High Value Manufacturing

ADVANCED RESEARCH IN VIRTUAL AND RAPID PROTOTYPING

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Shape analysis in the design process of products with embedded microelectronics

Álvaro M. Sampaio & Ricardo Simões
Polytechnic Institute of Cávado and Ave, Campus do IPCA, Barcelos, Portugal
Institute for Polymers and Composites, IPC/I3N, University of Minho, Campus de Azurém, Guimarães, Portugal

António Pontes
Institute for Polymers and Composites, IPC/I3N, University of Minho, Campus de Azurém, Guimarães, Portugal

ABSTRACT: Surgical Instruments (SI) are a major asset and a significant share of the total capital spending of a hospital. It is therefore important to track the product inside the health provider's facilities. One of the technologies available to face this problem is RFID. In order to tackle this issue, the first approach was to develop a polymeric add-on product that features an embedded RFID, and which could be coupled to the surgical instrument without the need to redesign it. Nevertheless, there are many challenges in incorporating an RFID tag in SI. Aside from usability issues, it is vital to ensure that the tag is placed in the same zone of the SI. For this purpose, shape analysis has been conducted with all instruments of a SI generic set (25 SI) in order to find similarities and common geometries. In this paper we describe those results and how they were employed to design a solution. The development product should allow for a fast and accurate count during surgical and sterilizing operations. This system can help to prevent several typical errors, such as miscounting, misplacement, and the accidental disposal of SI.

1 INTRODUCTION

When producing medical devices, manufacturers must design them to fit the intended purpose not only in design, manufacture and finish, but also by selecting adequate materials. For SI generally only stainless steel (hardened, non-rusting) can meet the tough requirements in terms of tenacity, rigidity, blade characteristics, wear resistance, and corrosion resistance. SI are a major asset and represent a significant share of the total capital spending of a hospital. Typically, they have high unit cost compared with many other industries. It is therefore important to be able to track the product as it moves along the supply chain. It is even more important to track the product inside the health provider's facilities, during use, cleaning and sterilizing. As such, we present as a case study the issue of coupling an RFID to SI in order to track them.

Despite first appearances, this is not a trivial task, as there are many challenges in the incorporation of a microelectronic device in SI, including: the environmental conditions, as the device needs to perform in high humidity, contact with metal surfaces, need to withstand extreme temperatures, and other factors. Also, it must be insured that the placement of the microelectronic device poses absolutely no threat to the patient, nor hampers or limits the performance of the health professional using the surgical instrument.

Although the major improvement in coupling a microelectronic device will be seen in the performance of the scrubbing nurse and on the sterilization technician, surgeons' procedures and requirements are the most critical issue. Therefore, one of our goals is the development of a product that features an embedded microelectronic device, and can be physically coupled to SI, with no impact on its usability. The major task is to develop this product in a way that allows it to be coupled to a large number of existing SI.

2 METHOD FOR MICROELECTRONIC INCLUSION

2.1 *Introduction*

As the goal was to achieve a solution through a polymer-based add-on product that features the embedded RFID, this task unquestionably requires a detailed analysis of the shape, size, and other physical and functional characteristics of the SI. Only in this way it is possible to develop the product with the embedded technology to be coupled to the SI (Sampaio et al. 2010).

Another crucial issue is to involve the end-user in the development process. Healthcare facilities are environments where human error can result in tragedy, including the loss of lives. As such, changes or improvements to medical devices, protocols or procedures must be carefully studied (Alexander et al, 2002). Placing a novel feature in SI (such as an externally coupled product) is one of such case, as surgical

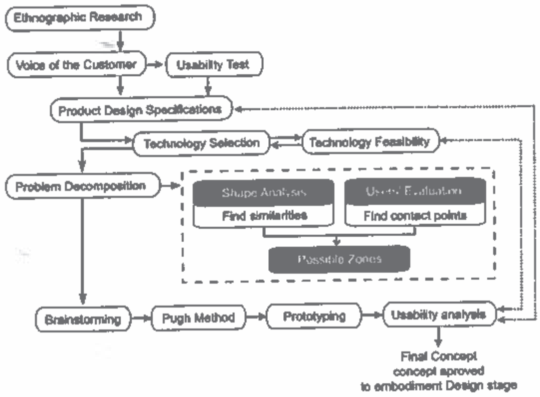

Figure 1. Process flow of the design process.

protocols cannot be modified easily, nor can these modifications to the SI hamper the way surgeons handle them. In this framework, it was necessary to developed a method (Fig. 1 – solid black rectangles) that allowed to investigate the two major aspects of the this phase of the product design process, which did not exist in any of the usual product development processes (Sampaio et al. 2009):

- characterizing the shape and functional features of all SI in a generic SI set, in order to find similarities and common geometries, and;
- understanding exactly how surgeons use SI.

Understanding how surgeons grab the instruments would provide knowledge about neutral zones (possible zones where the add-on can be attached). In the same way, the shape analysis will provide the knowledge on where to geometrically couple the add-on product. Although the users' evaluation is not the focus of this paper, both studies were required to establish which areas of the instruments were more appropriate for coupling an external component.

3 SHAPE ANALYSIS

As stated the shape analysis was centered in the analysis of the shape and form of the SI in order to find similarities and common geometries. Since the project is focused on all SI of a generic set this analysis began with two needle holders, twelve hemostatic forceps, three scissors, two dressing forceps, two tissue forceps, two scalpel handles, a backhaus towel forceps and a McGivney forceps, in a total of twenty five SI.

As there are several variations in each type of surgical instrument (e.g. Kelly Haemostatic straight; Kelly Haemostatic curved), changing only the tip while maintaining the main geometry of the part that has contact with the surgeons' hands, it is possible to extrapolate this analysis to more SI than the ones of the evaluated set.

Since this was a large number to analyze the number of SI have been restricted. The procedure was to establish two groups ('Straight instruments' and 'Scissors-like instruments') and then with these groups it was possible to identify seven subgroups of SI, as can be seen in Figure 2. The group classification was based on shape similarity and the subgroup based on types of SI. This classification scheme has enabled to focus the analysis on only seven types of SI.

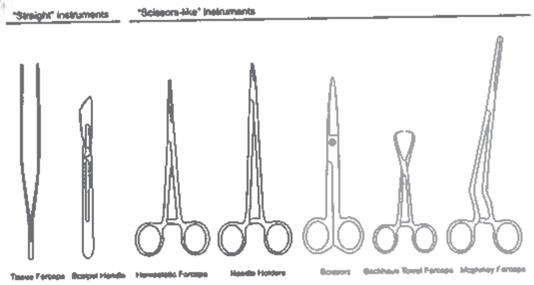

Figure 2. Groups and sub-groups of a generic surgical instruments set.

3.1 *Procedure*

To begin the analysis previously discussed, a 3D scanner was employed to obtain 3D computer models for each type of SI in a generic set. The 3D scanner employed was a Roland LPX-600DS. The scanning pitch was in plane scanning, and the accuracy of the scanning was in the maximum level (0.05 mm). Before the scanning, instruments needed to be sprayed with white developer liquid (used for nondestructive testing) in order to cover the metal; without this procedure the laser of the scanner would be reflected, disabling the scanning.

After the scanning process the scanned models were analyzed in terms of 3D comparison of forms and the measurement in the most similar part of the shapes. To perform this analysis the Geomagic Qualify v.12 software was employed. This analysis began by conducting a study on the 'Straight' instruments. Then conducting two general studies on the "scissors like instruments'. Comparing the biggest and the smallest instrument first (Macgivney Forceps and Backhaus Towel Forceps, respectively) and then comparing the Needle Holder and the Hemostatic Forceps (more similar ones). The fourth study was conducting comparison analysis with all 'scissors like instruments', but only with half of their shapes since the shapes were symmetric. Then it was developed a fifth analysis, within this group, with only one of the spindles of all instruments. In this paper only the results of the first, fourth and fifth are presented and discussed since they were the relevant analysis for the development of a design solution.

3.2 *Results from the first analysis*

The first analysis that was developed involved the two instruments of the 'Straight' group. To start the analysis, a similar shape was selected in both instruments. In other words, the analysis was only conducted in a

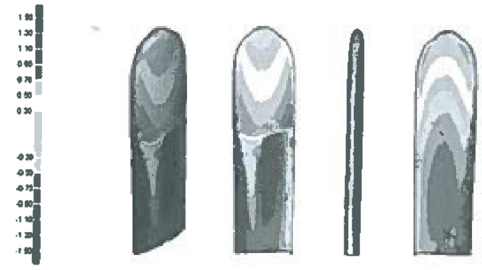

Figure 3. 3D comparison for the Scalpel with the Tissue Forceps instruments.

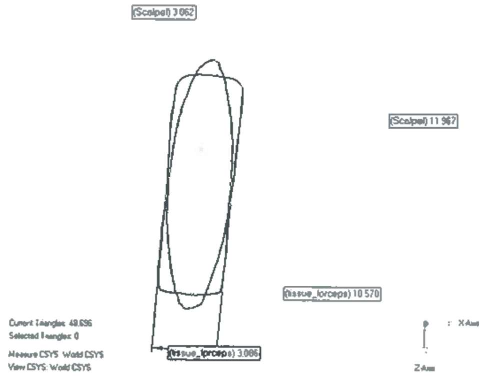

Figure 4. Measurement of the scalpel and tissue forceps.

small part of the instrument. This was due to one reason, as the shapes of the instruments are very different, conducting an analysis in all its shape would let us with the impossibility of matching the forms. Even if those shapes could be matched, at any given area, the number of points in the superficies that were not in the range of the area matched, would lead to an incorrect standard deviation analysis. Therefore, in all the analysis that was performed in any of the approaches they were conducted with parts of the instruments. So, in the first comparison analysis the scalpel was selected as the reference instrument. A '3D compare' was developed with a maximum and minimum tolerance defined between +1.5 and −1.5 mm. The result can be seen in Figure 3.

From Figure 3 one can see that some points are out off the matched area (Grey zones) and that most parts are in blue color. This is due to the fact that the tissue forceps is smaller than the reference instrument. The green zones are surfaces of contact between the two instruments and the red zones indicate that the reference instrument is bigger than the test model.

Since the more homogeneous zone is the one that is register in blue (Fig. 3), it has been made a 2D transversal cut (Fig. 4) in that zone to try to measure the perimeter in order to find the range between them.

The Tissue Forceps is approximately a rectangle and the perimeter is 27.3 mm.

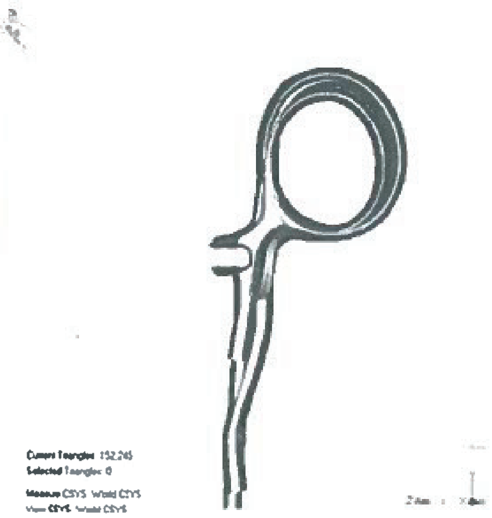

Figure 5. Alignment of the 'Scissors-like instruments'.

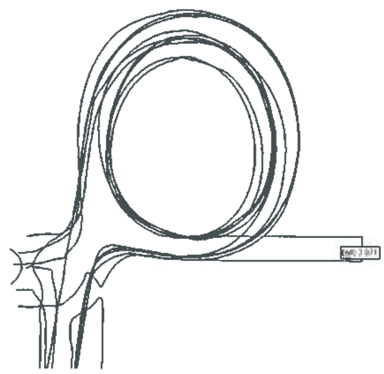

Figure 6. 2D measurement of the more identical part.

The scalpel is elliptical and the perimeter is 25.7 mm. So, these two SI in their similar part have a perimeter of 1.6 mm of difference.

3.3 *Results from the fourth analysis*

As previously stated, the fourth analysis was developed with just one side of all instruments of the group 'scissors-like'. In order to match all instruments, they were aligned one by one with the 'manual registration' software tool. For this alignment the previous instrument was always the reference model. Figure 5 represents the alignment of the instruments.

After performing the alignment of the five instruments that represent this group, measurements were taken in order to establish the range between them. The investigating was focused on the biggest and smallest measurement in the more similar part of the shapes analyzed. In order to conduct this search, a longitudinal cut in all instruments (Fig. 6) was made and the lower part of the ellipsoidal handle was measured (the most similar one).

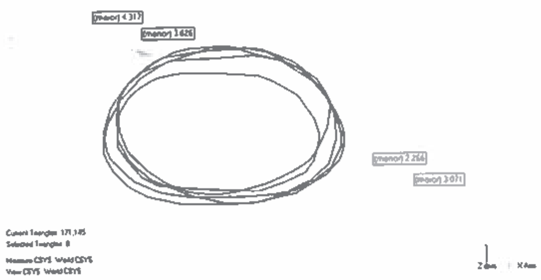

Figure 7. 2D measurement of all circles in the more identical part.

Figure 8. 3D comparison for all spindles of all instruments of the 'Scissors-like instruments'.

The value of this part was 3.071 mm. As this value did not evidence the similar part in detail, it was developed a section in that zone (Fig. 7).

As it can be seen from Figure 7 the biggest and the smallest ellipse were measured. Since the importance was centered in the perimeters they were calculated for the two instruments. The biggest had 11.7 mm and the smallest had 9.38 mm. So, the instruments range from a difference of 2.33 mm.

From this analyses it was possible to state that the spindles are very similar, therefore it has been conducted another shape analysis with only these parts.

3.4 *Results from the fifth analysis*

In this fifth analysis one spindle of each 'scissor-like' were analyzed in-group. A 3D comparison was developed with no maximum and minimum tolerance defined. The results can be seen in Figure 8.

In Figure 8 it is possible to see that the maximum tolerance was defined by the analysis with 0.25 mm and the minimum with −1.89 mm. Another important fact is that, from the colors in all the views, the similarities are concentrated in the smallest deviations. This is corroborated by the standard deviations plot (Fig. 9).

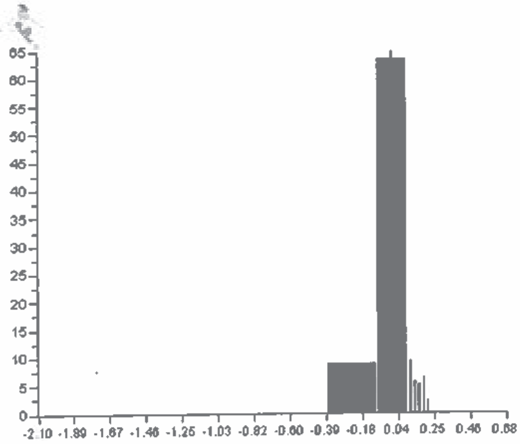

Figure 9. Standard deviations (with all spindles).

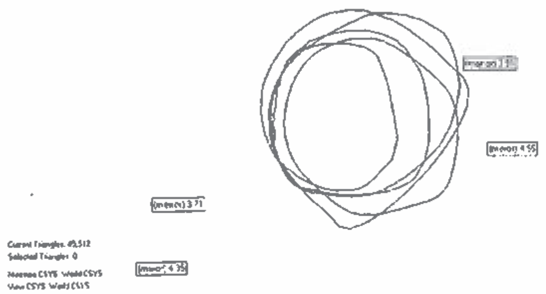

Figure 10. 2D measurement of all circles of the spindles.

Almost 65% of the points analyzed are within a range smaller than 0.15 mm, and all points are within −0.39 mm and 0.25 mm.

To understand the real measures of the instruments a transversal cut in the middle of these shapes was developed (Fig. 10).

As in the previous analysis it has been measured the biggest and the smallest ellipse to determine their range. So the biggest instrument had 14 mm of perimeter and the smallest had 12 mm. All instruments are with a difference range of 2 mm.

3.5 *Overall results*

After conducting the analyses of the shape of all the instruments of a generic surgical set, it is possible to state that in terms of similarities there are two different groups. One containing the Scalpel and the Tissue forceps, and the other containing, the Hemostatic forceps, the Needle Holder, the Scissor, the Macgivney Forceps and the Backhaus Towel Forceps. These groups have been named 'Straight' instruments and 'Scissors-like' instruments, respectively. As the analyses were been developed, the focus of the investigation was centered on finding similar shape-parts of a combination of instruments and then measuring those shapes in order to identify their variations.

The first combination of shape-parts analyzed was from the 'straight' instruments, where a common

Table 1. Shape similarities with measurements (in millimeters)

Shape-part	Biggest	Smallest	Difference
'Straight' instruments			
Upper Scalpel/Tissue forceps	27.3	25.7	1.6
'Scissor-like' instruments			
Ellipsoidal handle	11.7	9.38	2.32
Spindles	14	12	2

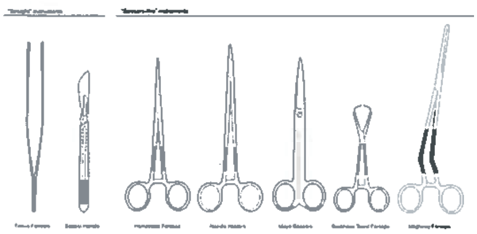

Figure 11. Likely coupling areas, in black, for each type of SI.

geometry on the extreme top of the instruments was found and find that this similarity had a range unit of 1.6 mm.

The other combinations were centered in the group of the 'Scissors-like' instruments. Within this group two common geometries were found: the ellipsoidal handle part and the spindles. The similarities of these shapes ranged within 2.32 mm and 2 mm, respectively. These measurements can be seen in Table 1.

If the add-on were a universal product that had to embrace the SI, it would have to range from 9.38 mm to 27.3 mm, so it needed to have 17.92 mm of flexibility. In the end the final shapes with common similarities can be seen in Figure 11.

4 CONCLUSIONS

In most cases the inclusion of microelectronics in products requires new design methods and new technical specifications for the product. One paradigmatic case is the need to incorporate microelectronics into already existing products. The difficulty/impossibility of simple embedding the microelectronic device into the product creates complex obstacles. For this case, a solution is to develop an add-on product that will be coupled to the original product or family of products. In this paper we have focused on this problem specifically applied to SI. The scope of this study was to investigate similarities and common zones of 7 types of SI that represent a generic SI set. In this way, a shape analysis was developed to provide the knowledge on where to geometrically couple the add-on product (RFID tag) in a possible universal way. This analysis was developed using 3D comparison software. The results showed the existence of 2 different groups of shape-similarities. First the 'Straight instruments' with the common zone being the upper part of the instruments and, second the 'Scissors-like instruments' with two suitable zones, the ellipsoidal handles and the spindles.

With the shape analysis and the users' evaluation it was possible to establish the likely areas to couple the add-on product on the SI.

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