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Process Optimization Regarding Geometrical Variation and Sensitivity Involving Dental Drill- and Implant-Guided Surgeries

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***Abstract*—**Within dental-guided surgery, there has been a lack of analytical methods for optimizing the treatment of the rehabilitation concepts regarding geometrical variation. The purpose of this study is to find the source of the greatest geometrical variation contributor and sensitivity contributor with the help of virtual variation simulation of a dental drill- and implant-guided surgery process using a methodical approach. It is believed that lower geometrical variation will lead to better patient security and higher quality of dental drill- and implant-guided surgeries. It was found that the origin of the greatest contributor to the most variation, and hence where the foci should be set, in order to minimize geometrical variation was in the assembly category (surgery). This was also the category that was the most sensitive for geometrical variation.

***Keywords*—**Variation Simulation, Process Optimization, Guided Surgeries, Dental Prosthesis.

I. Introduction

MODERN medical rehabilitation approaches a more classic manufacturing process, meaning that many technologies and activities are performed to accomplish the intended purpose[1]. Examples of this include CT scanning of patients in order to achieve structures of bones for use in the CAD planning of surgery, rapid prototyping as a means of designing and developing medical devices and instrumentation, telemedicine for real-time consultation between medical specialists, and robotic surgery for minimally invasive surgical procedures.

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This means that, to a great extent, rehabilitation is pre-prepared and pre-planned, with the help of both physical and virtual models.

The reason for this is, for example, among other reasons, to minimize the actual time of the rehabilitation, to enable treatments that have not been possible or were difficult to achieve, to minimize the proportion of the surgery, and to make surgeries safer.

In this paper, the focus is on where to set the emphasis for process optimization regarding the minimization of geometrical variation and finding the source of the most sensitive parameter for dental drill- and implant-guided surgeries (guided surgery). It is a treatment plan and surgical implementation system that enables the transfer of extra oral planning (CAD) into the mouth[2-4].

In the guided surgery concept, rapid prototyping, based on CT scanning, for example[5], is used for manufacturing the surgical template, hence mass customization. The prototyping is based on the reverse engineering of anatomical structures of the jaw. It also allows the design of three-dimensional models of anatomical structures. This means that a new specification of requirements has to be altered each time a new model is manufactured. This also means that the requirements need to be met due to safety reasons.

A production system with such flexibility places high demands on the process, considering both software and hardware. From a general point of view within the medical area, precision and accuracy is of high interest due to patient safety. However, because of reality, a treatment that is always nominal is desirable regarding patient safety. Yet, it is not possible, due to variation throughout the treatment concept, and manufacturing process. Therefore, it is also of great interest to optimize the processes in a geometrical variation-suppressing way in order to meet the high demands set within the medical discipline.

Earlier research has shown that the prediction of the results of guided surgery can be performed. It has also shown that variation simulation can predict the greatest variation contributor[6]. Due to these results, it is also possible to discover what to focus on when an optimization of the process needs to be made regarding geometrical variation.

If an optimization of the process is made, the process also approaches a more robust design, suppressing variation. This means that the treatment converges towards a safer treatment. For this study, with prior results in mind, the following hypothesis has been stated:

Geometrical variation suppressing optimization can be performed for the most critical dimension if the part of the process that contributes the most to the geometrical variation can be shown statistically.

Generally, all manufacturing processes are influenced by variation, both considering mass production and mass customization[7]. This means that the nominal value of a manufacturing dimension may not be expected at all times. Instead, a manufacturing dimension may be described by an expected range and probability distribution[8].

For most processes, manufacturing costs rise with decreasing geometrical variation. This is the primary reason why design concepts with functionality based on small geometrical manufacturing variation ought to be avoided. However, in guided surgery, these trade-off balances are complex. This is due to high demands on small variation and cost effective manufacturing due to cost-demanding equipment and patient safety.

Furthermore, in order to perform surgery, meeting geometry requirements is fundamental to assuring that the final product functions as planned and is high quality. If the requirements are not met, the product may not comply with functional, esthetic, geometrical and assembly demands[9-11].

For guided surgery, this could mean that implants do not fit the prosthetic restoration as intended, due to pre-preparation process. Hence, geometrical variation throughout the manufacturing process affects the final result. An example of the chain reaction causing the misfit between the bridge (teeth setup) and implants could be that: the implants are finalized in a non-favorable position, caused by non-advantageously drill-guide position and/or guide sleeves in a non-nominal angle and/or position, where the source to it is manufacturing, and/or positioning of surgical template this in its turn causes stress on the bridge due to pre-manufactured bridge, where the bridge might have the fixture out of its non-nominal position. Further on the loss of functionality might cause patients to suffer headaches, due to unbalanced bite occlusion. The reason to the loss of functionality could be less complex than in this example. More over loss of functionality might also cause more serious injuries, for example, the implants may penetrate a bone or nerve [12].

Due to different geometrical sensitivities in the manufacturing of complex products, variation in each production step requires optimization and the consideration of tolerance allocation[8].

Generally, geometrical variation in critical product dimensions and features typically result from a number of different sources (see Fig 1[13]). Size and form variation in the geometry of the individual parts originate from the individual manufacturing process used, which will vary over time. Similarly, the assembly process contributes to variation originating from a variation in fixtures and clamping tools. This may vary over time as well. An important contributor to final variation is also the robustness of the design concept itself. A sensitive design concept amplifies part and assembly variation. A robust concept, on the other hand, suppresses variation.

When considering guided surgery, the robustness of the concept is mainly determined in two stages:

1. The design of the guided surgery concept.
2. The placement of the anchoring system between the surgical template and jaw.

This gives the process great flexibility to undergo complex surgery. However, it also means that a control method regarding the flexibility of the system is required [6, 14]. Again, this is due to variation throughout the process. The tolerances that contribute to the final variation in the manufacturing processes are often defined with the help of different types of probability distributions. For example, the accuracy of stamping could be explained by a uniformly distributed probability due to the play in the fixating of the tool, a melting process by a normal distribution. A few other common probability distributions defined in the industry today are trapezoid-, and beta distribution. According to the central limit theorem, the sum of many distributions tends to be close to the normal distribution. For example, assume that the tolerance in a machined part is the sum of a large number of infinitesimal effects. These could be the humidity, the cutting angle, fixturing variations, the variation in the material, and so on. If the component errors are independent and equally likely to be positive or negative, then the total error can be shown to have an approximate normal distribution, which is favorable in processes like the one analyzed here.

The means of managing variation and secure function, form and assembly, is by assigning tolerances that restrict the permitted variation of a geometrical feature. Properly done, tolerances are allocated in a top-down fashion. There, overall product constraints are broken down into component constraints and, finally, into tolerances for individual geometrical features [7]. This is a complex process, where functional and quality aspects must be balanced with manufacturing constraints and cost aspects (see Fig. 2 [6]).

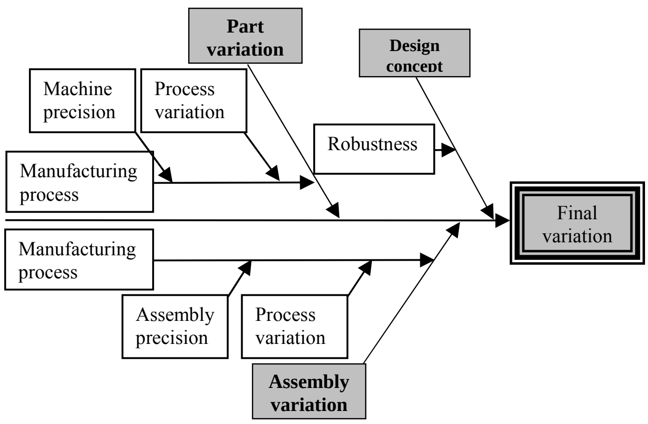

Fig. 1 Geometrical variation contributors, process industry [13]

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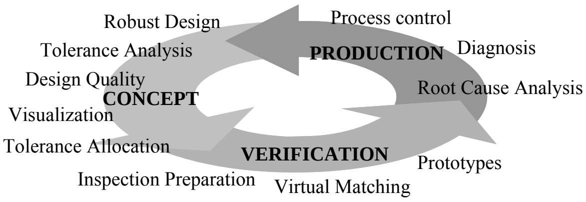

Fig. 2 Geometry assurance activities [13]

• In the concept phase, the product and the production concept are developed. Product concepts are analyzed and optimized to withstand the effect of manufacturing variation. They are also tested virtually against available production data. In this phase, the concept is optimized with respect to robustness and verified against assumed production systems through the use of statistical tolerance analysis[2, 7, 15]. The visual appearance of the product is optimized, and product tolerances are allocated down to part level [7, 16, 17].

•In the verification and pre-production phase, the product and the production system are physically tested and verified. Adjustments are made to both product and production system to adjust errors and prepare for full production. In this phase, inspection preparation takes place. This is the activity in which all inspection strategies and routines are decided[7].

• In the production phase, all production process adjustments are completed, and the product is in full production. The focus in this phase is on controlling production and detecting and correcting errors[7].

II. Method

To discover where to set the focus for process optimization regarding the minimization of the geometrical variation and finding the most sensitive parameter of guided surgery, a variation simulation (Monte Carlo) of the surgery needs to be made[6, 15]. The variation simulation is the foundation for the sensitivity and contribution analysis for predicting the foci for process optimization.

The guided surgery is a treatment planning and surgical implementation system that enables the transfer of extra oral planning into the mouth. Within this concept, the placing of the implants, abutments, and restorative bridge are simultaneous. It is done with the help of a CAD-planned surgical template based on CT-Scans and rapid prototyping [5]. Fig. 4 presents a cause and effect diagram specific to drill- and implant-guided surgeries. It is worth noting that Fig. 1 is a general diagram of all manufacturing processes, whereas Fig. 4 is an extracted diagram, valid as a general cause and effect diagram for drill- and implant-guided surgeries. The purpose of Fig. 4 is to present the contributions to the effect of drill- and implant-guided surgery in a straightforward way. The categories of the effect - Part Variation, Design Concept, Examination of Patient, and Assembly Variation (Surgery) - are general ones, the effect being the final variation in general drill- and implant-guided surgery. Only the sources within each category differ between guided surgeries.

The sources of the categories in the drill- and implant-guided surgery considered in this article are the following, see Fig. 1 and Fig. 4:

• *Part variation*:
Consists of the surgical template (individual geometry), anchor pins, implants, and the patient. The variation originates from machine precision, manufacturing process, and individual variation.

• *Design concept*:
Consists of the scan data converting, the treatment planning, and the CT scanning procedure. The variation originates from the robustness of the design concept.

• *Examination of patient*:
Includes variation where the patient is involved, jaw impression, bite impression, and CT scanning. The variation contribution in this group not only involves material and the accuracy of the CT scanner, but also the patient (i.e. small movements during the scanning and teeth occlusion). The variation of this group is often difficult to predict.

• *Assembly variation (Surgery)*:
Includes the assembly of the surgical template, drilling, and implant installation. The main variation originates from the assembly of the surgical template and the human factor,

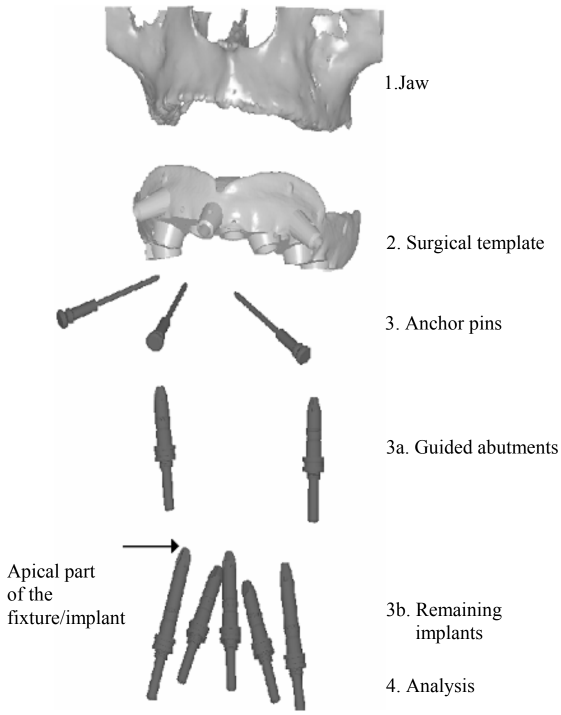

Fig. 3 Order of the simulation and surgery

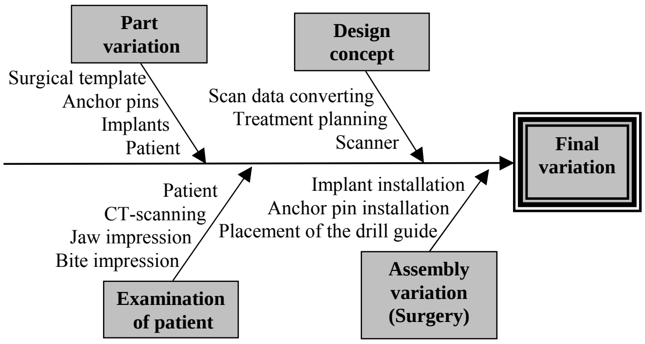

Fig. 4 Cause and effect diagram, for dental drill- and implant-guided surgery

considering both patient and surgeon during the operation. This group is in many ways dependent on the prior-groups. A few examples include the manufacturing process, pre-planning, and the process variation.

In earlier research, the range of the variation was found to be between 0.171-1.790 mm at the apical part of the fixture, when the same examples as here were used [6]. In it, the critical measure was defined at the apical part of the fixture (see Fig. 3), as in this case. All the groups within Fig. 4 interact with each other in a complex way. This means that the final variation depends on the relationship between the sources. Each source influences the final geometry and variation of the assembly of the implants. The mapping for the relationships between actors and activities were performed with the help of a design structure matrix.

The Assembly (surgery) and the variation simulation are performed in the following manner (see Fig. 3):

1. The surgical template is positioned on the jaw.

2. Then the surgical template is fixed on the jaw through the use of anchor pins.

3. Next, the implants are installed.
   a) The guided abutments are assembled (they correspond to the template abutments during the real surgery, and they could be any predefined combination). These implants prevent the surgical template from moving in the axial implant direction during surgery.

   b) The remaining implants are installed.

For the theoretical analysis, the two following steps are also carried out:

1. Sensitivity analysis
2. Contribution analysis

Meanwhile, the method for the theoretical analysis is as follows:

1. Sensitivity analysis is carried out. This means that a variation simulation is executed with equal tolerances of +/- 1 mm, normally distributed for each source.
   - This analysis method reveals the most sensitive parameters in the concept.
   - The concept needs to be re-designed in order to optimize these results.

2. Contribution analysis is executed with the mated tolerances mapped out from each source in the process.
   - This gives the greatest contributor to the final geometrical variation. Hence, here is where the primary foci of the process optimization should be set.

With the help of the results, a decision as to where to set focus for the process optimization can be made, with the most geometrical variation-contributing parameter and the most sensitive parameters in mind.

The results are demonstrated with the help of two examples: first, by surgery intended for the upper jaw (Maxilla), three anchor pins and seven implants, and then second, by surgery intended for the lower jaw (Mandible), four anchor pins and nine implants[6].

III. SOFTWARE

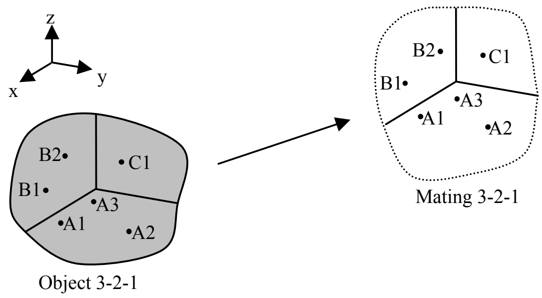

Fig. 5 General 3-2-1 Locating scheme

As mentioned above in the method section, a variation simulation of the guided surgery is performed before a contribution analysis is completed [6]. The fundamental theory for the variation simulation is that the calculation takes the geometrical key characteristics into consideration. The Monte Carlo simulation method is used. The method randomly generates numbers for all input parameters according to defined distributions and builds up distributions for the output parameters (critical product dimensions). Here, the same serial was stabilized for both cases. It was also found that in this assembly case 100,000 Monte Carlo iterations were needed before the results converged towards a stabile solution, regarding the third decimal number[6]. The analysis utilizes a virtual assembly model, with all mating conditions defined (locating schemes), together with distributions on all inputs. The method captures non-linearity, and allows any kind of distribution of input parameter variation. The simulation predicts, among other things, the expected mean value, standard deviation, range, and capability indices for the specified critical dimensions on the basis of the number of Monte Carlo iterations.

The purpose of a locating scheme is to lock a part or subassembly to its six degrees of freedom in space. A number of different locating schemes exist and are used in various industrial situations[7]. In the guided surgery simulation presented here, the following system is used: three primary locating points (A1, A2 and A3) control three degrees of freedom and lock the object to a plane, translation in Z (TZ), rotation around X (RX) and another around Y (RY). The two secondary locating points (B1 and B2) control two degrees of freedom, locking the object to a line, translation in X (TX) and rotation around Z (RZ). The last, tertiary locating point controls one degree of freedom, translation in Y (TY) (see Fig 5). It is worth noting that the minimum amount of locating points is three, and then the same points are used several times. This is, for example the case here (point group 1: (A1, B1, C1), point group 2: (A2, B2), and point group 3: (A3)) (see Fig. 6). The orthogonal 3-2-1 locating system is the most frequently used locating system. Other non-orthogonal systems exist (see [3 and 4]), but are not used here.

IV. RESULTS

The results are exemplified and based guided surgery plannings [2]. The first example is a planning intended for the upper jaw (Maxilla) (see Fig. 7), while the second is a planning intended for a lower jaw (Mandible) (see Fig. 8).

The result of the guided surgery was predicted using RD&T [15]. One hundred thousand Monte Carlo iterations were used. The critical measure was defined at the apical part of the fixture (see Fig. 3). The simulation assembles the parts in the same order as the surgery is performed (using the pre-defined tolerances). The analysis for predicting the greatest variation contributor is performed in two steps.

First, the calculations are performed using equal tolerance distribution. This analysis method captures each component's contribution at the pre-defined critical measure at the apical part of the fixture, dimensionless.

Second, the calculations are carried out by using unique tolerances for each component, considering both manufacturing and assembly. The results are dependent on the unique tolerances. This analysis method captures each component's contribution to the critical measure regarding unique tolerance. This gives the actual result, whereas the equal tolerance calculations analyze the concept itself.

With the help of the results from the second calculation, an emphasis of the foci can be drawn using unique tolerances.

Table I shows equal tolerance distribution, and Table II shows unique tolerance distribution for the upper jaw (Maxilla). The results are summarized and presented with each component defined in their acting group in the process: Assembly variation (Surgery), Part variation, and Examination of patient.

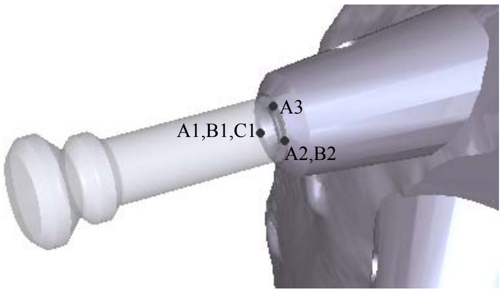

Fig. 6 3-2-1 locating scheme used in this application

TABLE I
SENSITIVITY ANALYSIS. EQUAL TOLERANCE DISTRIBUTION, MAXILLA

Activity	Contribution
Assembly variation (Surgery)	48.3%
Part variation	45.0%
Examination of patient	6.7%

TABLE II
CONTRIBUTION ANALYSIS. UNIQUE TOLERANCE DISTRIBUTION, MAXILLA

Activity	Contribution
Assembly variation (Surgery)	37.9%
Part variation	31.1%
Examination of patient	31.0%

Table III shows equal tolerance distribution of the results for the lower jaw (Mandible), while Table IV shows the unique tolerance distribution for the same example. The results are summarized and presented with each component defined in their acting group in the process: Assembly variation (Surgery), Part variation, and Examination of patient.

TABLE III
SENSITIVITY ANALYSIS. EQUAL TOLERANCE DISTRIBUTION, MANDIBLE

Activity	Contribution
Assembly variation (Surgery)	46.9%
Part variation	41.6%
Examination of patient	11.5%

TABLE IV
CONTRIBUTION ANALYSIS. UNIQUE TOLERANCE DISTRIBUTION, MANDIBLE

Activity	Contribution
Assembly variation (Surgery)	35.0%
Part variation	31.5%
Examination of patient	33.5%

Table V summarizes the results from Tables I and III.

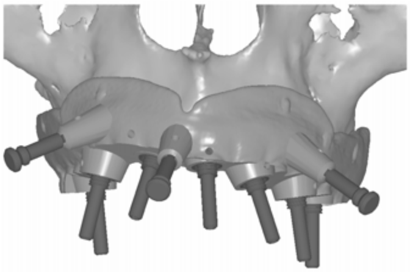

Fig. 7 Simulation model of the upper jaw (Maxilla)

TABLE V
SUMMARY FOR SENSITIVITY ANALYSIS, REGARDING MAXILLA AND MANDIBLE

Activity	Contribution
Assembly variation (Surgery)	47.6%
Part variation	43.3%
Examination of patient	9.1%

Table VI summarizes the results from Tables II and IV.

TABLE VI
SUMMARY FOR CONTRIBUTION ANALYSIS, REGARDING MAXILLA AND MANDIBLE

Activity	Contribution
Assembly variation (Surgery)	36.45%
Part variation	31.3%
Examination of patient	32.25%

V. DISCUSSION AND CONCLUSION

The results clearly quantify what to focus on when a process optimization of guided surgery is intended, regarding the minimization of the geometrical variation of a predefined critical product dimension, here defined at the apical part of the fixture. Besides minimizing the geometrical variation, focusing where it is most needed is also of great interest for the assigning actor, regarding time, cost, and increased quality.

The sensitivity analysis with equal tolerance distributions tells us that the Assembly and Part variations are significantly more sensitive to the final variation than the Examination of patient group. The background to this is that parts within these groups often depend on a smaller assembly system (locating system where the individual locating points are close) compared to the Examination of patient group. One example, for instance, is that a sleeve, mounted at the drill- and implant-guide, which anchor pins secure to the jaw, guides the drill. This means that there are several relatively small assembly systems guiding the drill. A typical contrary in this case is when the surgical template is positioned on the jaw. In this case, the whole occlusial-index area and the mucosal area determine the assembly system (locating system where the individual points are relatively far from each other). Hence, the assembly system is relatively large. An optimization of the results from the sensitivity analysis means that the concept itself needs to be re-designed. If this is done, the concept converges towards less sensitive concepts.

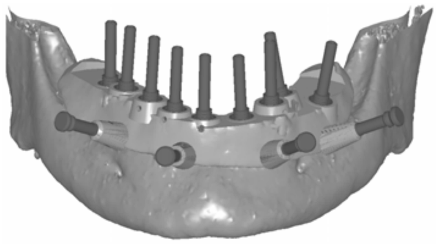

Fig. 8 Simulation model of the lower jaw (Mandible)

When optimizing the actual variation (Table VI), the focus should also be set on the Assembly group. The background to this is that the concept is relatively sensitive due to its flexibility. For example, an anchoring system that is designed such that the anchor pins are close to each other contributes to the final variation more than a relatively large anchoring system. A clear relationship between the cause and effect can be shown.

An important impact of this work is that variation suppressing optimization of medical treatments can be performed with the greatest contributor in mind, in order to set the focus where it is most needed. Eventually, this will lead to a higher degree of patient safety.

One benefit of suppressed geometrical variation is that patients suffering from diseases that lead to great bone loss can undergo pre-secured surgery. In other words, if the process is optimized regarding geometrical variation, more complicated surgeries can be performed.

Finally, future work in this field would be to analyze the robustness of the concept and find methods to increase it. A nominally robust concept will always be difficult to achieve, as the concept requires great flexibility. Nevertheless, something could be found that might increase the robustness, or at least guide in the pre-planning of a treatment, which may provide even further increased process stability and patient safety.

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