# Case Study: Evaluation of Point-to-Point Quality Control Method for Multi-Unit Medical Devices

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**Abstract:**
Multi-unit dental devices with multiple interfaces require very sophisticated quality control software which may not be financially justifiable.

**Keywords:** Quality Assurance, dental device, medical device, CMM, quality control

This case study proved following;

- A simple point-to-point quality control is inadequate for multi-unit dental devices
- Investment in an adequate quality control software may not be financially justifiably

## 1 Introduction

The multi-unit devices covered in this case study are produced per design by the practitioners involved in the device design and surgery. Each device is designed for its specific patient, and it is critical that the device can align properly with the implants in the patient or the device may fracture prior the expected >30 years life cycle due to the ceramic material with its brittle characteristics. The connection between the device and implant is known as interface.

This case study investigates the ability of a simple point-to-point "best-fit" quality control with feedback from dental practitioners.

## 2 Device characteristics

The devices range from 2-units to 14-units. An example of a device is illustrated in Figure 1. The interfaces are marked in Figure 2, and with implants attached in Figure 3. Figure 4 displays how a typical CMM (Coordinate Measurement Machine) probes the interface for dimensions, location, and vector. Figure 5 illustrates where the vector is determined while Figure 6 displays and example of the illustrated device with all its vectors and locations determined.

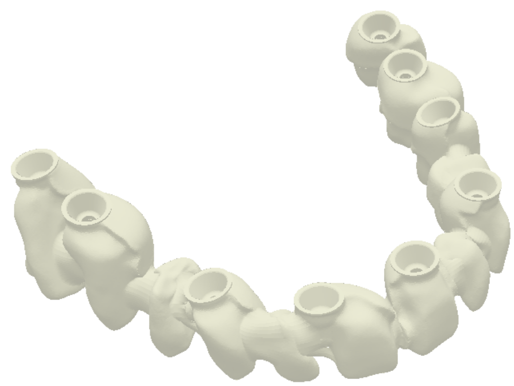

*Figure 1. Example of a 14-unit device*

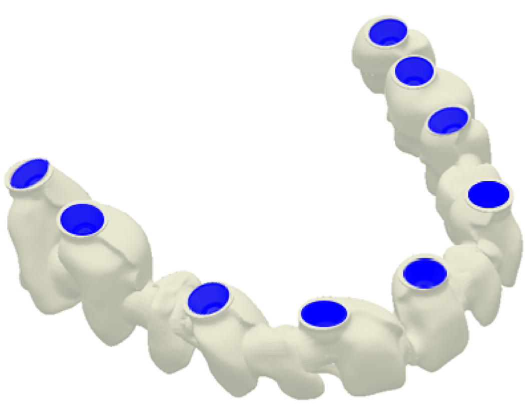

*Figure 2. The interface locations marked in blue*

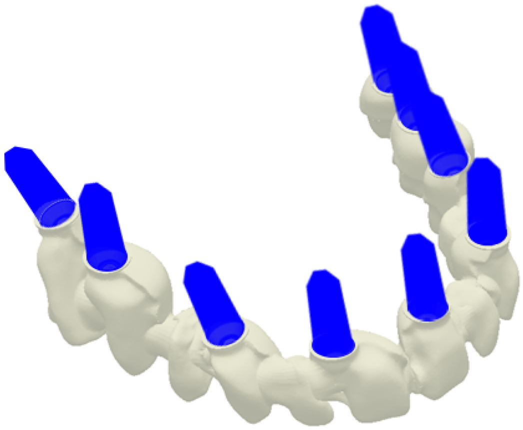

*Figure 3. The device mated with the implants*

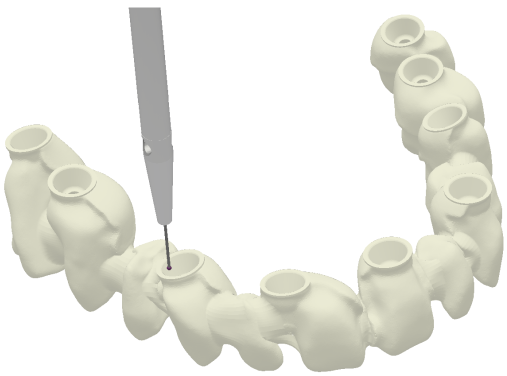

*Figure 4. The quality control is commonly performed with a CMM*

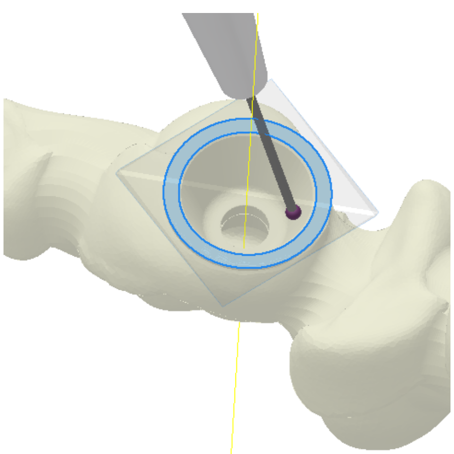

*Figure 5. The CMM software creates a vector (yellow line)*

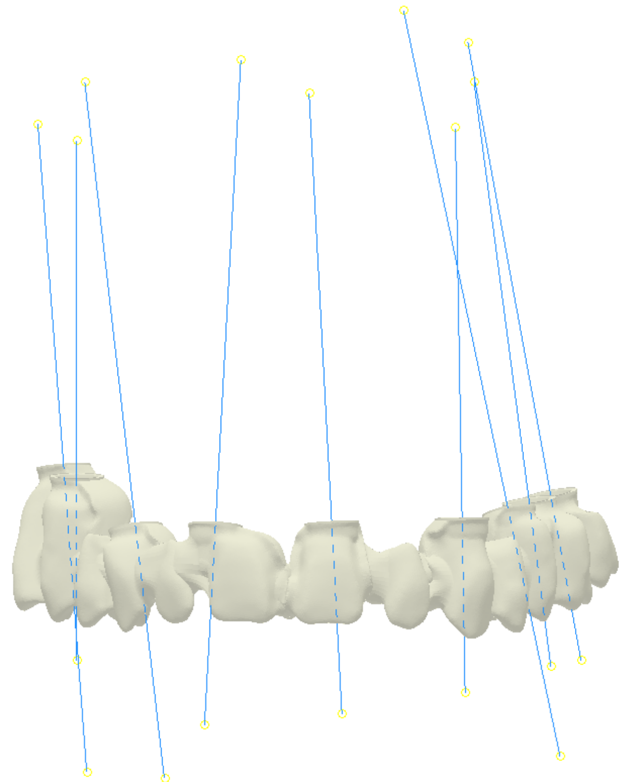

*Figure 6. Final out with all vectors*

## 3 The point-to-point quality control

A multi-unit device with four interfaces is used for visual demonstration. Figure 7 displays an actual device with four interfaces marked (green points), and measured points (blue) by the CMM.

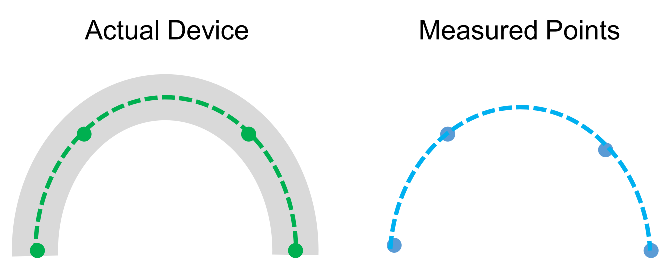


*Figure 7. Interfaces marked on actual device and points measured with CMM*

The quality control software performs a series of iterations until the smallest distance between the points within the order file and CMM is achieved as per Figure 8.

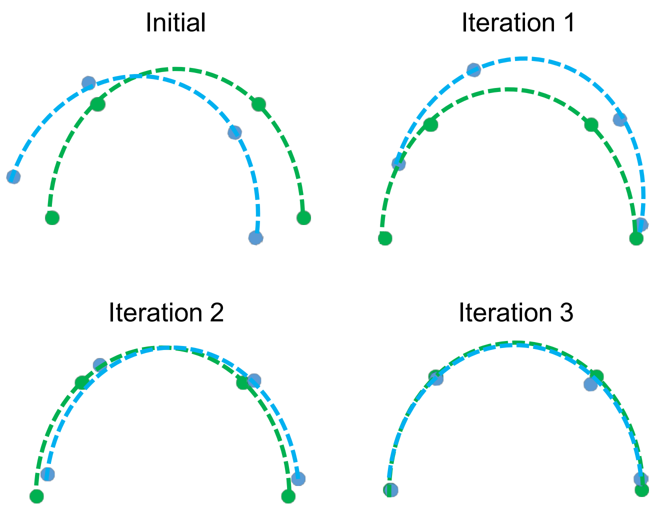


*Figure 8. Illustration of iterations until smallest distance[s] achieved between order and measurement result*

## 4 Studies with Customer Complaints

Two studies were performed where the feedback from the dental practitioners were compared to the result from the quality control for ceramic and metallic devices. First year 2015 as per Figure 9;

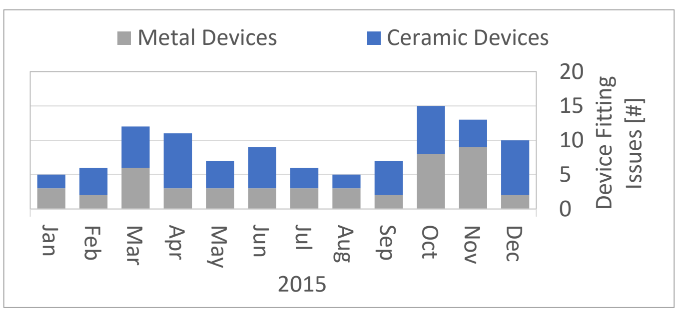


*Figure 9. Feedback from the dental practitioners 2015*

The accuracy by the quality control for metallic devices were 0/47 = 0% (or below resolution, respectively), and for ceramic devices 1/59 = 1.7%.

The second study was performed 2016 as per Figure 10;

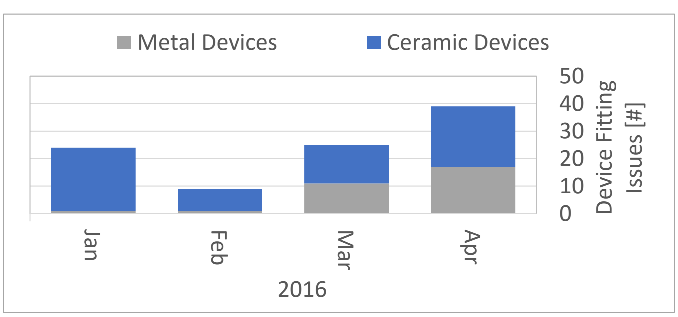


*Figure 10. Feedback from the dental practitioners 2016*

The accuracy by the Quality Control for metallic devices showed 0/30 = 0% accuracy (or below resolution, respectively), and 1/67 = 1.5% accuracy for ceramic devices. A simple point-to-point quality control method seems not be an adequate control method for this kind of devices.

## 5 Possible fault discussion

### 5.1 Production impact

The production method impacts the interface location (deformation) of the device. It was observed that gravity could deform the device un-evenly when being sintered.

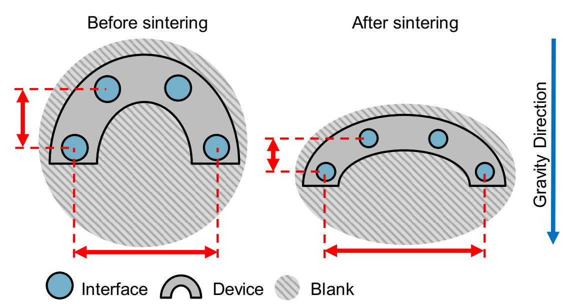


*Figure 11. Gravity impacting deformation of the device*

### 5.2 Combination of errors

The deformation could drift in opposite direction from each other, creating a larger real error than possibly observable with a simple point-to-point measurement.

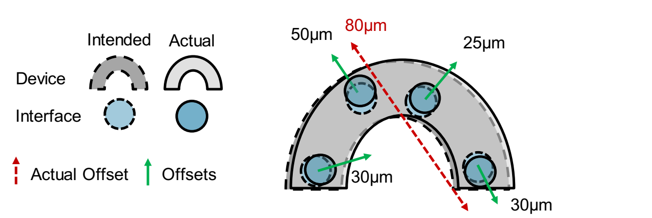


*Figure 12. Example of interfaces drifting in opposite directions*

### 5.3 Combination of errors further detailed

Each point has an error tolerance (error space);

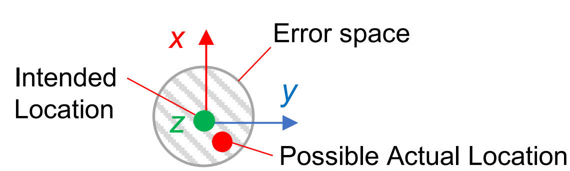


*Figure 13. Tolerance space (error tolerance)*

The errors from each interface adds up to a total (actual error).

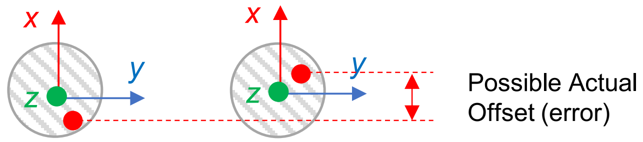


*Figure 14. Two errors adding up to a larger combined error*

A device with four interfaces thus will have four errors all combining each error to a total error of the device.

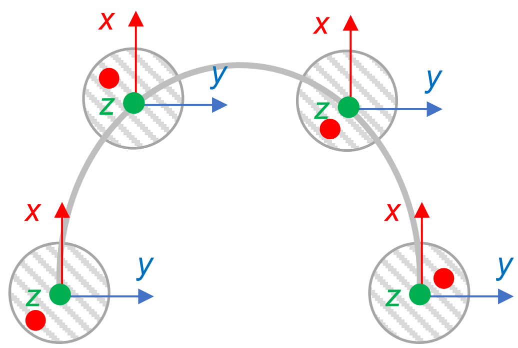


*Figure 15. Device with four interfaces with respective error*

Even if all the interfaces have the errors within respective tolerance, the total error creates a quite deformed device;

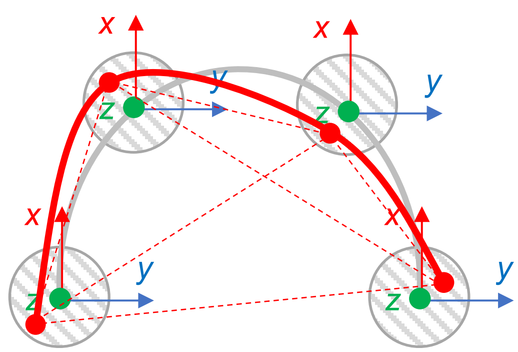


*Figure 16. Example of deformed device from the errors*

### 5.4 Interface form consideration

The design of the interfaces also impacts the actual tolerance space. The vector affects for instance the angle, and the design of the interface may then cause a collision creating a significantly larger fitting issue than observed with a simple point-to-point measurement.

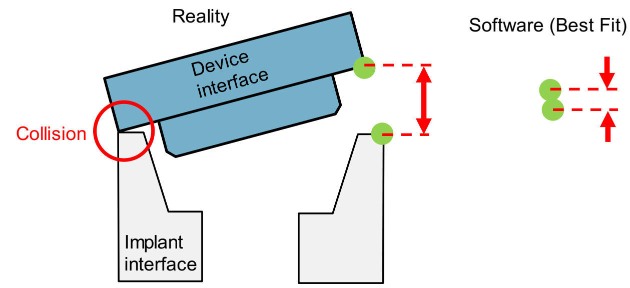


*Figure 17. Example of actual error larger than measured*

The error is not only enlarged by angle, but the interface design may also affect fitting in planar direction as in Figure 18;

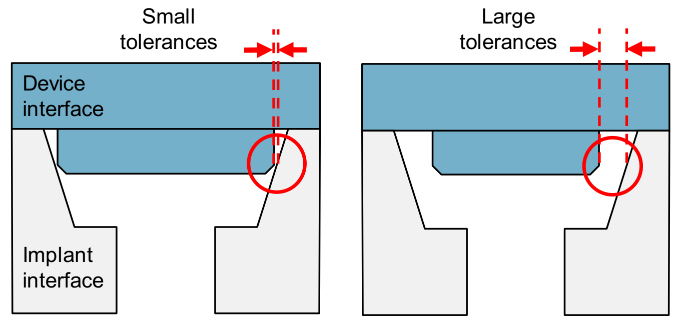


*Figure 18. Example of fitting impacted in planar direction*

## 6 Conclusion

A simple point-to-point quality control is inadequate to control complex devices such as individualized multi-unit dental devices. Multiple factors must be considered, such as combined errors (total error) and design of the interfaces. To develop such software is likely a quite expensive and complex project. A simple point-to-point quality control will likely cause false acceptance and false rejects, causing fitting issues for the practitioners while also creating costs for manufacturer from false rejects.

In addition, there are several other errors observed but not covered in this case study impacting the design of the device, such as the performance of scanners and the software used with the scanner. The dental practitioners therefore still must control the manufactured device against model and patient for adequate fit even if the quality control software was adequate.

It is considered a low priority to invest in an adequate quality control software, due to complexity involved to develop, the errors from the practitioners and low patient health risks for fitting failures.