant \(i\) \(n_i\), there are only two scenarios. Each Trial Bipolar Head can be used in three ways, given the three options of Femoral Head Sizers. In contrast, each Femoral Head Sizer can be used in ten different ways given the ten options of Trial Bipolar Head. From the design variants results, the minimum value, \(3/30 = 0.1\), is selected as the design variant for the product. In order to correctly represent the relationship between design variant and complexity, a subtraction is performed to yield 0.9 \((1-0.1=0.9)\).

While the approach described above includes the selection of a particular design ratio, two additional approaches are defined to provide an aggregated measure of all the design ratios. This is necessary given that Roy et al. [22] did not define this metric as a direct assessment of complexity, but as an indicator of complexity based on commonality. These two additional approaches include a summation (Equation 6) and multiplication (Equation 7) of the values obtained for each part variant (from Table 3).

\[
\sum_{i=1}^{n}(1 - \text{Design ratio}(i)) = (6)
\]

\[
\prod_{i=1}^{n}(1 - \text{Design ratio}(i)) = (7)
\]

### 4.3 Keating's Complexity Metric

Keating's [13] complexity metric was originally developed to quantify the relevant complexity due to the number of modules and interactions. However, for the purpose of this study, the definition of modules is relaxed where they are considered to be components, which do not modify the original metric formulation. Equation 8 illustrates the complexity metric, which includes variables relevant to number of modules and interfaces.

\[ C = M^2 + I^2 \]

where,

\(C\) is the complexity

\(M\) is the number of modules

\(I\) is the number of interfaces between the modules

The modules are the components used in the mapping diagram. Consequently, the interface is related to the interactions between two or more modules. On the other hand, they do not consider the effects of failures or breaking interaction between the components \(I = 0\). This is necessary due to the characteristics of medical devices. Keating's [13] complexity metric is fairly easy to implement as seen from Equation 8, where the complexity depends on the number of modules and the number of interactions between modules. However, the major challenge is to quantify the number of components and interactions from the point of view of the surgical procedure. A connectivity graph is created to represent the interactions between components.

The application of this metric is explained as follows:
Step 1: Create a connection diagram of components and their interactions.
Step 2: Calculated the number of components.
Step 3: Calculated the number of components interactions.
Step 4: Calculated the complexity using Equation 11.

Based on the data from Medacta Bipolar Head’s BOM, a diagram of the components and their interaction is generated (Figure 5). The components include: Short Multifunction Handle, Impactor Adapter, Extractor Key, Trial Bipolar Head, Femoral Head Sizer, Femoral Trial (which is not included in the BOM), and the Adapter for Trial Bipolar Head. The Femoral Trial is included given that it is specified as part of the surgical procedure. As a result, there are seven components. On the other hand, the number of interactions is determined from the surgical procedure obtained from the company's website. For this example, the surgical procedure explained below is obtained from Medacta [26].

1. Use an Extractor Key in case that a Bipolar Head needs to be removed.
2. Use a Head Sizer to determine the Bipolar Head Size.
3. Mount the Adapter for Trial Bipolar on the multifunction handle.
4. Placed Trial Bipolar Head to the Femoral Trial.
5. Use the Impactor Adaptor and the handle for final implant impaction.

In summary, there are seven components and six interactions, which result in a complexity value of 85. The calculation for this value is explained by Equation 9.

\[ C = M^2 + I^2 \]

\[ M = 7 \text{ and } I = 6 \]

\[ C = 72 + 62 = 49 + 36 = 85 \]

The results from the implementation of the complexity metrics described are shown in Table 4 along with the device name, company and product information for the 21 devices that serve as the sample for this research. These products were selected randomly from the U.S. Food Drug Administration (FDA) database, with the constraint that the manufacture datasheet must include the BOM and surgical procedure.

Table 4. RESULTS FROM PRODUCT CHARACTERISTICS.

<table>
<thead>
<tr>
<th>ID</th>
<th>Device Name</th>
<th>B &amp; T</th>
<th>R (Volume)</th>
<th>R (Surface)</th>
<th>R (Interact)</th>
<th>K (multi-product)</th>
<th>Number of Components (main product)</th>
<th>Number of Interactions (main product)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MEDITAMA BIPOLAR HEAD</td>
<td>13</td>
<td>0.900</td>
<td>3.7875</td>
<td>3.7875</td>
<td>113</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>RJ CONSTRAINED LINER</td>
<td>11</td>
<td>0.875</td>
<td>1.25</td>
<td>0.0009625</td>
<td>80</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>TRILogy LONGITY CONSTRAINED LINER</td>
<td>13</td>
<td>0.915</td>
<td>1.7472</td>
<td>0.30065</td>
<td>85</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>4</td>
<td>HCAPPA PRESS-FIT FEMORAL</td>
<td>19</td>
<td>0.975</td>
<td>0.8596</td>
<td>1.3225</td>
<td>10</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>5</td>
<td>NOVATION CERAMIC ARTICULATION</td>
<td>0</td>
<td>0.955</td>
<td>2.14665</td>
<td>1.4201</td>
<td>101</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>6</td>
<td>REGENEXX RINGLOC + MODULAR ACETABULAR SHELLS</td>
<td>8</td>
<td>0.967</td>
<td>1.68611</td>
<td>1.9258</td>
<td>10</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>BIO-MOORE MODULAR PROSTHESIS</td>
<td>24</td>
<td>0.967</td>
<td>0.15833</td>
<td>0.00013574</td>
<td>145</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>8</td>
<td>PLATFORM HIP STEM</td>
<td>19</td>
<td>1.000</td>
<td>1</td>
<td>1</td>
<td>365</td>
<td>13</td>
<td>14</td>
</tr>
<tr>
<td>9</td>
<td>TIEF V4</td>
<td>12</td>
<td>0.958</td>
<td>0.26064</td>
<td>0.00027656</td>
<td>340</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>10</td>
<td>U3 HIP SYSTEM - BIPOLAR</td>
<td>24</td>
<td>0.953</td>
<td>1.200281</td>
<td>0.95806</td>
<td>128</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>11</td>
<td>U2 HIP SYSTEM - BIPOLAR</td>
<td>24</td>
<td>0.995</td>
<td>1.22685</td>
<td>1.29998</td>
<td>302</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>12</td>
<td>BI-METRIC HIP REPLACEMENT</td>
<td>24</td>
<td>0.953</td>
<td>0.578617</td>
<td>0.27385</td>
<td>91</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>13</td>
<td>LATER FIT TOTAL HIP SYSTEM</td>
<td>16</td>
<td>0.9815</td>
<td>0.245032</td>
<td>0.00012308</td>
<td>25</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>14</td>
<td>TEECA TOTAL HIP SYSTEM LATERAL OFFSET</td>
<td>19</td>
<td>0.9475</td>
<td>0.339076</td>
<td>2.35748-06</td>
<td>32</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>15</td>
<td>SMITH ANTHOLOGY</td>
<td>19</td>
<td>0.980</td>
<td>0.144579</td>
<td>1.18750</td>
<td>41</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16</td>
<td>MEDITAMA TOTAL HIP SYSTEM - QUADRA I AND 2 FEMORAL</td>
<td>24</td>
<td>0.941</td>
<td>0.51792</td>
<td>0.00009375</td>
<td>41</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17</td>
<td>BREMAP TC FEMORAL HIP</td>
<td>24</td>
<td>0.975</td>
<td>0.489286</td>
<td>1.3298-10</td>
<td>101</td>
<td>10</td>
<td>9</td>
</tr>
</tbody>
</table>

Table 4 provides the results for the three complexity metrics and their variations. These variations include complexity metrics with one approach for Bashir and Thomson’s [21], three for Roy et al. [22] and one for Keating [13]. While two of these metrics, [13,21], consider the complexity of the design and the surgical procedure, the metric developed by Roy et al. [22]’s is adapted to become an indicator of complexity.
### 5. RESULTS AND DISCUSSION

#### 5.1 Analysis of Correlations

An analysis of correlations is performed for the 17 hip devices included in the study. This analysis helps designers understand the relationships between the complexity metrics in addition to the product information with the Pearson correlation measure. The Pearson correlation is a goodness of fit statistic that evaluates the strength of the linear relationships between two variables. The correlation result is a value between zero and one, where the higher the value, the higher the correlation. Table 5 shows the correlation results for all pairs of variables indicating the Pearson correlation (top cell) and corresponding p-values (bottom cell). The correlation is considered significant with a confidence level of 95% (p-value < 0.05, highlighted with darker color). The significant correlations at a confidence level of 90% (p-value between 0.05 and 0.10) are also highlighted in the table for illustration purposes.

Although Roy et al.’s [22] (multiplicative) metric was not clear, given that they did not develop it to measure complexity directly (but as an indirect indicator), its strong correlation with Keating’s [13] (main product) metric shows that the proposed adaptation of it in this paper measures complexity. Further analysis, with a larger data set, will be required to better understand the proposed adaptations of Roy et al.’s [22] metric.

Other important correlations are the ones observed with the product information. These variables are used to calculate some of the metrics and also serve as indicators of complexity. In addition to the relationships described above, Bashir and Thomson’s [21] (function) is correlated with the number of components (p-value: 0.007) and interactions (p-value: 0.015) for the surgery. Meanwhile, there are also correlations between the different variables providing product information: (1) number of combinations with number of components (surgery) (p-value: 0.004), interactions (surgery) (p-value: 0.006), and components (main product) (0.031); (2) number of components (surgery) with number of interactions (p-value: 0.000) and components (main product) (p-value: 0.034); (3) number of interactions (surgery) with number of components (main product) (p-value 0.028); and (4) number of components (main product) with number of interactions (main product) (0.000). These relationships are as expected given the nature of these values. For example, the number of interactions depends on the number of components.

#### 5.2 Proposed Factors Influencing Design Complexity

Using a similar approach to existing metrics, factors for a standardized and generalized metric are introduced under some parameter that must be included in a new metric. The number of components and their interaction should be included given that this was a common factor correlated with most of the metrics in this study. Also, the functions of the system must be included in the new metric. Meanwhile, additional parameters will be

### Table 5. CORRELATION ANALYSIS.

<table>
<thead>
<tr>
<th>Factors/Factors</th>
<th>B &amp; T (function)</th>
<th>B &amp; T (surgery)</th>
<th>R (1-Min(dr))</th>
<th>R (summation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B &amp; T (surgery)</td>
<td>0.276</td>
<td>0.424</td>
<td>-0.208</td>
<td>-0.429</td>
</tr>
<tr>
<td>R (1-Min(dr))</td>
<td></td>
<td></td>
<td>0.321</td>
<td>0.535</td>
</tr>
<tr>
<td>R (summation)</td>
<td></td>
<td></td>
<td>0.086</td>
<td>0.086</td>
</tr>
<tr>
<td>R (multiplicative)</td>
<td></td>
<td></td>
<td>-0.162</td>
<td>-0.09</td>
</tr>
<tr>
<td>K (surgery)</td>
<td>0.056</td>
<td>0.832</td>
<td>0.08</td>
<td>0.088</td>
</tr>
<tr>
<td>K (main product)</td>
<td>0.345</td>
<td>0.863</td>
<td>0.08</td>
<td>0.088</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cell Contents:</th>
<th>Pearson Correlation P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Correlation with P-Value &lt; 0.05</td>
<td></td>
</tr>
<tr>
<td>Pearson Correlation with P-Value between 0.05 and 0.10</td>
<td></td>
</tr>
</tbody>
</table>

### Table 6. CORRELATIONS

<table>
<thead>
<tr>
<th>Factors/Factors</th>
<th>Num of Components (surgery)</th>
<th>Num of Interactions (surgery)</th>
<th>Num of Components (main product)</th>
<th>Num of Interactions (main product)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Num of Interactions (surgery)</td>
<td>0.989</td>
<td>0.952</td>
<td>0.417</td>
<td>0.094</td>
</tr>
<tr>
<td>Num of Components (main product)</td>
<td>0.515</td>
<td>0.532</td>
<td>0.034</td>
<td>0.028</td>
</tr>
<tr>
<td>Num of Interactions (main product)</td>
<td>0.419</td>
<td>0.417</td>
<td>0.886</td>
<td>0.061</td>
</tr>
<tr>
<td>Decision Time</td>
<td>0.094</td>
<td>0.079</td>
<td>0.028</td>
<td>-0.013</td>
</tr>
</tbody>
</table>

TABLE 6. CORRELATIONS

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<thead>
<tr>
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<th>Num of Components (surgery)</th>
<th>Num of Interactions (surgery)</th>
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<th>Num of Interactions (main product)</th>
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</tr>
<tr>
<td>Decision Time</td>
<td>0.094</td>
<td>0.079</td>
<td>0.028</td>
<td>-0.013</td>
</tr>
</tbody>
</table>
necessary to quantify the complexity of other sources that were not addressed in the literature. One of these parameters is design uniqueness. This can be presented on a 0-1 scale with 1 being a revolutionary design that departs from existing designs and 0 being a new design that is indistinguishable from existing designs. Another variable that should be considered in the new complexity metric is related to the product’s internal/external use. This will be 1 if the device is operated inside the body and 0 if the product is used outside of body. The need for such a variable is due to the significant differences in regulations between products designed for internal/external human use.

Incorporating these added factors, the proposed Design Complexity Metric (DCM) can be mathematically represented as follows:

\[
DCM = \frac{\text{Number of Components}}{\text{Number of Components} + \text{Number of Interactions Between Components}} + \text{Innovation} + \text{Product Intended Use}
\]

(10)

For all hip replacement devices used in this paper the invention and the product intended use parameters are the same for each device, 0 and 1 respectively. The results of the DCM are shown in Tables 6 and 7.

### Table 7. RESULTS FOR NEW COMPLEXITY METRIC.

<table>
<thead>
<tr>
<th>Device</th>
<th>S K (main product)</th>
<th>Number of Components (main product)</th>
<th>Number of Interactions (main product)</th>
<th>New Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDACATA BIPOLAR HEAD</td>
<td>0.2883</td>
<td>7</td>
<td>8</td>
<td>15.288</td>
</tr>
<tr>
<td>RJ CONSTRANGED LINER</td>
<td>0.2041</td>
<td>4</td>
<td>6</td>
<td>10.204</td>
</tr>
<tr>
<td>TRILOGY LONGEVITY CONTRAINE L</td>
<td>0.2168</td>
<td>6</td>
<td>7</td>
<td>13.217</td>
</tr>
<tr>
<td>RECAP HA PRESS-FIT FEMORAL</td>
<td>0.0332</td>
<td>9</td>
<td>4</td>
<td>13.033</td>
</tr>
<tr>
<td>NOVATION CERAMIC ARTICULATION</td>
<td>0.4617</td>
<td>9</td>
<td>10</td>
<td>19.462</td>
</tr>
<tr>
<td>REGENERX RINGLOC + MODULAR ACETABULAR SHELLS</td>
<td>0.2168</td>
<td>7</td>
<td>6</td>
<td>13.217</td>
</tr>
<tr>
<td>BIO-MOORE MODULAR PROSTHESIS</td>
<td>0.3699</td>
<td>9</td>
<td>8</td>
<td>17.37</td>
</tr>
<tr>
<td>PLATFORM HIP STEM</td>
<td>0.9311</td>
<td>13</td>
<td>14</td>
<td>27.931</td>
</tr>
<tr>
<td>EXETER V40</td>
<td>0.8673</td>
<td>12</td>
<td>14</td>
<td>26.867</td>
</tr>
<tr>
<td>U1 HIP SYSTEM - BIPOLAR</td>
<td>0.3265</td>
<td>8</td>
<td>8</td>
<td>16.327</td>
</tr>
<tr>
<td>U2 HIP SYSTEM - BIPOLAR</td>
<td>1.0000</td>
<td>14</td>
<td>14</td>
<td>29</td>
</tr>
<tr>
<td>BI-METIC HIP REPLACEMENT</td>
<td>0.1556</td>
<td>6</td>
<td>5</td>
<td>11.156</td>
</tr>
<tr>
<td>TAPER FIT TOTAL HIP SYSTEM</td>
<td>0.0638</td>
<td>4</td>
<td>3</td>
<td>7.0638</td>
</tr>
<tr>
<td>EXCIA TOTAL HIP SYSTEM LATERAL OFFSET</td>
<td>0.0816</td>
<td>4</td>
<td>4</td>
<td>8.0816</td>
</tr>
<tr>
<td>SMITH ANTHOLOGY</td>
<td>0.1046</td>
<td>4</td>
<td>5</td>
<td>9.1046</td>
</tr>
<tr>
<td>MEDACTA TOTAL HIP PROSTHESIS SYSTEM - QUADRA H AND R FEMORAL</td>
<td>0.1046</td>
<td>4</td>
<td>5</td>
<td>9.1046</td>
</tr>
<tr>
<td>BIOPRO PC FEMORAL HIP</td>
<td>0.4617</td>
<td>10</td>
<td>9</td>
<td>19.462</td>
</tr>
</tbody>
</table>

As we expected the new metric is correlated to the number of components, interactions, combinations, Keating [13]'s and Bashir and Thompson [21]'s metrics. However, the results of this new metric are not correlated to FDA decision time. However, this will be part of future study because this may require a set of more data points and/or other parameters in the metric, which will be a topic for future work.

### Table 8. CORRELATIONS OF THE NEW METRIC.

<table>
<thead>
<tr>
<th></th>
<th>New Metric</th>
<th>B &amp; T (function)</th>
<th>B &amp; T (surgery)</th>
<th>R (1-Min(dr))</th>
</tr>
</thead>
<tbody>
<tr>
<td>B &amp; T (surgery)</td>
<td>0.495</td>
<td>0.37</td>
<td>0.026</td>
<td>0.108</td>
</tr>
<tr>
<td>R (multiplicity)</td>
<td>0.415</td>
<td>0.033</td>
<td>0.197</td>
<td>0.097</td>
</tr>
<tr>
<td>K (main product)</td>
<td>1</td>
<td>0.199</td>
<td>0.494</td>
<td>0.055</td>
</tr>
<tr>
<td></td>
<td>0.069</td>
<td>0.891</td>
<td>0.404</td>
<td>0.684</td>
</tr>
<tr>
<td>Num of Combinations</td>
<td>0.474</td>
<td>0.256</td>
<td>0.439</td>
<td>0.089</td>
</tr>
<tr>
<td>Num of Componets (surgery)</td>
<td>0.376</td>
<td>0.474</td>
<td>0.418</td>
<td>0.332</td>
</tr>
<tr>
<td>Num of Interactions (surgery)</td>
<td>0.403</td>
<td>0.457</td>
<td>0.436</td>
<td>0.371</td>
</tr>
<tr>
<td>Num of Componets (main product)</td>
<td>0.92</td>
<td>0.283</td>
<td>0.5</td>
<td>0.031</td>
</tr>
<tr>
<td>Num of Interactions (main product)</td>
<td>0.026</td>
<td>0.226</td>
<td>0.025</td>
<td>0.897</td>
</tr>
<tr>
<td>Decision Time</td>
<td>0.272</td>
<td>0.278</td>
<td>0.349</td>
<td>0.022</td>
</tr>
<tr>
<td></td>
<td>0.247</td>
<td>0.235</td>
<td>0.131</td>
<td>0.928</td>
</tr>
</tbody>
</table>

### 6. CONCLUSION

This paper is intended to increase designers’ awareness on complexity in order to develop improved and cost/effective products. Complexity metrics can be used as tools to improve the design of medical products by understanding, detecting, and reducing the complexity. To reduce the complexity of medical devices designers may have to reduce the number of components and their interactions. Also, they have to consider the functions of the components in order to understand and detect the sources of high complexity.

As per the analysis presented above, we have seen that although existing metrics can be applied in medical device design contexts, their inconsistent pairwise correlations point to the different facets of complexity they cover. There is a need for robust metrics that can used to reflect a comprehensive review of complexity.
REFERENCES


