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**In-vitro-study to the dimensional accuracy of  
Implant Impressions in dependence of  
material, technique and tray**

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I dedicate this work to my dearest parents, my brother and my friend

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**Vergleichende In-vitro-Untersuchungen zur Präzision von  
Implantatabformungen in Abhängigkeit von  
Material, Methodik und Abformlöffeln**

*Dissertation zur Erlangung des Grades eines Doktors der Zahnheilkunde  
an der Medizinischen Fakultät  
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Diese Arbeit widme ich meinen lieben Eltern, meinem Bruder und meinem Freund.

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## 1. Summary

**Statement of the problem:** An often debated issue is still existing concerning implant impression techniques, the trays to be used and the impression materials. The precise transfer of the intraoral relationships of implants to laboratory working models is central to the success of an implant born prosthesis.

**The purpose of this in-vitro-study** is to evaluate the accuracy of two impression materials with two impression techniques and three various impression trays.

These three aspects were considered important for the accuracy of implant impressions made of a master model.

**Materials and Methods:** A master model was designed to simulate a representative clinical situation. Impressions were made by using two techniques: (1) open tray impression technique (pick-up) and (2) closed tray impression technique (snap-fit). The trays varied: (a) prototype tray (K), (b) custom tray (I) and (c) Miratray®Implant (M). All trays were used for both impression techniques, except for the Miratray®Implant, which only was used for the open tray impression technique. Two impression materials were used: (i) a polyether (Impregum™) and (ii) a vinylsiloxanether (Identium®) .

Of each tray type there were 10 impressions taken with the polyether and 10 impressions taken with the vinylsiloxanether. At the end there were all together 60 impressions. To assess the dimensional changes that may have occurred during impression taking and the fabrication of the casts, a coordinate measuring machine (Zeiss Prismo) was used to compare the casts with the implant master model. The coordinate machine recorded in the X-, Y-, Z-dimensions, with a precision of 1 µm. The measurements of the Angulation (in degrees) took place.

**Results:** Comparing the master model to the various casts produced, the 95% confidence interval (CI) was used. Both techniques, materials and trays achieved this in the X-direction. In the Y-direction the open tray impression technique with the prototype and the custom tray, using Identium® did not achieve the 95% confidence interval as well as the closed tray impression technique, using the custom tray with Identium®. In the height only the custom tray, the open tray impression technique using Impregum™ and only in the position 46 achieved the 95% CI. In the angulations the confidence intervals were achieved in 46 x to z, 36 x to z and 32 y to z.

By comparing the various casts produced to each other, the outcomes achieved with the two impression materials were similar. Significant differences were seen for the prototype tray (between the two impression materials) regarding the heights.

The outcomes achieved with the three impression trays K, I, M with Impregum™ were similar. Significant differences were seen in 32 Z Height (K1-K10 vs. I1-I10)

The outcomes achieved with the three impression trays K, I, M with Identium® were similar. Significant differences were seen in 46 Z Height (K11-K20 vs. I11-I20 and I11-I20 vs. M11-M20) and 34, 36 Z Height (K11-K20 vs. I11-I20)

**Conclusion:** Within the limitations of this study, the exact reproduction of implant positions in a cast obtained from an impression was not possible even under idealized and standardized conditions. A perfect impression seems to be impossible. But as yet, no definition or parameters for horizontal nor vertical nor angular discrepancies have been established as to what constitutes to a passive fit. Yet in daily practice, the used techniques seem to be acceptable under clinical conditions.

## 1. Zusammenfassung

**Fragestellung:** In der zahnmedizinischen Implantologie stellt sich die Frage, mit welchem Abformverfahren, Abformlöffel und Abformungsmaterial die besten Ergebnisse zu erzielen sind, um die intraorale Implantatsituation auf laborgefertigte Arbeitsmodelle mit größter Genauigkeit zu übertragen, damit eine spannungsfrei einzugliedernde Restauration angefertigt werden kann.

**Das Ziel dieser In-vitro-Studie** war die Untersuchung der Übertragungspräzision von zwei Abformmaterialien, zwei Abformungsverfahren und drei Abformlöffeln.

**Material und Methodik:** Es wurde ein Urmodell hergestellt, das die klinische Situation darstellen soll. Am Urmodell wurden Abformungen durchgeführt mit zwei Verfahren: (1) offenes Verfahren und (2) geschlossenes Verfahren. Es wurden drei verschiedene Abformlöffel verwendet: (a) Prototyp (K), (b) Individueller Löffel (I) und (c) Miratray® Implant (M). Alle Löffel wurden für beide Verfahren angewendet, außer der Miratray® Implant-Löffel, dieser wurde nur für das offene Verfahren angewendet. Zwei Abformungsmaterialien wurden verwendet: (i) ein Polyether (Impregum™) und (ii) ein Vinylsiloxanether (Identium®).

Mit jedem Löffeltyp wurden jeweils 10 Abformungen mit dem Polyether durchgeführt und 10 mit dem Vinylsiloxanether. Insgesamt wurden also 60 Abformungen durchgeführt. Zur Beurteilung der Genauigkeit der hergestellten Modelle im Vergleich zu einem Urmodell wurde ein drei-dimensionales Achsen-Koordinaten-Messgerät (Zeiss Prismo) verwendet. Die Vermessungen von linearen Abweichungen erfolgten in x-, y- und z-Dimension (Präzision 1 µm); zusätzlich wurden auch Winkelmessungen (Grad) durchgeführt.

**Ergebnisse:** Beim Vergleich des Urmodells mit den hergestellten Modellen wurde das 95% Konfidenz-Intervall angewendet. Beide Abformverfahren, beide Abformmaterialien und alle Abformlöffel erreichten das Konfidenz-Intervall in der x-Dimension. Bei den Kombinationen offenes Verfahren, Prototyp-Löffel, Identium® und offenes Verfahren, Individueller Löffel, Identium® wurde das Konfidenz-Intervall in der y-Dimension nicht erreicht. Die einzige Kombination, die in der z-Dimension (Höhe) das Konfidenz-Intervall erreicht hat, war ein offenes Verfahren mit einem individuellen Löffel, Verwendung von Impregum™ in Position 46. Bei den Winkelmessungen wurde das Konfidenz-Intervall erreicht bei 46 x zu z, 36 x zu z, 32 y zu z.

Beim Vergleich der zwei Abformmaterialien getrennt für die drei verschiedenen Löffeltypen, ergaben sich signifikante Unterschiede zwischen beiden Abformmaterialien bei Verwendung des Prototyplöffels in der z-Dimension (Höhe).

Beim Vergleich der drei verschiedenen Löffeltypen getrennt für die beiden Abformungsmaterialien, ergaben sich signifikante Unterschiede bei Verwendung von Impregum™ in Position 32 z-Dimension (K1-K10 vs. I1-I10).

Beim Vergleich der drei verschiedenen Löffeltypen getrennt für die beiden Abformungsmaterialien, ergaben sich signifikante Unterschiede bei Verwendung von Identium® in 46 z-Dimension (K11-K20 vs. I11-I20 und I11-I20 vs. M11-M20) und 34, 36 z-Dimension (K11-K20 vs. I11-I20).

**Diskussion:** Unter Rücksichtnahme auf die Rahmenbedingungen der Studie, kann festgehalten werden, dass eine absolut exakte Reproduktion einer intraoralen Implantatsituation auf laborgefertigte Arbeitsmodelle selbst unter idealen standardisierten Bedingungen nicht möglich ist. Bislang gibt es allerdings keine verbindlichen Vorgaben darüber, wie stark eine Abweichung sein darf, um noch einen spannungsfreien Sitz einer Restauration auf Implantaten (passive fit) zu gewährleisten. Die tägliche Praxis zeigt aber, dass die Verfahren unter klinischen Maßstäben akzeptabel zu sein scheinen.

## **2. Introduction**

The introduction of osseointegration has dramatically affected the discipline and current perspective of implantology and improved the quality of life of many patients [1, 2, 3].

The pioneering work of Professor Brånemark and his co-workers, termed the clinically observed adherence of bone with titanium as “osseointegration” and in 1965 placed the first titanium dental implant into human volunteer.

They studied the biocompatibility of implant materials, identified the process of osseointegration and determined the surgical parameters for the successful placement of implants [1, 4, 5, 6, 7].

Most of the scientific literature about dental implants has dealt with the process of osseointegration. Literature evaluates the failures of implants system based on the osseointegration, peri-implant tissues and the failures in the components connected to the implants [8].

The connection of a suprastructure to an osseointegrated implant produces a unified structure. Any misalignment of the suprastructure to the osseointegrated implant may induce internal stresses in the suprastructure, the implant and the bone matrix [9, 10].

Successful reconstruction, however, means more than successful integration. Functional and aesthetic prostheses involve careful diagnosis and fixture placement. Predetermination of the framework design, the components to be used, aesthetic and speech requirements will ensure a more predictable prosthodontic result [11].

### **In our research**

We will focus on implant impression taking with various methods and materials. This will allow us to compare accuracy and keeping in mind, that it is not just about materials and impressions, but that at the end of the day there is a greater meaning behind graphs and numbers. Observations and results that may influence the longevities of foreign bodies placed in our patients.

## 2.1 Passive fit

### Definition

Fit - is defined as the clearance between two mating parts. The closeness of the clearance indicates the precision of fit. In this context precision is used to describe what has been referred to as the accuracy of fit between a crown margin and the tooth in fixed prosthodontics [12, 13, 14].

Passive fit (syn. ideal fit/tension-free situation) is assumed to be one of the most significant prerequisites for the maintenance of the bone-implant interface. To provide passive fit or a strain-free superstructure, a framework should, theoretically, induce absolute zero strain on the supporting implant components and the surrounding bone in the absence of an applied external load [3, 15].

A passively fitting prosthesis is fabricated to prevent prosthodontic complications or even loss of fixture integration [2, 16, 17, 18, 19, 20, 21, 22].

As with any prosthodontic technique, a multitude of factors could contribute to the ultimate accuracy of the final prosthesis. Although the accuracy of each component is important, it is the accuracy of the total system that is most vital [9]. The firm connection of a fixed partial denture to osseointegrated fixtures produces a structure capable of bearing loads in all directions, however, any misalignment of the fixed partial denture to the fixtures will produce abnormal stress in the prosthesis, the fixtures, and the bone [9, 10].

Relatively few methods have been scientifically proven to improve fit in implant prosthodontics. Most of the tested strategies still resulted in a slight misfit of the frameworks to the implant abutments/analogues [23]. Many literature reviews even state that a perfect passive fit cannot be obtained [3, 24, 25].

### How to measure misfit?

In a review by TAYLOR ET AL. one of the major problems was stated as the following: "If it is assumed that misfit is a real problem when dealing with dental implants, 2 questions must be asked:

First, what level of misfit is clinically important, beyond which damage is likely to occur? The answer to this question is obviously very complex and probably depends upon such factors as bone quality, length and diameter of implants, and implant surface characteristics. Secondly, assuming that misfit is a concern, how does one measure it in a clinical situation?” [3, 26].

As yet, no definition or parameters for horizontal nor vertical nor angular discrepancies have been established as to what constitutes to a passive fit [25].

Absolute passive framework fit has not been achieved in the last three decades. There is no consensus but rather a number of suggestions regarding the acceptable level of misfit. In light of current knowledge, although there are claims that passive fit is a governing factor over the maintenance of osseointegration and implant success, there is a rising opposing trend in relevant literature.

The materials and the techniques used for fabricating cast-frameworks are not dimensionally accurate and require further research and development. Obtaining a passive fit does not seem to be possible and may in fact be unnecessary [3, 22, 23].

Most of the literature reviewed, resulted in slight misfit of frameworks to the implant/analogues [23].

An unacceptable fit influenced the pattern and magnitude of internal stress scientific documentation to support these claims has not been reported, nor has data defined what is considered to be a clinically acceptable precision of fit [12, 13, 19, 25, 27].

Without systems capable of measuring the precision of fit between the mating implant components, neither the mechanical nor the biologic questions can be addressed. However, with valid and reliable instrumentation and measurement methods, the mysteries of fit can be explored, from impression making, to the fabrication of different implant framework, to the process of joining the prosthesis to the abutments [13, 28].

### **Literature**

A study by KUNAVISARUT ET AL. measured the stress distribution in implant components, prostheses and bone when the implants were connected with a misfitting prosthesis in a three-dimensional finite element model. The amount of distortion may reach a level such that a 500  $\mu\text{m}$  marginal gap may not be detectable with an explorer [3, 27].

The study varied with the gaps located between the gold cylinder and the abutment (no gap present, gap on the distal implant, gap on the mesial implant) accompanied with stimulating biting force (100 N, 50 N, 200 N and 300 N). By achieving a passive fit, the stress was widely distributed in all components, producing less peak stress in each component [27].

The research showed that when the occlusal forces increased, the corresponding force increased on each implant component (significantly in the gold screw) and the surrounding bone. Stress also increased, when the gap was present, the greatest increase in stress was calculated on the crown and gold screw, whereas the lowest increase was found on the abutment [27].

JEMT describes four methods which can most likely measure the fit at the prosthodontic interface. Two systems are based on stylus contact techniques, one system uses a laser as its reader source, and one system is photogrammetric, the later being the only one that records fit data intraorally [12, 13].

Photogrammetry technique is valid as an alternative to conventional impressions while following the computer numeric controlled milling technique for framework fabrication and that it could also be used to measure the mucosal topography around dental implants [12, 13].

A non-passive fit is suggested to be one of the reasons for biological complications with or without component failures [11, 12, 13, 21].

### **Recommendations**

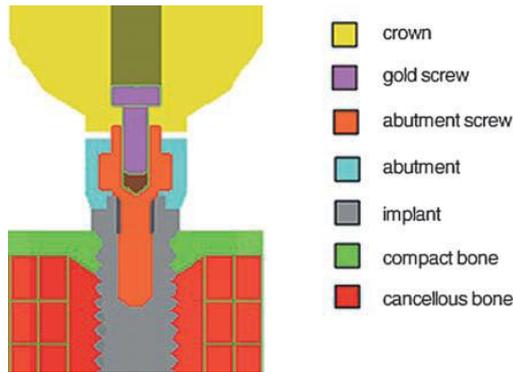
Using accurate implant prosthodontic procedures and the appropriate use of advanced strategies continue to be the recommended mean of achieving precise fit of the implant prosthesis to the intraoral abutment [23].

## **2.2 Implant failures**

Although osseointegrated implants used in dentistry today enjoy a high success rate, clinical complications exist that may lead to delayed implant component failure. Causes of component loosening and fractures are multi-factorial, but the influence of non-passive fit cannot be stressed enough throughout literature [2, 10, 16, 18, 19, 20, 21, 22, 29, 30].

Lack of passively fitting prosthesis and force tightening of the superstructure may result in component failures include abutment, framework, and gold screw loosening or fracturing [27].

Complications include patient discomfort, mobility of the prosthesis, loosening of prosthetic-retaining screws and fracturing and/or locking of abutment-retaining screws as well as implant and prosthetic fractures [11, 12, 13, 23] and even the loss of osseointegration [31].



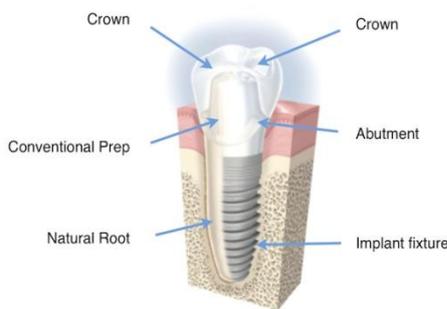
*Fig. 1: Cross-sectional diagram of the gap model, taken from KUNAVISANT ET AL [27]. A gap of 111  $\mu\text{m}$  in height was uniformly created between the abutment and the crown margin. (Note: part of the gold cylinder still engages with the abutment screw hex)*

### **In the screwed type restoration**

The fixation screw is designed to be the weakest point in the system. When excessive load is applied, the screw loosens. If the screw does not loosen, excessive stress will build up in the metal framework and the load will be transferred to the abutment or to the implant [19]. The fixation screw is regarded as a safety feature, as it is the easiest item to retrieve. However, if the fractured abutment screw is buried within the internal threads of the fixture, it may be irretrievable. The osseointegrated fixture may be destined for nonuse and buried beneath the mucosa [11]. In a case report by HAAS ET AL. the most common complication observed was abutment screw loosening, which occurred with 12 crowns out of 76 single tooth implants [8].

### **In the cemented type restoration**

There is no loosening mechanism, and over-loading may result in cement breakage or component fracture. Overload is more likely to be transferred directly to the implants or the bone-implant interface or implant coated interface resulting in the separation of the coping material separating from the implant [19]. Thus, in certain cases the excessive force will not damage the weak link of the screws system, but rather will be transferred to the implant body or to the implant-bone interface [19]. In addition, the increased stress may result in microfractures of bone, marginal ischemia, and healing with a nonmineralized attachment to the implant fixture [18].



*Fig. 2: Diagram showing a cemented type restoration [32]*

### **Occlusal forces**

Research has also been done on occlusal forces measurements [33], by usage of the gonial angle size [19]. SONES AND MONTEITH also mention a lack of passive fit and unbalanced occlusion, but include other factors of importance when considering abutment screw fractures, like the amount of ridge resorption, the length and number of fixtures, the angulation of the fixtures and parafunctional habits [11, 33].

KOHAVI ET AL. evaluated cases demonstrating complications in osseointegrated implant supported prostheses. The reasons for the complications being a lack of passive fitting between the restoration and the abutment and destructive occlusal contacts [19].

Occlusal contacts change their pattern over time, by the wear of the prostheses material or by the changes in the opposite restoration, causing uneven concentration of the forces [19, 27]. Therefore regular follow ups and reevaluation of the occlusal status are of vital importance.

## **2.3 Biomechanics**

A successful implant insertion results in an equilibrium between the loaded implant device, the biological structures of the oral environment and the psycho-social adaptation of the patient [34].

Biological complications include increased retention of the biofilm, crestal bone loss around implants and loss of osseointegration [2, 3, 12, 23, 35]. Causes of early failures are to be found in tissue damage due to inadequate surgical technique, resulting in excessive bone necrosis and in bacterial contamination of the implant and/or the wound [34].

Many suggestions are made on how to monitor the health status of an implant. In a study by KAO ET AL. diseased implant sites were identified based on rapidly increasing pocket depth (> 2mm in 6 months), suppuration, radiographic bone loss, pain and loss of resonance upon tapping. Samples were taken from these crevicular fluids and results indicated an increase of Interleuken-1 $\beta$  in the crevicular fluid of diseased implants. This may be used as a diagnostic technique for the monitoring of the disease activity around dental implants [36].

### **2.3.1 The lack of implant flexure**

Implant units, unlike natural teeth cushioned in the alveoli by periodontal fibers, are somewhat intolerant of movement in their adaptation to the demands of the metal supporting structure. The slight mobility of osseointegrated implants is ascribed to the “elasticity” of the investing bone [37]. An osseointegrated implant has extremely limited movement in the range of 10  $\mu$ m [25].

The lack of implant flexure means that any tensile, compressive and bending forces introduced into an implant-supported restoration because of misfit will certainly remain there and problems as screw loosening and loss of osseointegration are reported to occur [21, 38].

Research in periodontometry has revealed that natural teeth exhibit bucco-lingual

movement between 56  $\mu\text{m}$  and 108  $\mu\text{m}$  and an intrusion of 28  $\mu\text{m}$  under applied load, which is particularly related to the existence of the periodontal ligament. The natural tooth can move up to 100  $\mu\text{m}$  within its periodontal ligament [2, 39].

Osseointegrated implants are completely surrounded by bone and the interface is nonresilient, minimal movement is observed that is attributed to the deformation of the bone under load. Dental implants and natural teeth follow different patterns to applied loads. The periodontal ligament has a cushioning effect, and natural teeth have the inherent tendency to migrate when overloaded. The implant response to misfit is not the same as tooth response [3, 16, 35, 40].

Implants distribute the applied load throughout the system and transfer it to the bone. This explains the cause of the intrusion of natural teeth in a tooth-implant-supported fixed prosthesis. When a fixed prosthesis is connected to osseointegrated implant, lateral forces are applied that may trigger cortical bone resorption or appear as prosthetic complications after superimposition of functional stresses. This scenario may change according to the treatment protocol followed. Although achievement of a 100% osseointegrated implant does not seem possible, there is a consensus that 70% bone-implant contact is capable of bearing in-vivo functional loads [3].

Whether the changes in the bone will be destructive or constructive in any given situation is not entirely predictable [37]. Constant static forces may lead to mechanical complications following implant function, but presumably, have negligible effects on bone reactions around implants [28].

The exact relationship between the fit of the prosthesis and implant complications is poorly understood. Early investigations revealed no correlation between misfit prosthesis and bone loss around an implant [3, 12, 13, 15, 27, 41].

CARR AND CO-WORKERS [35] wanted to investigate the response to bone regarding misfits. Screw-retained misfitting superstructures were connected to implants in baboons. The investigation revealed that it was not possible to distinguish a difference in bone response in two levels of misfit. One has to bear in mind that the investigation was carried out without of occlusal load (intraoral functional stress was not incorporated into this particular experiment).

It is important to take note when and how much load is placed on an implant. In the research by JEMT ET AL. misfit stress levels of clinical magnitudes did not seem to jeopardize osseointegration per se in the bone's response around implants placed in the tibia of rabbits. Clinical levels of preload seemed to promote bone remodeling at the tip of the implant threads [28].

KALLUS AND BESSING researched 236 patients wearing misfitting implant supported prosthesis for at least five years. These patients showed no signs of loss of osseointegration and that misfit of the superstructures did not affect the maintenance of marginal bone level. Therefore from their research it seems as though the biologic response for misfit levels between 38  $\mu\text{m}$  and 345  $\mu\text{m}$  is similar [42].

A significant statistical correlation between marginal bone level/marginal bone loss and prosthesis misfit was not found, and hence a biological tolerance for prosthesis misfit may be assumed, a compensating biologic tolerance mechanism [3, 23].

Similar to teeth, implants are subjected to load cycles during both mastication and swallowing. It has been calculated that about 2500 - 8000 such cycles are performed daily (1-3 million cycles per year) [34].

The magnitude of chewing forces placed on implant-supported fixed-bridge reconstructions has been shown to be considerably greater than the one placed on teeth in dentate patients: 131 and 58 N [34], respectively. This may depend on the lack of the periodontal proprioceptive feedback in the implant-supported reconstructions. An inverse relationship has been demonstrated between the intensity of force and the number of load cycles needed for failure to occur. In other words, lower forces applied for more load cycles may lead to mechanical failure of bone tissue [34].

Alveolar bone around implants undergoes continuous functional adaptation. This concept is frequently referred to as Wolff's law, which states that the course and the balance of bone remodeling can be affected by mechanical function [34].

The increase in radiopacity and the rearrangement of the bony trabeculae around loaded implants represent a response of the tissue to the increased functional demands. An equilibrium is thus formed that allows dispersion of the loading forces from the bone implant

interface along the trabecular bone, possibly in the absence of micro movements at the interface [34].

Evidence of bone remodeling has been extensively reported in the bone around dental implants as an increase in tissue labeling with fluorochromes. Such a remodeling process appears to be more intense at the implant-bone interface, where forces are expected to concentrate. Clinically, loss of osseointegration is evidenced by such signs as peri-implant radiolucency and mobility [34].

## **2.4 Impression taking**

The first stage in achieving an accurate, passively fitting prosthesis is reproducing the intraoral relationship of the fixtures with an impression. Currently, each implant system has its own set of machined impression copings that connect to the implant to transfer the position of the implant to a stone cast [43, 44].

For this reason a big variety of prosthetic components (conical/tapered copings and square copings), impression techniques and impression materials are available.

The procedure differs significantly from conventional crown and bridge techniques, because the critical aspect of the implant procedure is maintaining the position of the copings as they are transferred from the intraoral situation to produce a working cast, the implant cast must also reproduce the adjacent hard and soft tissues.

The use of an accurate implant prosthodontic procedure and the appropriate use of advanced strategies continue to be the recommended means of achieving precise fit of the implant prosthesis to the intraoral abutments.

The accuracy of the cast is dependent on the impression procedure [9, 18, 20, 22, 23, 25, 29, 31, 37, 44, 45,46].

The tolerable discrepancy of a framework over several implants is not known, but because discrepancies of less than 30  $\mu\text{m}$  (micrometer) in the fit of an implant-retained framework on multiple abutments cannot be detected clinically by experienced operators; this figure could serve as a criterion between acceptable and unacceptable frameworks [44].

In a good impression, there is a possibility of finding a discrepancy of 50  $\mu\text{m}$  in any axis [47].

A minimal discrepancy (22–100  $\mu\text{m}$ ) exists between impression copings and either the prosthetic abutment or the abutment replica. This should be considered when making the final impression and during master cast production [14].

The ideal master cast has inspired the use of various transfer materials and techniques [9]. Various factors also influence the accuracy of implant impressions. Such as the different connection levels (implant level and abutment level), different impression trays, implant depth and the time delay for stone pouring [48].

By-passing this traditional method of impression taking is by using optical digitizing and CAD-CAM. Yet, a totally "passive" fit is probably unachievable in any method to date [14].

A meaningful method for checking the passive fit is the Sheffield Test. On a mesostructure the distally positioned implant replica or abutment is fastened with a screw on the model. If there is a gap between the mesostructure and the remaining abutments or implants there will not be an exact fit [49].

A SAE spark erosion machine (EDM 2000, manufactured in 2012) allows a passive fit of structures whether they are cast or milled using the CAD/CAM technique.

The SAE technology enables a gap-free and tension-free precision fit of the dental structures on implants and implant-abutments.

A maximum gap of 5  $\mu\text{m}$  can be achieved [49].

A recent in-vitro-study by GÜTH ET AL. compared linear shift (X-, Y-, Z-axis) and angle deviations using direct digitalization with an intraoral scanner and indirect digitalization, using plaster casts that were digitized.

This study showed that the direct digitalization showed lower values in the linear shift (in Y- and Z-axis) and that the direct digitalization showed smaller angle measurements than the conventional impression technique followed by digitalization. Hence the study showed that the intraoral scanner has the potential to achieve comparable or even higher accuracy compared to the conventional impression method.

This study introduced an innovative approach and method to evaluate the accuracy of intraoral scanning devices without the application of a best-fit alignment (superimposition of virtual datasets) in order to avoid influences of the process/quality of the superimposition and the interpretation of differences [50].

An in-vivo-study by ENDER ET AL. impressions were taken using seven digital impression systems and two conventional impression methods. This study varied in comparison to the above mentioned study as it was in-vivo and here the impressions were then superimposed within the test groups. The maximum deviations in all groups did not exceed 100  $\mu\text{m}$ .

Newer digital systems delivered more precise impressions than older systems this showed that there is an ongoing development of the CAD/CAM technique in hardware and software. The precision differed significantly between the digital impression systems, but all the digital systems reached accuracy levels clinically sufficient for restoration production [51].

A one step, single mix impression technique will be used in our laboratory experiment. The same consistency impression material is injected around the abutments and some material is placed in the tray. The one step technique has shown as a clinically proven and most accurate; it revealed low shrinkage, low displacement and low endogenic stresses [52, 53].

Distortion may result from dimensional changes of the impression material, as well as the movement of impression copings within the impression during tightening of the laboratory abutment analogue.

### **2.5 Definitions and Understanding**

A technician uses an impression to create a highly precise stone model that becomes the basis for the entire implant treatment plan. The implant treatment plan can only be as accurate as ones impression.

In our study we will be using two different implant impression techniques for transferring the impression copings from the implant to the cast.

### **2.5.1 The open tray impression technique (pick-up/direct pick-up technique)**

The open tray impression technique uses square copings and an open tray, allowing the coronal ends of the impression coping screw to be exposed. Before removing the impression tray, one has to separate the coping from the implants: the copings have to be unscrewed to be removed along with the impression.

The implant analogues are then connected to the copings (which are in the impression) to fabricate the definitive cast [24, 48, 54, 55].

According to many implantologists, the “Golden Standard” is using an open tray impression technique, with a custom tray and the use of the polyether material Impregum™ (3M ESPE, Seefeld, Germany) because of the highest available Shore hardness of elastomeric impression materials [15, 18, 54].

#### **Disadvantages:**

The problem in this procedure is that there may be an accidental rotation of the impression copings. Unscrewing the guide pins from the impression copings when the tray is removed from the mouth or screwing the matching abutment replicas in the impression, may cause minor movements and thus influence the cast accuracy [37].

Another disadvantage being that, in daily work, the technician and clinician use different closure torques and tightening sequences, which can also lead to discrepancies.

The necessity of unscrewing guide screws retaining the transfer copings before removing the impression can be a disadvantage in clinical practice [54, 56]. In situations, for example, where limited interarch space and a gagging tendency are expected.

There are more parts to manipulate when fastening. There is also some horizontal range of fastening, and also the blind fastening of the analogue.

#### **Advantages:**

The copings remain in the impression (there is no concern for replacing the coping into the respective space).

The angulation of the implant is not a factor.

There is no or a minimum of plastic deformation of the impression material upon recovery from the mouth [26].

### **2.5.2 The snap-fit plastic impression coping technique (closed tray direct snap-on impression technique)**

Some implant manufacturers have developed a snap-fit plastic impression coping. This technique is not a pick-up impression because it does not require an open tray, but instead uses a closed tray, where plastic impression copings are picked up in the impression material. [24, 48].

These caps are picked up in the impression without the use of screws. This alternative method seems to combine the advantages of direct and indirect impression techniques. It seems simple and easy to handle, however care must be taken that the three-dimensional positioning of the cylinders with the impression caps in the impression may be a problem during the removal of the impression [54].

The resin cap remaining in the impression should improve the accuracy of repositioning the transfer copings and the resulting cast [24, 29]. This technique resulted in some investigations with similar dimensional accuracy as that achieved with a nonsplinted direct (open tray) impression technique [54], or similar accuracy as a splinted direct (open tray) technique [29].

#### Advantages:

Visual fastening of the coping

Similar procedure as the conventional impression making of natural teeth

#### Disadvantages:

Multiple deformations of the impression material may occur especially if the implants show angulated positions to each other.

Difficulties in replacing the copings into the impression material at the respective positions  
“Blind” seating of the copings into the impression material [15].

There were four studies that examined the accuracy of the closed tray direct snap-on impression technique [17, 55, 57, 58]. Two studies reported the snap-fit technique was more accurate than the open tray (pick-up) technique [17, 58].

One study reported the snap-fit technique was more accurate than the closed tray (transfer) technique [55] and one study reported there was no difference between the snap-fit and pick-up (open tray) technique [57].

Fabricating a well-fitted implant-supported fixed prosthesis, requires the mechanical adaptation and biological seal of mating implant components. This requires an accurate three-dimensional transfer of the implants. The impression techniques are based on a direct or indirect impression technique. Depending on the preferred impression method one may mix and match the techniques with various impression materials and trays.

There is still a third impression technique which we is not investigated in this study, but due to some studies using this method, it should be mentioned:

This technique is similar to the snap-fit plastic impression coping technique (closed tray direct snap-on impression technique), but it has no snap-fit plastic impression coping.

### **2.5.3 The transfer technique (also known as closed tray/indirect transfer technique/repositioning impression coping technique)**

The transfer technique uses tapered copings and a closed tray to make an impression.

The copings are connected to the implants, and an impression is made and separated from the mouth, leaving the copings intraorally.

The copings are removed and connected to the implant analogues, and then the coping-analogue assemblies are reinserted in the impression before fabricating the definitive cast [24, 48, 54, 55].

This procedure is simple, but repositioning the copings accurately into their respective imprints is crucial, and often these copings are not correctly replaced back into the impression [22, 54, 55, 56, 58]. The design of the transfer copings influences the accuracy [58].

No difference in using the indirect transfers technique and the direct snap-on impression technique was found by HERBST ET AL [44] AND HUMPHRIES ET AL [45]. Yet some investigators have found the indirect method (i.e. without the snap-fit plastic impression copings) to be less accurate [15, 47].

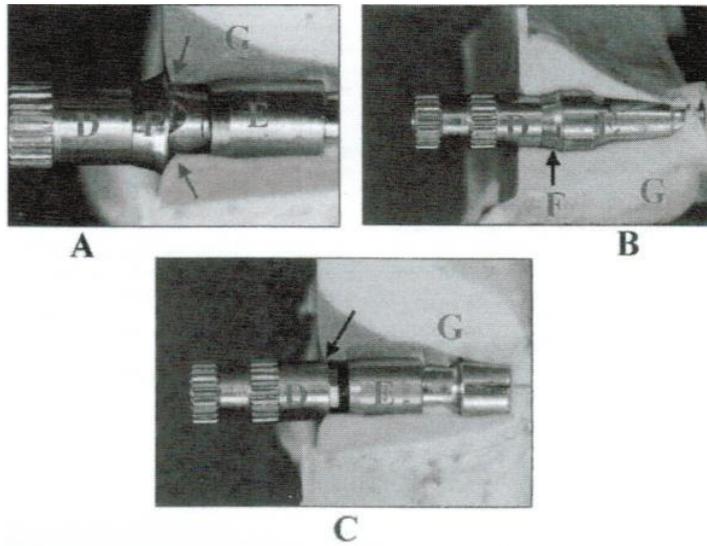
Impression copings may either be retained within the impression as it is removed from the mouth (squared impression copings) or retained on the implant and later removed and replaced in the impression (tapered transfer impression coping) [58].

Limitations do exist when it comes to the impression-retained copings (open tray technique), and then tapered transfer impression copings (closed tray technique) may be necessary. In situations, for example, where limited interarch space and a gagging tendency are expected.

Table 1: Recommendation of coping transfer [59]

Implant/copings	Tray	Impression Technique	Impression Material
Single	Closed	all	Polyether or A-silicone
snap-on caps (abutment level)	Closed	custom or stock	Polyether
squared (implant level) (pick-up)	Open	custom	Polyether
Tapered (implant level) (transfer)	Closed	custom	A-Silicone

A study by DE LA CRUZ ET AL. [60] showed interesting longitudinal-sections through abutments:



*Fig. 3A: An open tray technique on a conical/tapered abutment. Note that the implant analogue/conical abutment assembly must be inserted in an undercut area of the impression material*

*Fig. 3B: Closed tray technique on conical/tapered abutment. Note that the implant analogue/conical abutment assembly is not be inserted in an undercut area of the impression material. This does not happen in the closed tray technique.*

*Fig. 3C: An open tray technique on an implant. The analogue/conical abutment/impression coping assembly is inserted as one piece or in an open tray technique at implant level (no undercut area is present in the impression material)*

Fig. 3 A-C: Longitudinal sectional views of an open tray technique that showed a significant greater inaccuracy in the vertical plane. Keys: D implant analogue, E impression coping, F conical abutment, G polyvinyl siloxane impression material [60].

**Another point of interest is the connecting level which can be placed close to the bone or in the area of the marginal gingival.**

#### **2.5.4 The Implant Level**

The implant level impressions can also be referred to as "fixture head impressions". One can use closed tray or open tray techniques [12, 13, 55].

This is an impression of just the implant integrated in the patient's bone but without an abutment attached to it. An implant level impression means that we are taking an impression of just the implant in place.

In conventional terms this would be like taking an impression for an indirect post and core. However the conventional impression is not going to work here and one needs a special transfer device.

The benefits of using the implant level:

It facilitates the provision of a temporary restoration. It allows the proper abutment selection in the laboratory and it can enable the use of custom-made or adjusted abutments [13, 55]. Furthermore it can help to improve the aesthetics of the restoration, reduce treatment visits and it is also helpful to compensate a malposition of implants [13, 55]. There is also a benefit seen for situations where the vertical space and/or the angulation of the abutment are difficult to determine intraorally [2]. It also eliminates the need to cover the abutments with a temporary restoration or protective cap.

A disadvantage in using an implant level repositioning technique is that it is difficult to reposition the impression copings correctly in the elastic material [55]. This is also reported in a study by LIOU ET AL. where the repositioning was not accurate in either a polyether or a polyvinyl siloxane [58].

Yet another factor being, that because of the implant head being relatively small, having a short axial surface, and lying far away from the occlusal plane, it is suggested from DAOUDI ET AL., that it is particularly susceptible to rotation, axial inclination and seating errors occurring at implant level [55].

### 2.5.5 The Abutment Level

An abutment level impression means that an impression is taken of an abutment already in place in an implant. This is therefore very similar to conventional crown and bridgework. In fact sometimes the impression is exactly as you would take for a conventional crown. However there are also transfer devices available which make impression taking even easier. One can use closed tray or open tray techniques for this purpose [55].

#### Type of copings

The following photographs (Fig. 4) are taken from DEL'ACQUA ET AL. [57].

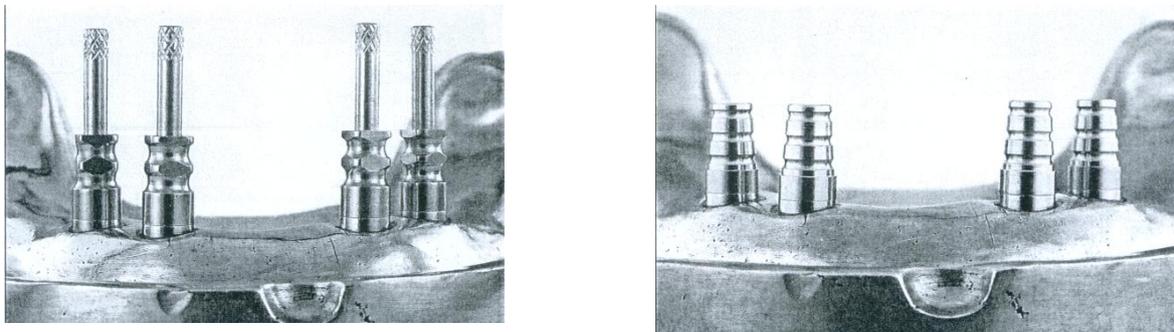


Fig. 4: Left hand side the square copings. Right hand side the tapered copings. In a research done by SAHIN [3], showed that dimensional changes related to the use of square impression copings are relatively lower than tapered copings.

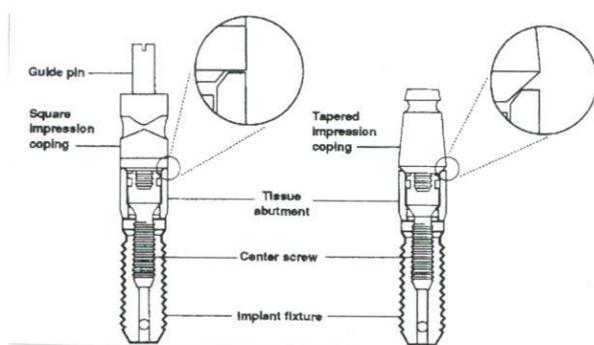


Fig. 5: Schematic representation of the implant assembly, showing the configuration of both the square and the tapered copings taken from BARRETT ET AL. Squared coping are on the right side, for the open tray impression technique (pick-up/direct pick-up impression technique) [43].

## 2. Introduction

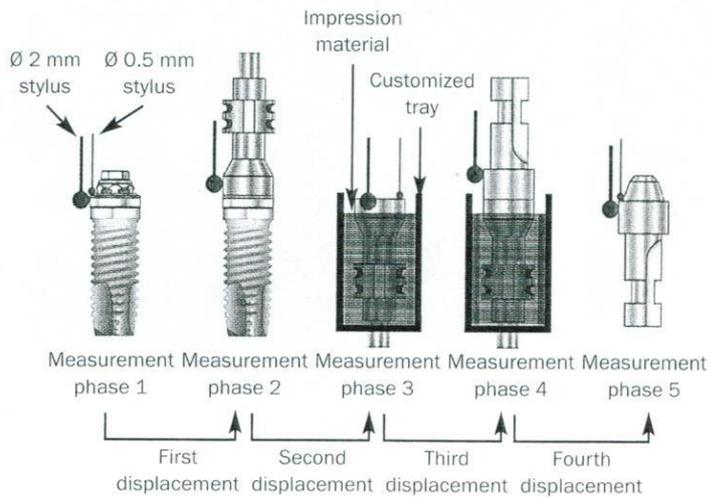


Fig. 6: Diagram regarding copings displacement possibilities. Taken from KIM ET AL [61]

### 2.5.6 Displacements of the copings

When making a definitive cast there have been four types of displacements that may occur as mentioned in the study of KIM ET AL [61].

- 1) Firstly, the impression coping may be displaced on the mating surface of its abutment.
- 2) Secondly, the displacement of the impression coping due to the impression technique or material used.
- 3) Thirdly, the displacement of the abutment replicas on the mating surface of each coping in the impression tray.
- 4) And fourthly the displacement of the abutment replicas in the definitive cast, due to the dimensional change of the dental stone [61].

The torque needed to rotate the copings has also been investigated [37]. One also has to keep in mind that the clinician's and the technician's torque strength vary and this can also lead to inaccuracies in the technical and clinical process.

## 2.6 Impression Technique Modifications - General Overview

Literature has shown intensive efforts made to increase the precision of implant impression taking [9, 17, 18, 44, 45, 61]. Several impression techniques have been advocated to achieve a definitive cast that will ensure the passive fit of prosthesis on an osseointegrated implants [37].

Modifications were made in order to increase the precision and to inhibit movements of the copings and hence to optimize the accuracy of the impression [54].

Suggested methods of splinting transfer copings include acrylic resin on a matrix of dental floss, orthodontic wire, acrylic scaffold, luting the resin to the impression tray, modified autopolymerizing resin custom tray and applying an adhesive coating/airborne abrasion onto the impression copings.

### **2.6.1 Airborne Particle Abrasion and Adhesive Coating**

The simpler and less time-consuming procedure of airborne particle–abrading and coating the copings with impression adhesive before impression making, is usually the privileged choice [10, 37, 58].

Theoretically, airborne particle abrasion and adhesive coating of the impression copings increase the intimate contact between the impression material and the impression copings decreasing the degree of micro movements of the copings inside the impression material during clinical and laboratory phases.

Consequently resulting in a definitive cast that closely replicates the clinical situation, allowing the laboratory technician to fabricate a restoration that may require fewer corrective procedures [10, 37, 58].

### **2.6.2 The splinted technique**

A lot of research indicates that the closed tray (indirect) impression technique produces a greater mean distortion than the open tray (direct) techniques [9, 15, 18, 22, 31].

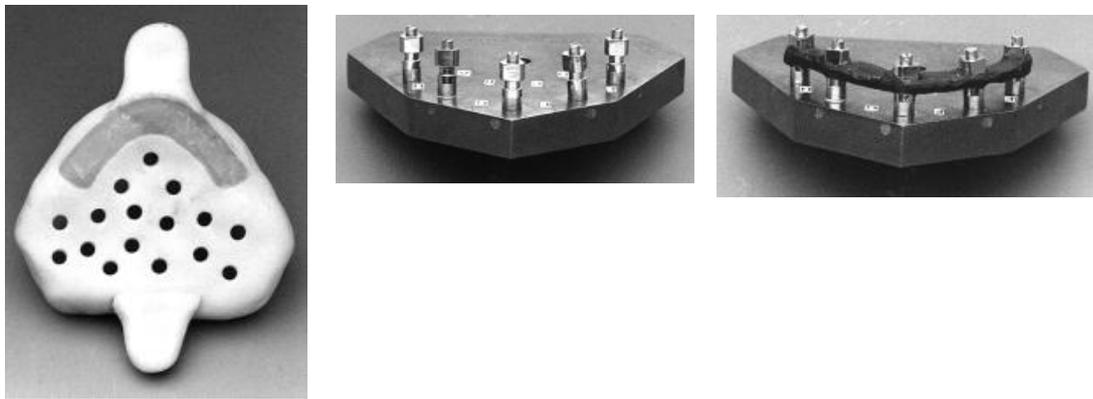
When comparing the open tray technique and using copings that are splinted and not splinted, conflicting results have been reported regarding their accuracy. However, most of the studies found the open tray without splinting to be more accurate than the open tray and splinted technique [13, 17, 22].

Different methods and materials have been tested to splint the transfer copings. These ranged from splinting with plaster [13, 62, 63], dual-cure acrylic resin [62], autopolymerisation acrylic resin used alone [9, 10, 13, 25, 37, 47, 62] or in combination with dental floss [9, 17,

22, 44], or even orthodontic wire [9], or directly connect the coping to the acrylic resin custom tray [25, 64]. Prefabricated resin bars were also investigated [65].

BRÅNEMARK ET AL. [1] reported that the procedure of linking copings together intraorally with the application of an autopolymerizing acrylic resin (for example Duralay) to a scaffolding of dental floss. More accurate definitive casts can be obtained for splinting internal connection implants than when unsplinted [9, 10, 25, 31, 37, 43, 45, 47, 66, 67, 68, 69].

Whether splinting or not splinting HERBST, HSU AND HUMPHRIES found no significant differences [9, 44, 45].



*Fig. 7: Photos taken from HERBST ET AL. Prefabricated custom impression tray with superior window (left) to expose transfer impression copings and guide pins. Unsplinted squared impression copings (middle) splinted square impression copings (right) [44]*

Caution must be taken as an autopolymerizing resin can increase the temperature of the implant shoulder by up to 4°C till 5° C and could cause damage to the implant-bone interface [63].

### **The usage of resin**

MOJON'S research regarding polymerization shrinkage of acrylic resin, when splinting, revealed the following results. Little change occurs in the first 2 minutes and after 24 hours. After 30 hours no change occurred. Linear shrinkage was at its maximum at 17 minutes and 80% of tested samples changed before 17 minutes. There was a peak of chemical reaction in the first 30 seconds and 10<sup>th</sup> minute.

Therefore, the bulk of the materials should be kept to its minimum when fresh polymerization is to occur (as with scaffold resin) and the main scaffold is to be prepared 24 hour prior its usage [70].

To avoid problems related to resin polymerization contraction and to save chair time, the resin scaffold may be prepared one day in advance, and the final connection should be performed just before the impression procedure, by re-splinting a narrow gap space between the implants with a powder and liquid brush application technique using a minimum of material to reduce the effects of polymerization shrinkage when indexing. The dental technician may fabricate a restoration that may require fewer corrective procedures [10, 22, 37, 62, 64, 65, 70, 71].

SPECTOR ET AL. [22] evaluated three impression techniques and concluded that the magnitude of distortion was similar in each and that none of the techniques produced an accurate cast. He questioned whether there might be a significant error factor (distortion when using an acrylic resin to splint the impression copings (polymerization shrinkage)) was introduced when transfer copings splinted with Duralay acrylic resin are removed from the implants.

### **2.6.3 Unsplinted techniques**

INTERREGUI ET AL. [18] noted high deviations in splinted techniques and recommended the unsplinted technique, but they also stated that any of the techniques that were investigated should be regarded as clinically acceptable. Their study investigated the use of polyether alone, polyether and impression plaster and polyether combined with an acrylic resin. None of the impressions resulted in an absolutely passive fit and the polyether alone resulted in the closest duplicate of the master cast.

VIGOLO ET AL. [10] stressed the necessity of nonsplinted impression copings in a given situation where implants may often have a greater divergence than 8 degrees. As it is difficult to recover from the distortion with nonparallel implants, the impression materials are very rigid (high Shore hardness A) due to the possible multiple deformations caused to softer impression material [15].

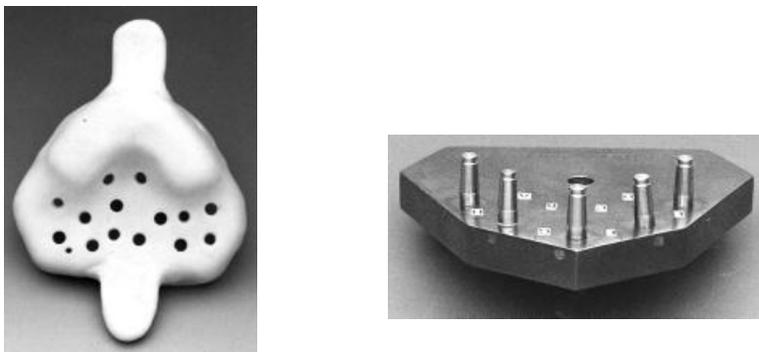
BURAWI ET AL. [17] reported that splinting techniques exhibited more deviations from the master cast than the unsplinted techniques. He found that plastic transfer caps are superior to splinted resin. Errors of the magnitude of those found here for the horizontal anteroposterior

plane when the splinted technique was used ranged from 0.26 to 0.85 mm and would certainly prevent accurate seating of a rigidly constructed gold cylinder-framework assembly. These errors were smaller for the technique using the plastic caps and were, apart from the value at one site, within acceptable limits ( $< 50 \mu\text{m}$ ) [17].

The research of LEE ET AL. [48] mentioned that out of 17 studies, 3 reported to be more accurate with the unsplinted technique [17, 18, 48].

LORENZONI ET AL. [24] used an indirect technique with transfer copings. His findings were that addition-silicone and polyether are the materials of choice for implant transfer procedures, where the polyvinyl siloxane with the transfer caps provided most precision.

HERBST [44] concluded that, splinting the copings first is a far more time-consuming and technically demanding procedure. Clinicians may feel that this procedure would produce a greater degree of accuracy. However, the experience of implantologists and technicians seems to be just the opposite. i.e that this procedure does not produce a greater degree of accuracy.



*Fig. 8: Photos from HERBST ET AL. [44]: Prefabricated impression tray without superior window (left) for unsplinted tapered impression copings (right).*

LEE ET AL.[48]found that out of 17 reviewed studies 7 reported to show no significant difference between splinted and nonsplinted [2, 9, 18, 43, 44, 57, 61].

#### **2.6.4 Other influences**

##### **The elastomeric impression material**

HERBST ET AL. [44] mentioned the importance of the impression material to be used. A two-stage addition-reaction silicone impression material (President) was used in their study. It may well be that an impression material such as the Impregum™ (a polyether) has properties ideally suited to coping transfer (for example, excellent resistance to permanent deformation, low strain under compressions and high initial tear resistance). It may therefore provide a sufficient rigidity to prevent rotation of the squared transfer coping during analogue fastening and cast formation, and thus splinting may not be necessary.

Hardness is the resistance of a material to permanent surface indentation. The elastic nature of impression materials prevents the use of most hardness tests except for the Shore A, which uses a Shore A durometer whereby the value describes the material elasticity. The value is provided with two numbers: one represents the hardness at 90 seconds after removal from the mouth; the other at two hours. The hardness of the impression material affects the force necessary to remove it from the mouth [72].

For all practical purposes, it seems that the nonsplinted technique using an adequate impression material will reduce some of the complexity of transfer procedures and save clinical chair time.

With a variety of impression techniques, one has to bear in mind, that every technique is accompanied by other technical aspects, as for example polymerization shrinkage, time consumption and or costs.

##### **The amount of implants**

A further aspect to be mentioned is the number of implants present, that have an influence on ones outcome and hence the relationship between the choice of technique (open vs. closed tray) and the number of implants present.

Five studies could be found in the literature using three or fewer implants [25, 27, 40, 43, 45] and four of them showed no difference between the open tray (pick-up) technique and closed tray (transfer) techniques.[55, 66, 73, 74]. DAOUDI [55] did however find that the indirect pick-up technique at the abutment level seems to be more predictable.

Research done by CARR [15] showed that open tray (direct) techniques produced more accurate casts. DE LA CRUZ [60] showed in their study more accurate impressions with the closed tray (transfer) technique. And research by SPECTOR ET AL. [22], showed that the resultant positions of transferred abutment analogues were different for the closed tray (indirect) and open tray (direct) techniques.

In studies with four or more implants, the comparison of the accuracy of open tray (pick-up) and closed tray (transfer) impression techniques were also researched. Out of nine studies [15, 43, 44, 45, 46, 56, 57] five showed more accurate impressions with the open tray (pick-up) technique, [15, 43, 57], one with the closed tray (transfer) technique [45] and three showed no difference [44, 46, 56].

For situations in which there were three or fewer implants, most studies showed no difference between the pick-up/open tray and transfer/closed tray techniques, whereas for situations in which there were four or more implants, more studies revealed more accurate impressions with the pick-up (open tray) technique than the transfer technique. Polyether and VPS were the recommended materials for the implant impressions [48].

### **The angulation**

The different implant angulations in relation to the alveolar ridge may also influence the accuracy of the impression. A study done by ASSUNCAO ET AL. [47] revealed that most favourable angulation of implants is when the implants are perpendicular to the alveolar ridge. They produce the most accurate casts.

Implants with a 65° had the greatest dispersion of the values. The study noted that the worst combination was a closed tray, with 65° angulated implants.

The best results came from splinting square copings with an autopolymerizing acrylic resin and an open tray using either a polyether or an addition silicone [47].

Lack of parallelism between implants and implants and teeth commonly encountered in implant prosthodontics and may create an undesirable path of withdrawal and subsequent distortion of the impression.

The other aspect with regard to passive fit was that the effects of angular misfit are aggravated as the degree of misfit triples the angular discrepancy [47].

### **The torque**

The importance of avoiding movement of the impression copings inside the impression material throughout procedures associated with fabrication of the master cast. Unscrewing the guide pins from the impression copings when the tray is removed from the mouth or screwing the matching abutment replicas in the impression may cause minor movement and thus influence cast accuracy [37].

WEE ET AL. [75] studied the torque required to rotate a square impression coping in an impression. Polyether (medium consistency) was found to produce the highest overall torque values, followed by addition silicone (high consistency), and then polysulfide (medium consistency).

The accuracy of the above mentioned materials resulted that the polyether or polyvinyl siloxane, are recommended for direct implant impressions [75].

All in all, throughout the literature reviewed, the results of the studies were inconsistent. Some showed that splinting improved the accuracy [10, 25, 46], others found no improvement when comparing the open tray to the closed tray impression technique [22, 29, 44, 45,] or none splinting implant impression technique, resulting in better accuracy [9, 18, 44, 45].

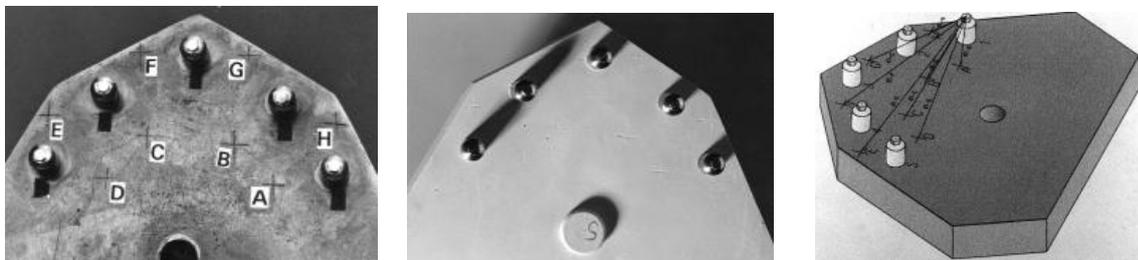
## **2.7 How is accuracy compared?**

Literature reveals a variety of studies to test for the accuracy of implant impressions. Various methods were described to assess the amount of distortion i.e. categorizing methods that address intraoral indexing and methods that used implant master casts [75].

In most studies, an indirect method was used. The impression technique was evaluated indirectly by measuring dimensional changes of the casts produced in relation to the master model/reference model, i.e. to compare the distortion to the definitive casts.

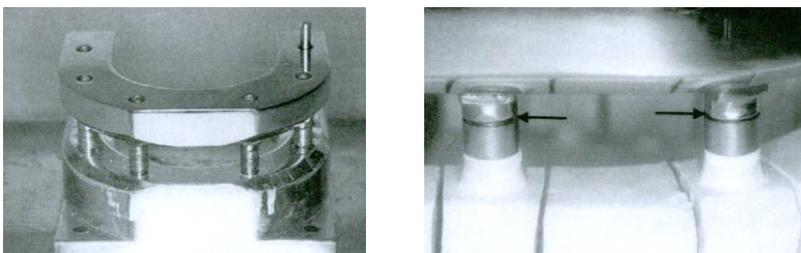
Some researchers used microscopes [9, 10, 15, 17, 22, 30, 37, 43, 44, 43, 76, 53, 56, 60, 77, 78, 79], others made used a profile projector, [9, 10, 37, 54, 66], and photogrammetry [12, 13, 24, 41, 54], others incorporated a certain software and a computerized coordinate measuring machine and laser videography to calculate the amount of distortion/rotation of the implant components in the definitive casts [12, 13, 24, 41, 54, 56, 61, 80].

Others wanted to create three-dimensional reading and references [13, 44, 55, 74].



*Fig. 9: Indicating reference points on the master model (left). Right side a diagram illustrating distance measured from one implant to eight reference points. Cast replica (middle photo) taken from HERBST ET AL. [44].*

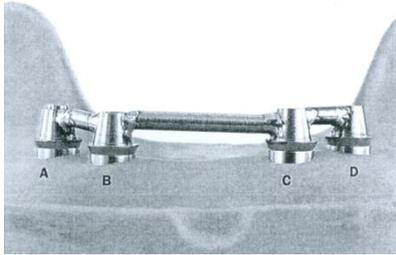
Other studies used a fabricated superstructure fitting the master model and this was then placed on the produced casts and comparisons of the distortion and fit were examined. [15, 17, 18, 25, 62].



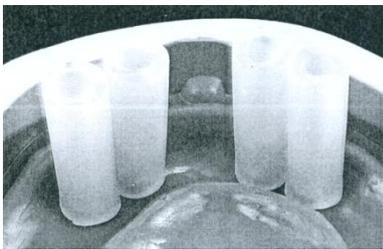
*Fig. 10: VIGOLO ET AL.[10] left hand side machined metal model with 6 implants and abutments and a passively fitting matching template. Right hand side visible discrepancies (arrows) between two abutments and template on master cast.*

In their investigation they used a passively fitting matching template. Impressions were made with nonmodified square impression copings, nonmodified square impression copings splinted with acrylic resin and airborne particle-abraded coated with impression adhesive.

Discrepancies were analyzed between the abutments and the template on the master casts obtained from the impressions. The nonmodified copings showed the worst results [10].



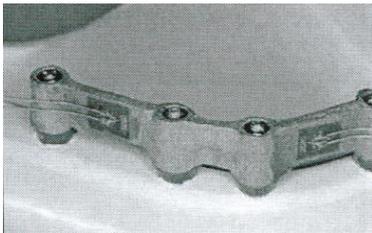
*Fig. 11: Another example of a framework taken from DEL'ACQUA ET AL. [57].*



*Fig. 12: The photograph demonstrating a special pouring technique, using latex tubes fitted onto the analogues. This technique is used in order to compensate for the gypsum expansion.*

*From DEL'ACQUA ET AL [57].*

To measure the stresses on the fitted framework, one compared the frequency values produced on in a metal framework by using strain gauges [2, 18, 25, 31, 46, 62].



*Fig. 13: Linear strain gauges are bonded on the flat surface of the connector parts of a superstructure supported by four implants. From JEMT [28].*

## 2.8 Impression Material - Overview

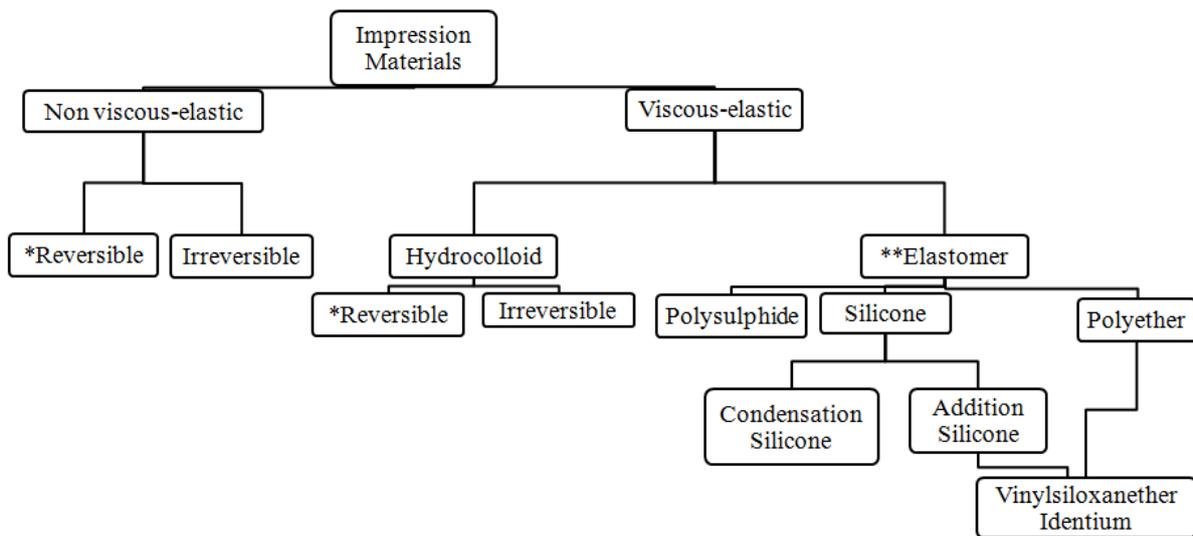


Fig. 14: Classifications of impression materials [81]

\*Reversible viscous and reversible non-viscous-elastic materials are also known as thermoplastic impression materials, as their reversibility is achieved by heating and cooling [81].

\*\*An Elastomer is a material that falls between a solid and a liquid (Rubber like) [81].

The history of Impression Materials [59, 81]

1925 Hydrocolloid

1950 Polysulphide

1955 C-Silicones (condensation silicone)

1965 Polyether

1975 A-Silicone (addition silicone, polyvinyl siloxane (PVS), poly-vinyl siloxane, vinyl polysiloxane, vinylpolysiloxane)

1986 hydrophilic A-Silicones

2000 Polyether Soft

2004 Polyether Soft Quick

2009 Vinylsiloxanether, Identium®

Despite technical improvements in the field of computer-aided design/computer-aided manufacturing (CAD/ CAM) systems and three-dimensional (3-D) imaging procedures, the conventional impression process still plays a role in transferring information from the patient to the dental laboratory [14].

The function of an impression is to get an accurate negative [39]. An impression is an imprint and one may describe it as being a mould for a model. If the laboratory is to produce restorations to fit precisely, then the cast on which it is produced must be as nearly an exact duplicate of the prepared tooth in the mouth [39]. For this to work, one needs an accurate, undistorted impression.

Paradoxically, the actual implant is not recorded by any impression. Instead, the implant related with machined precision to a transfer coping. The two primary objectives of an implant impression are (1) to record the precise interrelationship of the transfer copings and (2) to preserve this record during construction of stone casts with brass analogues of the oral implants [31].

The impression's additional purpose in implant cases is to transfer the relationship between the implant fixture and the attachment. For this reason it is important that the impression material used is sufficiently rigid in order to retain stable positioning for the connection and transfer lab implant attachments during impression taking procedures. It also requires for the abutment to be transferred to the stone model after the impression is poured.

Further requirements of the impression material used, is that it has to be stable in the tray in an unset state, yet offering a high degree of flowability once inserted in the oral cavity (unset form). This has to come along with an absolute minimum of dimensional change after polymerization and rigid for stable positioning of the coping.

Implant impressions seem to be the ultimate test for impression materials.

Various impression materials were suggested for the implant impressions, these ranged from polyvinyl siloxanes, C-Silicones, polyethers, hydrocolloid and impression plaster [18, 24, 45, 53, 54, 75, 82, 92].

Currently the most used impression material in Germany, are the polyethers and the polyvinyl siloxanes [83]. These are also the recommended materials for implant impressions [24, 47, 54, 58, 75].

Polyether (PE) and addition silicone (polyvinyl siloxane/VPS) impression materials should be preferred for transfer procedures because they have the lowest distortion values (around 100  $\mu\text{m}$ ) [24].

In various studies, the polyether and polyvinyl siloxane, resulted in the most accurate casts for implant impression techniques and are suggested to be more dimensionally stable than polysulfides and condensation silicones. [24, 44, 47, 54, 58, 75, 84].

No differences between the polyether and polyvinyl siloxane were noted by for example LIOU ET AL. [58]. Their research showed that these two materials produced the most accurate casts. DAOUDI ET AL. [55] used the closed and open impression technique for implant impressions, noted that no significant differences were noted between a polyvinyl siloxane and a polyether.

Eleven studies compared the accuracy of polyether and VPS impression materials [24, 43, 48, 54, 55, 56, 58, 75, 80]. Ten of 11 reported no difference between the two materials [15, 24, 43, 54, 56, 58, 75, 80] and only a single study [85] reported that VPS was more accurate than polyether when the implant was placed deep subgingivally [48].

In the implant impressions, the transfer of the exact position of the implants to the working cast is even more important, because implants lack the mobility of natural teeth [58]. A misfit will result in the accumulation of preload and loading stresses in the restorative complex, causing problems ranging from screw loosening to the loss of osseointegration [21, 30, 45, 62, 85].

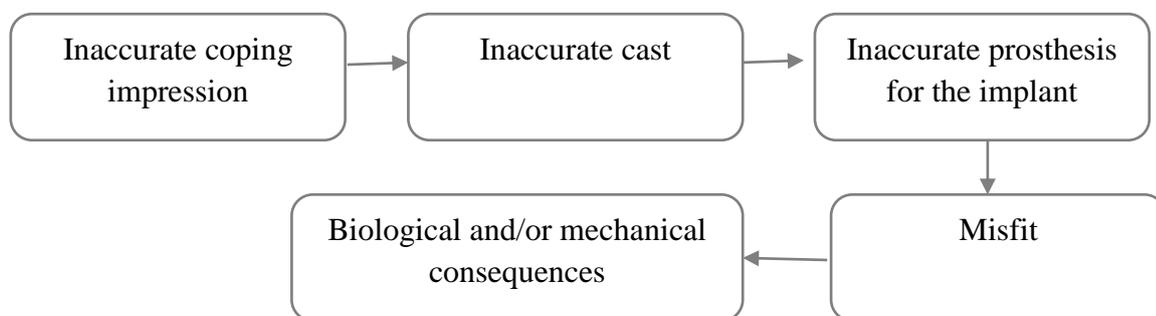


Fig.15: Flowchart showing the consequences of inaccurate coping impressions

LIYOU ET AL. [58] reported that indirect impression copings did not return to their original position when replaced in either polyether or addition silicones. It is assumed that the same is true when direct impression copings are accidentally rotated. Therefore, the practitioner may be less likely to accidentally displace the impression coping by using a more rigid impression material.

Accuracy of the impression is influenced by the impression technique, impression tray, and properties of the impression material also contribute to the accuracy of the impression [86]. By realizing why faults occur and learning to prevent them will lead to greater success in impression taking. By being aware of the range of techniques available and having an understanding of the behaviour of materials, clinicians can achieve the quality in their impressions that is possible and necessary to achieve excellence in indirect restorations [86].

Choosing an impression material for multi-implant-retained prosthesis requires a consideration of several factors, including the material's accuracy, the clinician's experience with the material, the length of the time before the impression is poured, and the amount of intraoral undercuts [75].

A lack of parallelism between implants and implant and teeth is commonly encountered in implant prosthodontics and may create an undesirable path of withdrawal and subsequently distortions of the impression [2]. Smaller angular deviations are more disastrous for the multiple-unit prosthesis than for the single-tooth restoration [58].

To achieve a structure with 100% passive fit to the abutment or directly to the implants is still quite impossible as a result of the number of variables involved in the prosthesis fabrication process [24, 47].

There are also certain factors which we do not have control of, as the tolerance among the components of the implant system. Other factors we are faced with everyday, impression transfer procedures, investing, casting, alloy and impression material properties.

Common clinical techniques used in the impression process have also been investigated, and potential consequences have been reported. Variables that have been compared include:

## 2. Introduction

- monophasic versus dual-phase materials [87, 88, 89, 90, 91]
- 1-stage versus 2-stage impressions [17, 44, 87, 92, 93, 94]
- polyether versus polyvinyl siloxane materials [31, 43, 54, 56, 55, 58, 75, 24, 48, 22, 80, 88, 90, 92, 93, 95, 96, 97, 98, 99, 100]
- stock versus custom impression trays [30, 31, 78, 101, 102]
- stock versus dual-arch trays [103]
- metal versus disposable plastic trays [103]
- the effects of disinfection on the accuracy of different impression materials have also been investigated [104, 105, 106]
- the time delay in impression pouring [53, 92]
- pouring techniques [57, 60]

The accuracy of implants impressions also looked at

- the different implant connection levels (Implant or Abutment Level) [55]
- implant depth [48]
- torque resistance [75]
- resin shrinkage regarding the splinted technique [62, 70, 78]

Kettenbach's (Eschenburg, Germany) new impression material Identium® is of great interest in our study, because it is a combination of a polyether (PE) and a polyvinyl siloxane (PVS/VPS), producing a vinylsiloxanether (VSE). The new vinylsiloxanether impression materials have been introduced with enough hardness and rigidity leading to improved implant impressions [107].

A study by ENKLING ET AL. [107], showed VSE to be equivalent or even superior to the polyether material. Not too much literature has yet been published regarding Identium®, therefore a lot of literature research has taken place, regarding polyether and polyvinyl siloxane, in order to presume how a vinylsiloxanether could act in a given situation. This new vinylsiloxanether has promising rheological properties, believed to maybe be an ideal material for implant impression techniques [107].

### **2.8.1 Elastomeric Materials**

An elastomer is a material that is placed between a solid and a liquid (rubber like) [81].

Elastomers are indicated for all dental impression purposes, because of their exceptional precision and a good dimensional stability.

Elastomers have the following characteristics [81]:

best elastic properties, elastic recovery, best detail reproduction, precision, good dimensional stability, storage possibilities (elastomers should be used within one year after opening, as their properties alter too much (shelf life)).

Elastomeric impression materials are classified as Type I, II, or III, according to their elastic properties and dimensional change after setting [68].

A Type II classification requires that a material not change more than 1.0% after 24 hours.

A Type I or III material must not exceed 0.5% negative linear change.

Properties for the elastomers fall under the European Norm (DIN EN 24 823) (DIN 1996) [81, 83]. The Norm tests specific aspects of a material:

elastic recovery, thixotropic, dimensional stability and detail reproduction

The above and others aspects will be discussed, as they influence our impressions and are consequently important for the presented study.

### **2.8.2 Elastic Recovery (The DIN 13 945 Test)**

An elastomeric material needs to have a good elastic recovery i.e flexible enough during the removal, in order not to cause any tearing of the fine detail reproduced in the impression.

Furthermore it should not cause any breakage of the gypsum model upon removal of the impression [81].

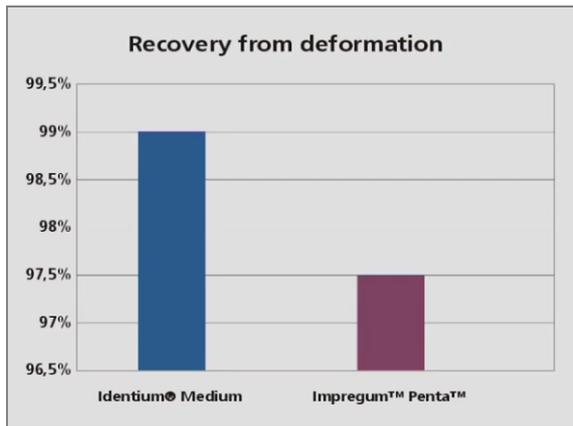


Fig. 16: Elastic Recovery/Recovery from deformation in % (courtesy of Kettenbach [108]). The graph compares Identium® Medium (Kettenbach) and Impregum® Penta™ (3M ESPE). Identium® Medium achieving an almost 100% recovery.

The elastic recovery of Identium® is almost at 100%. The physical properties of an A-Silicone are responsible for this physical property.

Removing the copings can cause less than ideal elastic recovery from the deformation and may cause an inaccurate relationship of working cast implants [15].

Discrepancies detected for both polyvinyl siloxane and polyether materials may result, among other reasons, from the incomplete elastic recovery or from the residual polymerization, resulting in the shrinkage of the impression [98]. During polymerization, new covalent bonds are formed within the molecules, reducing the volume occupied by them. Thus, the shrinkage resulting from material polymerization will contribute to the loss of accuracy over time [98].

### 2.8.3 Thixotropy

An important characteristic of impression material is the ability to cease flowing once the impression is fully seated in the mouth [109]. This is often described as the thixotropic behaviour. The shark fin test was introduced in 1994 and has been now established as a gold-standard for testing the thixotropic behaviour of an impression material.

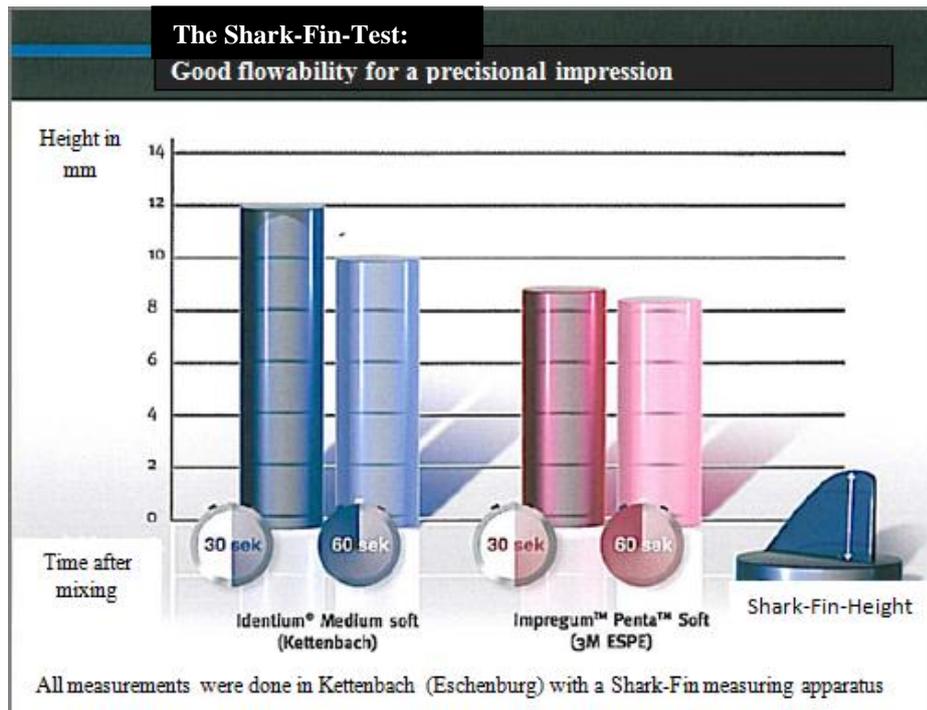


Fig 17: Results of the Shark-Fin-Test: The viscosities of Identium® Medium soft (Kettenbach) and Impregum® Penta™ Soft (3M ESPE) are being compared after 30 seconds and 60 seconds after mixing. (Courtesy of Kettenbach [108])

The above diagram showing studies with the shark fin test done by Kettenbach. The flowability of Identium® stays constant over the entire working time. A balance is achieved with the elasticity and the flowability.

### 2.8.4 Viscosity

The viscosity of a fluid is its resistance to flow.

A light body is least viscous, whereas a heavy body is most viscous. The viscosity of a material increases as time after the start of mixing increases [39].

The shear rate increases (i.e. the speed at which a liquid flows under external forces) as the material exhibits lower viscosity (e.g via a syringe) [39].

The viscosity of a fluid is its resistance to flow. This parameter is the ratio of the shear stress to the shear rate.

Shear stress: is the force per unit area acting on a fluid.

Shear rate: is the slope of the viscosity-distance curve or velocity gradient of the material [109].

A fluid may also have an elastic component to its deformation. For example, a mixed dental elastomer quickly develops an elastic modulus as the chain lengthening and cross-linking reaction proceeds. [109].

### **2.8.5 Detail Reproduction/Surface Reproduction**

The detail reproduction is influenced by the wettability, the compatibility with the die stone and again the viscosity (the monophase has an increase in voids and the dual phase mostly has a better detail reproduction) [99]. Good detail reproduction means that one can see the exact borders of the preparation line and hence a correct marginal fit [81].

### **2.8.6 Dimensional Accuracy/Dimensional Stability**

Materials with a high dimensional stability reveal low shrinkage during polymerization and also no swelling during storage in disinfection solutions [110].

In a study by BELL ET AL. [111] the dimensional change was influenced by the following: First the elastic modulus (stiffness) of the material will affect the amount of dimensional change taking place, a stiffer material being more resistant to dimensional changes than a flexible material during polymerization [111, 113].

Secondly, the loss of volatile constituents from the impression material may offset moisture absorption from the surrounding atmosphere [111].

Thirdly, and perhaps most importantly, the material may continue to polymerize after it is “clinically” set and this may cause shrinkage, the continuous polymerization after the removal from the mouth, cross linking of the polymer chains and hence reducing the volume [113].

### **2.8.7 The gypsum expansion**

In the research done by BELL ET AL. [111], all the materials lost weight and shrank when unrestrained and therefore such that oversized models were produced [111].

CLANCY ET AL. [110] tested the dimensional stability as well as the surface detail reproduction of three materials over specific time intervals.

All of the three products became smaller: This is probably due to the thermal contraction of the materials. For all three products the impression poured immediately lead to the most accuracy. The surface detail reproduction changed over time [110].

Dimensional stability of the polyether and the polysiloxane were statistically equivalent. Shrinkage of the C-Silicones can be observed from time zero to four hours. This is due to the volatilization of alcohol in the set material. The polysiloxane does not have a condensation reaction, hence no volatile evaporates and no such shrinkage is observed [110].

The surface detail reproductions were as follows: Reprosil (polysiloxane) remained the most distinct material throughout the investigation. The Polygel (polyether) was adequate and Elasticon (C-Silicone) had a high loss of the detail reproduction, especially beyond 24 hours. CLANCY ET AL. concluded that if a custom tray would have been used, the shrinkage would have presumably been less [110].

Research done by WALKER ET AL. [112] compared four impression materials and their dimensional accuracy. In spite of the significant differences between materials, all materials exhibited acceptable dimensional accuracy well below the ADA specification standard of  $\leq 0.5\%$  dimensional change [112].

### **2.9 Wetting**

Another aspect of importance of an impression material is the way they react to wetting. Wettability is the ability of a liquid to spread over the surface of a solid [99].

A hydrophobic material shows resistance to wetting, whereas a hydrophilic material wets readily [39, 100, 114, 115, 116]. Easiest to pour (hydrophilic) materials are the reversible and irreversible hydrocolloids. Polysulfides, polyvinyl siloxane, condensation silicone are most hydrophobic [100].

A method to measure the wettability is established by the contact angle measurement.

It has been postulated that contact angles that approximate or exceed 90 degrees increase the probability for entrapment of oxygen (air bubbles/void formation) during the pouring of the impressions [100, 114, 117, 118]. Both CHONG ET AL. [114] and CULLEN ET AL. [115] found that at the crucial sites as the margins and line angles of stone casts were voids present, but not on smooth surfaces.

These voids are probably caused by the inability of the gypsum slurry to readily wet and flow over the surface of the impressions. In an effort to improve the wettability of polyvinyl siloxane materials, surfactants have been incorporated by some manufacturers in their formulations. The improved materials have been termed hydrophilic. PRATTEN ET AL. [117] defined the term hydrophilic in this context to apply to those solids that produce a contact angle of 90 degrees or less when the wetting liquid is water [100, 114].

This decrease contact angle allows for displacement rather than entrapment of air. If a cast is produced with a void, the impression is usually re-poured, with a resulting loss of accuracy [114].

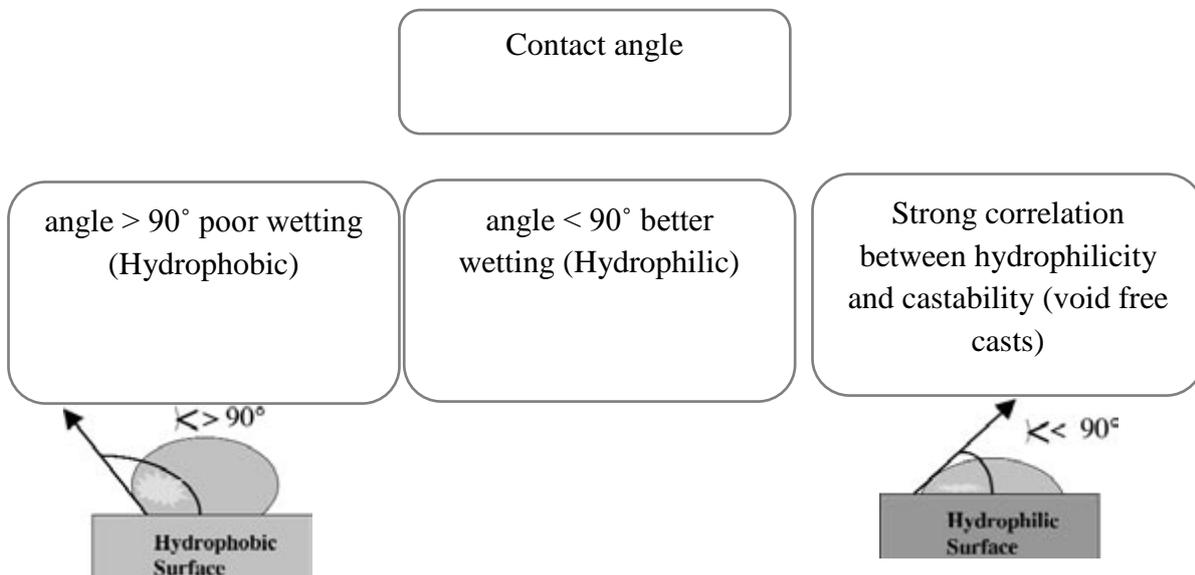
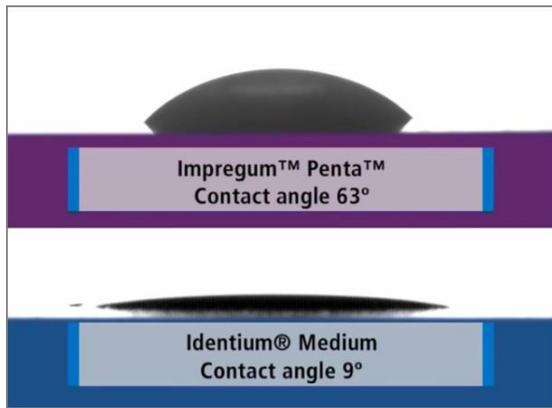


Fig. 18: Characteristic examples to describe the wettability of a material: The smaller the contact angle the better is the hydrophilic behaviour of the material (Diagrams courtesy of 3M ESPE [59]).



*Fig. 19: Results of the contact angle measurements of Identium® Medium (Kettenbach) and Impregum® Penta™ (3M ESPE) are being compared. (Courtesy of Kettenbach [108])*

The contact angle of Identium® after 1 second is below 10°. In comparison Impregum™ after 1 second results in 63°. (No further data is given whether this is in the pre- or post setting).

### **2.9.1 Increase wetting**

Literature suggests that the use of a surfactant can improve wettability of VPS materials after exposure to saliva, water and disinfectants [117, 118]. However further work is needed to determine the effect of surfactants on the surface properties of gypsum [116, 119].

Some polyvinyl siloxane materials are modified by the addition of intrinsic surfactants [117]. These materials are called hydrophilized additional silicone and tend to provide improved wetting, by creating a more intimate contact with teeth and tissues with the aim of capturing better surface detail and fewer defects [39, 99].

### **2.9.2 Pre- and post-setting hydrophilicity**

There are two aspects one has to distinguish in wetting. An ideal material should possess pre- and post-set hydrophilicity [100, 112, 120].

The pre-set-behaviour describes the ability of the non-polymerized material to closely adapt and impress teeth and tissue surface (to flow around the soft and hard tissues of the mouth) [87].

The post-set behaviour regards the capacity of the set material to be poured with gypsum products without entrapment of air (the ability of the material to be wetted by gypsum slurry) [87].

By nature VPS materials are hydrophobic. By adding surfactants, which are surface-active additives hydrophilic properties can be achieved. This results in a different wetting behaviour. When an impression material with surfactants comes into contact with moisture, the surfactant must “migrate” to the surface. This prevents hydrophilicity from fully developing at the very first contact with moisture [112, 119].

The polyether impression materials are more hydrophilic by nature in the unset stage than in the set stage. The degree of hydrophilicity in the set stage is optimized to ensure compatibility with the gypsum slurry for pouring out the impression and very good dimensional stability of the impression during disinfection [119]. The intrinsic hydrophilicity of polyether impression materials ensures lower contact angles compared with silicone impression materials in the unset stage [112, 119].

WALKER ET AL. [112] discusses in his research the fact, that PVS remain hydrophobic in their unpolymerized state. It seems as though the surfactants change the PVS so it seems more wettable in the gypsum slurry. The low contact angle of a polyether and a hydrophilic polyvinyl siloxane have shown not to be significantly different [117]. VASSILAKOS ET AL. [118] research shows that polyether is still the most wettable.

Studies [88, 112, 119] showed that polyether impression materials are characterized by the tendency to favour moist surfaces and produce precise reproductions, and suggest the potential for better intraoral results.

### **2.10 Temperature effects on the rheological properties**

Mouth temperature is believed to be between 33° to 35° Celcius. Materials all show rapid development of elasticity at the higher temperature. During impression taking, the material can shrink caused by cooling (if the impressions are not kept at same temperature) [88].

A study done by BERG ET AL, investigated the temperature effect on the rheological properties of polyether and polyvinyl siloxane [121].The variations in temperatures revealed significant

rheological property changes, differences in the setting time and the magnitude of the storage modulus. The setting time decreased more than 3-fold between 25°C and 37°C for the Aquasil Deca and it decreased more than double for the Impregum™ Penta. In the range investigated, the setting kinetics for Aquasil Deca and Impregum™ Penta Soft H were more temperature-sensitive than those for Impregum™ Penta [121].

## **2.11 Focus on specific Materials**

### **2.11.1 Polyether**

Polyether was the material of choice in 1985 by Brånemark. Other research shows polyether to be the most reliable and accurate for working casts [58, 90].

The rigidity of polyether provides resistance to the accidental displacement of the impression coping in the implant impressions [75]. Because of a low strain in compression (low flexibility) and favourable Shore A hardness, polyether has been recommended as an impression material for edentulous multiple implant-retained restorations [9, 15, 18, 31, 75, 122]. The benefits of a polyether is the long intraoral working time, whereas the A-Silicone has a shortened time.

Other usages are in the conventional functional impressions, post and core build up and the crown and bridge work.

However, the use of polyether also presents difficulties, as with a partially edentulous arch because of an increased difficulty for intraoral removal of the impression. High consistency addition silicones and medium consistency polysulfides are variable alternative materials of choice for experienced practitioners. Addition silicones with its more favourable modulus of elasticity (slightly less rigid), allow an easier removal of the set impression [75].

It seemed also that polyethers release volatile substances. The smell of even well cured Impregum™ may be an indicator for this assumption. Therefore, it is more likely that the enlargement observed in the replicas submitted to longer storage periods is supposedly related to the evaporation of volatile compound [98].

Polyether can also absorb water [98]. It is known that polyether is a highly hydrophilic material and absorbs water from the surrounding atmosphere in vapour saturated

environments, thus resulting in smaller dies [39, 98]. Impregum™ impressions should not be stored in sealed plastic bags, especially if the bag also contains a moist alginate impression - contact with moisture may result in swelling, with an accompanying loss of accuracy [53, 98]. A low humidity environment is quite easily produced with the aid of a silica gel [111].

Therefore, although the delay period should allow both the release of volatile substances and the elastic recovery of the material, it should not be too long, otherwise distortions over time will occur [53, 98]. An impression made from polyether should be poured only once and within 24 hours after impression making, because polyether absorbs water from the gypsum and swells with each successive pour [53].

Trays for polyethers should be stiff with an even space of ca. 3 mm for the material in areas with teeth to give a mechanical and chemical retention [98].

BARRETT ET AL. [43] and WEE ET AL. [75] found no significant differences between a polyether and a polyvinyl siloxane.

LIU ET AL. [58] also found no significant difference in implant transfer accuracy between polyether and polyvinyl siloxane impression materials.

CIESCO ET AL. [123] research revealed that a polyether material consistently yielded superior results with or without a custom tray.

In an investigation by THONGTHAMMACHAT ET AL, deviations for all tray types with silicone impression material were in the clinical acceptable range, but in the polyether material group, had some distortions that were not clinically acceptable [53].

### **2.11.2 Vinylsiloxanether**

Recently, a new impression material, classified as a vinylsiloxanether by the manufacturer, has been made commercially available. This material has been reported by the manufacturer to possess good mechanical and flow properties along with excellent wetting characteristics in the unset condition when applied to the prepared tooth, and also in the set condition.

Silicones have the advantage of their taste, handling, viscosity, dimensional stability, good elastic recovery and the compression of soft tissue [124].

One of their biggest disadvantage is, that by nature they are hydrophobic.

In contrast the polyethers show their strong points with their hydrophilicity, flowability, precision and dimensional stability [124].

Polyether's disadvantages are mostly seen in the very slow elastic recovery and therefore delayed pouring (1 hour up to 24 hours) and the unpleasant taste for the patient [83, 125].

For this purpose a clinical study was performed by comparing VSE (Identium®) against a polyether material Impregum™ [107]. Both materials were used in a single-phase with a custom tray and the open tray impression technique. Identium® had a positive feedback regarding a better taste, the handling seemed easier as it seemed less sticky and the removal of the impressions was easier. The immediate pouring and the removal of the impression after pouring proved to be of convenience [107].

A study by ROGGENDORF showed great satisfaction with the detail reproduction and its handling properties [125].

A study focusing on the immersion disinfection showed overall accuracy for the new VSE as well as for the polyether. The clinical impact of detected differences was considered to be minor [91].

The accuracy and dimensional stability of polyvinyl siloxane and polyether is well documented [89, 92, 96, 99, 109, 113, 120, 126].

## 2.12 Impression Tray

The important aspects of an impression tray are as follows:

It must cover all structures which are necessary for constructing the prosthesis.

It may not alter in shape and it should be rigid to prevent distortions of the impression material.

Any movement of impression copings inside the impression material using an open tray impression technique during clinical and laboratory phases may cause inaccuracy in transferring the three-dimensional spatial orientation of implants intraorally to the definitive cast. Consequently the restoration may require corrective procedures [37].

Elastomeric impression materials have no adhesive properties to the tray by itself. Therefore retention should be provided. Direct retention is often provided mechanically by the use of perforations and indirect retention is provided by the use of adhesives. (One should only use specific adhesive to specific impression material). Bonding strength of the adhesives used with polyvinyl siloxane can be improved by nearly 50% by adding perforations [39].

GORDON ET AL. reported that the interpreparation distance with polysulfide, polyvinyl siloxane and polyether impressions was 45-100  $\mu\text{m}$  greater in stock trays than in custom acrylic resin or thermoplastic trays.

A difference was also noted in the cross arch measurements, due to the stock trays flexibility [39].

On the other hand BOMBERG ET AL. [127] and SPECTOR ET AL. [22] found no significant difference from a single-tooth restorations made from polyvinyl siloxane impressions made in stock and custom trays.

### 2.12.1 Tray Wall

The tray wall may flex during removing the impression. Using putty materials one can expect also an outward flexure by seating the tray and residual stress may remain in the tray wall.

This causes recoil and deforms the impression upon removal. This creates an undersized die [79].

### 2.12.2 Tray Space

Tray spacing and tray design have often been cited as potential sources of error in impressions for fixed prosthodontic procedures.

Tray space that is the space between the teeth and the inner tray walls, of 2 to 3 mm is recommended and is considered standard [39, 41, 127, 128, 129]. Tray spacing was critical to minimize distortion due to uneven polymerization shrinkage in areas of greater impression material bulk.

BURNS ET AL. [30] studied two various tray spaces (close fitting of 3 mm and a spaced custom tray of 10 mm). He noted that no statistical difference in marginal gaps measurements of the prosthetic restoration between the 2 types of custom tray occurred.

Other studies suggesting space from 2 to 4 mm, or 3 to 4 mm [68, 69]. Some research included the full range by claiming that anything between 1 and 5 mm will not produce significant differences if the impression is poured immediately [68].

In BURNS' study however, there were no statistically significant differences in vertical gap measurements between the spaced fit 10 mm custom tray and close fit 3 mm custom impression trays. It seems that any influence of the impression material thickness on the spatial positioning of the transfer copings was negligible [30].

EAMES ET AL. underwent an investigation and produced a variety of trays with various space (2mm, 4mm and 6mm) using Impregum™ and a C-Silicone. The result being that the 2 mm spacing gave overall better accuracy than either the 4mm or 6 mm tray spaces [69].

Setting shrinkage is divided into two aspects [127].



Concentric shrinkage located in the free space where there is no adhesion of the impression material to the tray. The tooth is then smaller in size.

Eccentric shrinkage increases the size of the negative and hence increases the size of the model.

Another problem noted is the eccentric orientation of the tray to the arch in seating, which results in a nonuniform thickness layer of the impression material [127].

Another observation was improper extension of the tray. Underextension of the tray gingivally or on the most distal tooth left unsupported impression material. Gingival overextension that exceeded the suggested 2 to 3 mm beyond the gingival crest was quite common and found in half the trays examined. This could cause excess permanent deformation on removal. Incomplete seating with excessive material thickness on the occlusal surface was more common in custom trays, while overseating with a minimal occlusal thickness of material was found in slightly less than half the stock trays.

### **2.12.3 Undercuts**

Removal of impressions from the mouth or working casts from the impressions will be somewhat easier with "softer" materials, that means with a smaller Shore Hardness when large undercuts, mobile teeth, or small narrow working dies are found.

The lower flexibility of a polyether and polyvinyl siloxane creates more resistance when the impression and tray are removed from the mouth over undercuts [130].

### **2.12.4 Bonding of elastomeric adhesives**

Upon removal of an impression, both the impression material and its bond to the custom tray are stressed. As many dentists depend entirely on tray adhesive for retention of the impression material to a custom tray, it is obvious that the strength of the bond is of vital importance to the accuracy of the impression, model and subsequent casting [95, 27, 130].

Research done by BOULTON ET AL. [95] found that drying times of less than 15 minutes were found to be inadequate and decrease the bonding strength; they are clinically inadvisable. For drying times between 15 minutes and 72 hours, no significant change was found in bond strength of elastomer to tray material [38].

The theory is that the material may adhere to the adhesive of the tray, causing the impression to shrink towards the tray walls, causing the negative image of the master die (the prepared tooth/extra coronal) to enlarge and prevent complete seating of an extra-coral casting, clinically causing perhaps only open margins would be seen [69, 88]. BOMBERG ET AL. concluded that the usage of adhesive and the use of perforated trays were associated with the minimization of marginal opening [130].

The reverse phenomenon may occur when considering an internal tooth preparation. As far as the height of the impression is concerned, the stone height would be shorter. The impression material on the occlusal surface contract towards the tray (the impression adheres to the tray) and hence the models produced are shorter [69, 88].

The use of a tray adhesive may have contributed to an altered dimension, investigated by CEYHAN ET AL. [92] Gypsum distorted from their original spherical shape (abutment standard was perfectly circular) into an ovoid shape. The impression material shrinks toward the center of mass during polymerization, and the use of a tray adhesive would redirect this shrinkage toward the walls of the tray, resulting in a larger die in bucco-lingual direction [88, 92]. All of the investigated 3 impression techniques (complete arch tray, dual metal tray, dual plastic tray), produced gypsum dies that were larger bucco-lingually, smaller mesiodistally and shorter occlusogingivally than the implant solid abutment [88, 92].

As there is no tray adhesive interproximally, the smaller dimension observed mesiodistally may be in response to the material being stretched bucco-lingually, much like stretching a rubber band. BREEDING ET AL. [131] obtained similar results as CEYHAN [92].

### **2.12.5 Custom Tray**

The primary purpose of the custom tray is to provide a uniform thickness of material [127]. Any materials used to make custom trays must be dimensionally stable over time and must not permanently deform during the impression making procedure or as the impression is retrieved from the oral cavity [39, 53].

Distortion from polymerization shrinkage and residual stress relaxation shows that the acrylic resin is less than an ideal material for custom trays. It is suggested that custom trays should be fabricated at least 24 hours before impressions are made [39, 68, 69].

Studies with prepared teeth show that custom trays produce more consistently accurate impressions compared with stock trays [76, 77, 79, 95, 132, 133].

Many researchers have reported that custom trays provide more accurate dental casts than stock trays [53, 69, 76, 129].

Plastic stock tray consistently produced casts with greater dimensional change than the two different kinds of custom trays [69].

Using custom trays might be more predictable and more economical because less impression material is used. Material compatibility is another factor to be considered, as demonstrated by the material Fastray LC, which performed very well with silicone but not with polyether [53]. Yet it was concluded that accurate casts can be made with either stock trays or custom trays [53].

Studies reported undesirable dimensional changes and inaccuracies of the stone casts resulting from excessive and uneven thicknesses of the elastomeric impression material when stock trays were employed and due to under load the stock tray flexes [22, 52, 53, 68, 126].

It was possible to make accurate stock tray impressions, when an accurate impression material and good impression protocol are provided. A rigid stock tray may be a valid alternative to custom trays for implant fixture-level impressions [30].

### **2.12.6 Stock Tray**

Making custom trays is time consuming and costly. An alternative approach is the use of stock trays [52, 129]. Stock trays are readily available and easy to use [53].

Whether accuracy can be obtained from a stock tray has been researched throughout literature.

The main objective in stock tray construction is to provide a rigid tray, which also gives retention for the impression material. Metal and rigid plastic stock trays provide greater accuracy than flexible plastic ones [53, 132].

SAUNDERS ET AL. found that the use of a stock polycarbonate tray, with or without modifications to re-inforce the structure, did not affect the accuracy of the casts poured from impressions taken with a putty-wash polyvinyl siloxane impression material [76]. However, the use of the impression material in a one-stage technique did affect the accuracy. An explanation for the above would be that it seems that the way the material was manipulated was the more likely cause of the observed inaccuracies [76].

A further study regarded the manipulations of the materials. Medium-bodied monophase polyvinyl siloxane material using a number of different tray designs have no effect on the accuracy of impressions. Results of this study show that the use of a stock polycarbonate tray, with or without modifications to reinforce the structure, did not affect the accuracy of the casts poured from impressions taken with the medium bodied polyvinyl siloxane impression material [77].

It would appear that stock trays used in this study provided sufficient rigidity to support this impression material [77].

In another study by WASSELL ET AL. found that the choice of stock tray had little influence on the dimensions of the individual dies, but rather the impression techniques. The findings showed that the heavy-light body impression produced dies with minimal distortion for all combinations of tray and reinforcement. By contrast the putty light-body impression consistently produced the largest distortions [79].

THONGTHAMMACHAT ET AL. showed that a plastic stock tray and a metal stock tray performed as well as or even better than a custom tray. All of the impressions had relatively uniform thickness. Also the tray-seating position was precise [53].

BOMBERG ET AL. [127] found that no significant differences in tray selection were found for single tooth preparation marginal fit, especially if polyethers and PVS were used.

Most of these sources of inaccuracy may be controlled or eliminated by careful attention to the proper manipulation of materials and clinical technique. The selection of a custom tray or a stock tray is determined by the clinician and is independent of other clinical variables.

When deciding whether to use a custom tray rather than a stock tray, the dentist must decide if the advantages outweigh the disadvantages [134].

## **2.13 Other factors**

### **2.13.1 Working time**

The delayed seating of the impression at a time beyond the working time is recognized as being a potential source of inaccuracy or distortions. From a practical point of view, the value of the working time therefore takes on some significance [135].

According to ISO 4823 (1992) the total working time is defined as “the period of time between the start of mixing and the commencement of the development of elasticity and the loss of plasticity” [135].

### **2.13.2 Pouring time**

In addition to adhesive drying time, the accuracy of the casts is also impacted by the pouring time interval. Any delay in pouring renders the completed impression susceptible to dimensional change from possible dimensional instabilities of the tray and the impression material.

Polyvinyl siloxane impressions possess good dimensional stability and investigators have shown that there is no difference in casts produced from impressions poured at 1 hour, 1 day, and even up to 1 week [92].

Pouring the gypsum casts one hour after the impression procedure may not be a clinical reality when impressions are sent to an external laboratory because they are often poured several hours later. An impression made from polyether should be poured only once and within 24 hours after impression making, because of the distortion of the material over time [53].

Gypsum stones cannot reproduce detail much smaller than 20  $\mu\text{m}$  because their crystal size ranges from 15 to 25  $\mu\text{m}$ . Epoxy and polyurethane resins can reproduce detail down to 1 to 2  $\mu\text{m}$  making them highly compatible with the detail capture possible with polyvinyl siloxane impressions [53].

### **2.12.3 Working casts and effect of the die**

Distortion may result from dimensional changes of the impression material, as well as movement impression copings within the impression during tightening of the laboratory abutment analogues [65]. The expansion of the plaster setting may have a negative influence on positioning the analogues and consequently be a negative factor added to the basic requisites for achieving a passive fit [136, 137].

If a clinically passive fit is not achieved and the metal supporting structure rocks intraorally, the metal framework is usually sectioned, repositioned and soldered. To eliminate discrepancies in fit (even those not visually detectable), it is essential that work be done on a master cast that reproduces, as accurately as possible, the position of the abutments in the patient's mouth. Consequently, the laboratory technician can fabricate a restoration that may require fewer corrective procedures [136].

The clinical relevance reflects the fact that the quality of fabrication of prosthetic restorations is also related to the quality of the working models obtained [136]. Considering control of the effects of plaster expansion setting that may contribute to displacement of the analogues. The setting expansion of dental stone influences the final fit of frameworks, but this cannot be changed [3].

## 2.14 Summary about the literature

One has to ask oneself a few questions, when faced with an investigation with a threefold purpose. Where will the most influence lie within. The materials used, or the technique (open or closed) or in the variations of the trays? Or a combination of the above factors.

The results will lead us to see, whether a custom tray is good enough, even if a ‘weaker’ material is to be used (even though from the literature, one can see, that we have the most advanced materials in this study).

But one may inverse the situation and ask oneself whether a stock tray is sufficient enough, because the impression materials are so superior?

In order to get the optimal function of such a material, one has to know the characteristics and the rheological properties. Does the manipulation of the material play a vital role? Or does it all simply lie within the impression technique?

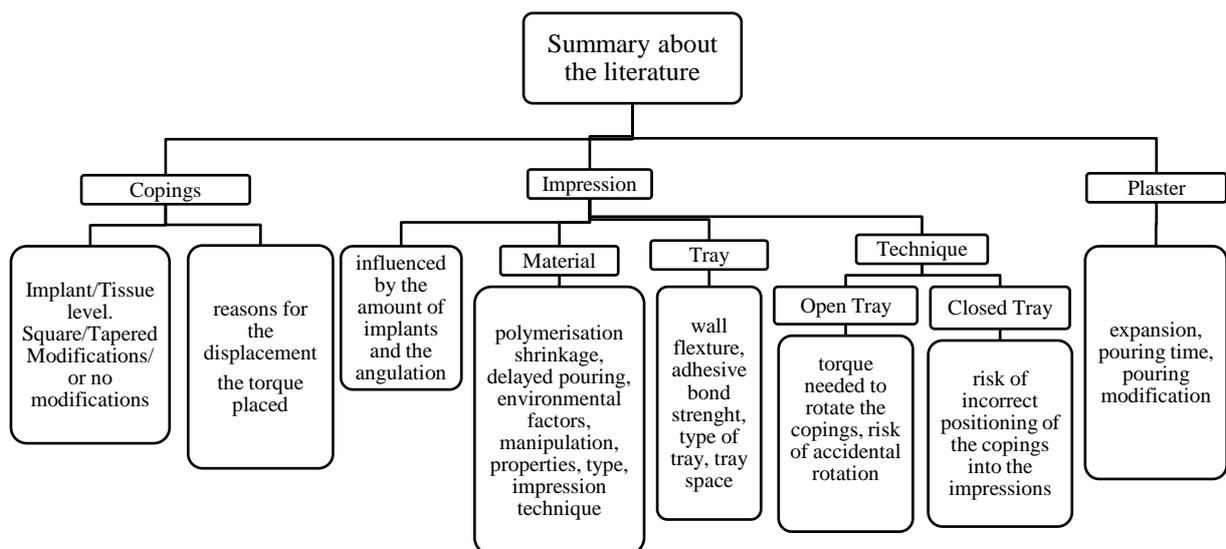
Or is it all of the above, rather a good combination of all factors?

The choice of material might show the effect of the tray or the technique.

The choice of impression technique might show the effect of the tray or material.

The choice of the tray might show the effect of the material or the technique.

These factors and the influences of accuracy will be discussed in the study design and the results in the investigation will lead us to some answers.



### 3. Material and Methods

A master model was designed to simulate a typical clinical situation with six implants in the positions 32, 34, 36 and 42, 44, 46. Impressions were made by using two techniques:

- (1) An open tray impression technique (pick-up/ direct pick-up impression technique) and
- (2) A closed tray direct snap-on impression technique (snap-fit plastic impression technique).

The trays varied (a) prototype tray (K), (b) custom tray (I) and (c) Miratray® Implant (M).

All trays were used for both impression techniques, except for the Miratray® Implant, which was used only for the closed tray impression technique.

The two monophasic impression materials used were:

- (i) A polyether, Impregum™ (3M ESPE, Seefeld, Germany) and
- (ii) A vinylsiloxanether, Identium® (Kettenbach, Eschenburg, Germany).

Of each tray 10 impressions were taken with the polyether and of each tray 10 impressions were taken with the vinylsiloxanether. Hence per tray, 20 impressions were taken. At the end there were all together 60 impressions. The Miratray® Implant was used only for the open tray impression technique.

For the prototype and custom tray, the open and closed impression technique, were done simultaneously on one model. The IV Quadrant being the open impression technique and the III Quadrant being the closed impression technique.

For this in-vitro-study a master model was produced, custom trays, holding elements for the trays during impression taking and gypsum pouring and a holding element for the measurements.

**Flow chart of the test set up**

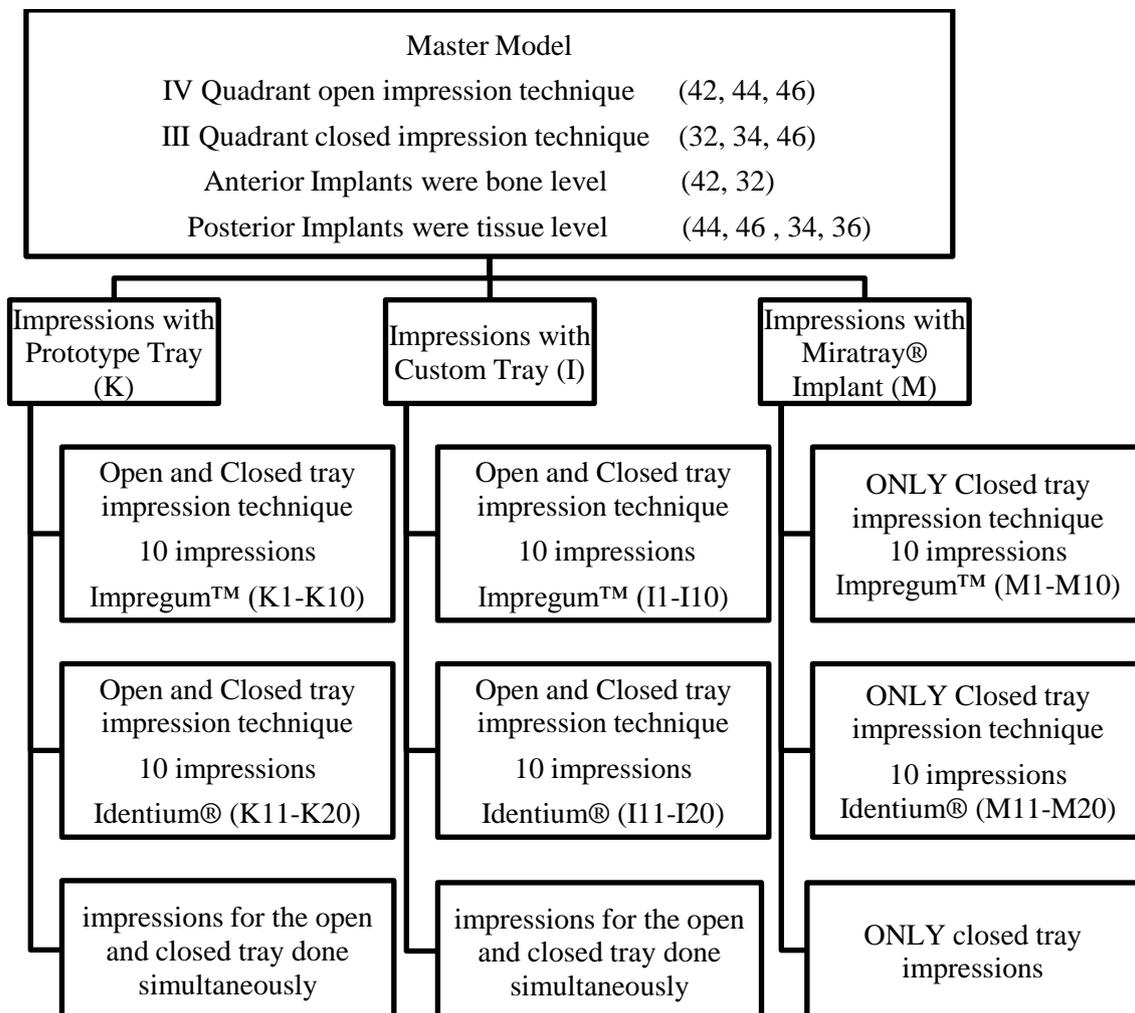
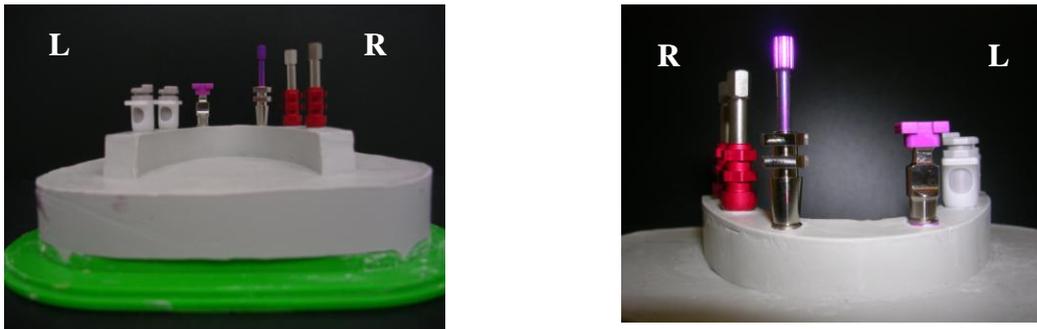


Fig. 20: Flow chart of the test set up

### 3.1 The Master Model

A master model, which represented the human mandible, was constructed from a synthetic material Exakto-Form grey (bredent GmbH & Co. KG), used to retain 6 laboratory analogues (Straumann ITI).

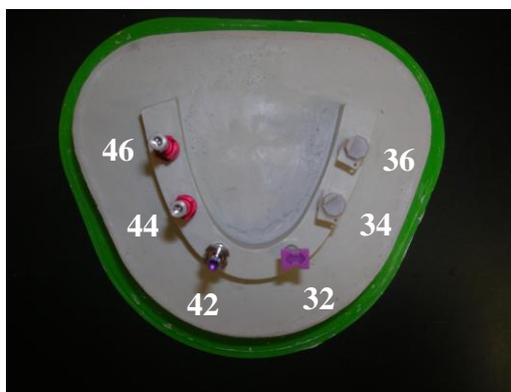
The most anterior implants (32, 42) were bone level and the two posterior implants on each side of the arch were tissue level (34, 36, 44, and 46).



*Fig. 21: Photos showing the lingual view (photo left) and labial view (photo right) with the impression copings.*

The right (R) side of the master model had squared impression copings for the open tray impression technique in the positions 46, 44 and 42.

The left (L) side of the master model had tapered impression copings with the snap-fit plastic impression coping for the snap-fit plastic impression coping technique (closed tray direct snap- on impression technique) in the positions 36, 34 and 32.



*Fig. 22: Photo showing the occlusal view of the master model with the impression copings.*

### 3. Material and Methods

The arch of the master model had to be designed in such a manner, that all three tray types allowed easy and accurate seating of the trays on this mandible.

To ensure a passive fit, the copings were tightened with finger pressure for all impression techniques by one operator. Special care was taken to make sure that all components were properly orientated and completely seated.

Materials used from Straumann ITI, during the impression taking, cast production and the measurements are listed in the table below.

Position	Impression Type	Analogue	Abutment	Impression Cap	Impression Cap	Guide Screws
Implant 46	open	Posterior Tissue Level Ø 4,1mm REF: 048.124 	RN SynOcta® Impression Cap, Screw Retained with integral guide screw H 10,1 mm, Al/Ti REF: 048.090 			REF: 049.083 
Implant 44	open	Posterior Tissue Level Ø 4,1mm REF: 048.124 	RN SynOcta® Impression Cap, Screw Retained with integral guide screw H 10,1mm, Al/Ti REF: 048.090 			REF: 049.083 
Implant 42	open	Anterior Bone Level Ø 4,1mm REF: 025.4101 	RC impression post open tray, short with guide screw, L 16,5mm, TAN REF: 025.4205 			REF: 026.4801 
Implant 36	closed	Posterior Tissue Level Ø 4,1mm REF: 048.124 	RN solid abutment 6° H 5,5mm, grey, Ti REF: 048.541 	RN impression cap, H 8,0 mm, plastic REF: 048.017V4 	Positioning cylinder for RN solid abutment REF: 048.541 h 10,2mm, plastic REF: 048.061V4 	REF: 049.083 
Implant 34	closed	Posterior Tissue Level Ø 4,1mm REF: 048.124 	RN solid abutment 6° H 5,5mm, grey, Ti REF: 048.541 	RN impression cap, H 8,0 mm, plastic REF: 048.017V4 	Positioning cylinder for RN solid abutments REF 048.541 h 10,2mm, plastic REF: 048.061V4 	REF: 049.083 
Implant 32	closed	Anterior Bone Level Ø 4,1mm REF: 025.4101 	RC impression post closed tray with guide screw & cap Ti alloy/polymer REF: 025.4201 			REF: 026.4801 

Fig. 23: Table showing the materials used from Straumann ITI

### **3.2 Producing the Custom Tray**

An impression was taken of the master model. Perforated metal trays were used with an irreversible hydrocolloid. The impression was poured with a type IV dental stone (Exakto-Rock S ivory from bredent GmbH & Co. KG) separated after 40 minutes and trimmed after 24 hours. On this master cast duplication, the custom trays were produced.

To insure uniform thickness of the impression material and to block out the impression copings on the master cast duplication a 3 mm space was provided for the vinylsiloxanether and polyether by using two layers of baseplate wax spacers.

Identical 2,5 mm-thick custom impression trays were made from a roll of light-curing pink acrylic tray material (bredent GmbH & Co. KG) prepared according to the manufacturer's instructions and stored at room temperature for 24 hours before impression-making to guarantee a complete polymerization shrinkage.

For the open tray technique a window was cut out in the area of the transfer screws on the right side (Quadrant IV).

In the III Quadrant the custom tray was left without superior openings because the closed tray direct snap-on impression technique was carried out.

Windows were also cut out for the open technique in the prototype trays.

The access holes created on the occlusal surface for the open tray impression technique (pick-up/direct pick-up impression technique) allowed easy and accurate seating of the tray, allowing the copings to protrude through the occlusal surface, yet be in close proximity to the impression copings to keep the bulk of the subsequent impression material to a minimum.

### **3.3 Constant positioning of the trays**

To standardize the impression procedure, and to ensure the same and constant path of insertion and removal, a bur stand was modified to suit the individual needs of this study.



*Fig. 24: Photos showing the individualized bur stand (left) and the base plate (green plate on the photo right).*

A base plate (green on the photo) secured the master model in a fixed constant position to standardize the impression procedure and later to standardize the pouring of the casts.

The upper part of the bur stand was modified to ensure that for each tray type, there was a constant positioning, uniform thickness in each dimension in the trays during impression taking and later for the gypsum pouring.

The Base of the bur stand.

The master model was secured with 4 retention grooves and a magnet to a base plate from the Master-Copy duplication system (bredent GmbH & Co.KG).

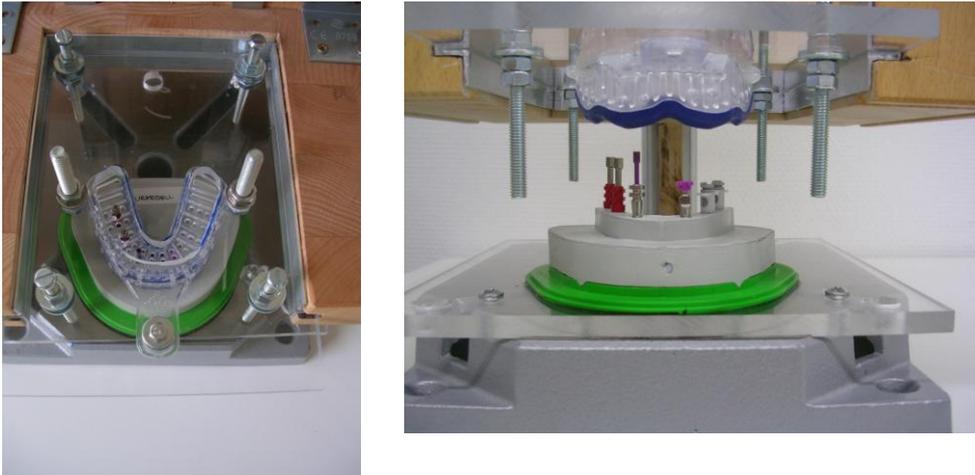
This base plate was secured to a base made of acrylic glass definitely fixed to the bur stand and was never removed from that.

So a consistent seating of the master model was provided and hence a constant position of the impressions to be taken and also of the pouring of the casts.

### **The upper part of the bur stand.**

Each of the three impression tray types received an individualized holding device made from acrylic glass.

A hole was made in the anterior region through the acrylic glass, in order to place a screw to hold the tray. For each tray type further 2 screws were placed buccally in order to inhibit rotation and to have a fixed defined position of the tray, but without artificially stiffening the tray or the tray walls.



*Fig. 25: Photos showing the individualized holding device.*

The height was determined for each tray type and controlled with 4 screws individually adjusted for each tray type to ensure constant height and to ensure a stop when a certain height was reached, during impression taking and gypsum pouring.

Four location marks were included on the acrylic glass and the base plate. Location marks were also provided between the bur stand and the acrylic glass, to have control of any movement that might have occurred.

### **The adhesive**

It is a routine procedure to apply a tray adhesive before impressions are made to bond the impression material to the tray and hence control the direction of polymerization shrinkage of the material. It is essential that the impression material is securely attached to the tray, especially when set impression is removed from the mouth.

The impression trays, both for the open tray technique and closed tray technique were coated with the polyether adhesive for Impregum™ impressions (3M ESPE, Seefeld, Germany) and

with Identium<sup>®</sup> Adhesive for Identium<sup>®</sup> impressions (Kettenbach, Eschenburg, Germany). All materials were used according to the manufacturers' instructions.

Tray adhesive was thinly and evenly applied over the inner surface of each tray to extend approximately 2 mm onto the outer surface of the tray along the periphery.

All trays received adhesive, except for the prototype, which did not received adhesive according to manufacturer's instructions.

### 3.4 Impression taking

The fitting surfaces of all components were cleaned with isopropyl alcohol (70 %) and dried before each connecting procedure for all techniques.

A one step, single mix impression technique, was used in the in-vitro research. The same consistency impression material is injected around the impression coping and some material is placed in the tray. The one step technique has shown to be the most accurate, because of low shrinkage, the lower displacement and lower endogenic stresses than other techniques [81, 98].

The impression materials were used according to the manufacturer directions applying the monophasic one step single machine-mixed procedure.

Machinery used was the Impregum<sup>™</sup> Penta<sup>™</sup> Pentamix; 3M ESPE for Impregum<sup>™</sup> and the Sympress Renfert machine for Identium<sup>®</sup>.



*Fig. 26: Photo showing the machinery (the Renfert on the left side and the Pentamix on the right side).*

For each impression it was ensured that the copings were oriented in the same direction, the components of the bur stand were always in the same position and that the heights to each tray type stayed constant.

To simulate intraoral conditions, in this in-vitro-study, the master model was kept under constant conditions, of room temperature and humidity. While making the impressions and pouring the casts.

The impressions were made in a temperature controlled environment at 26°C and relative humidity of around 50%  $\pm$ 10%, maintained by air conditioning and air humidification. Digital timers were used to standardize each step of the procedure.

Mouth temperature is believed to be 33°C - 35°C. All materials show rapid development of elasticity at the higher temperature and hence slower setting at room temperature. Therefore, impressions were allowed to set for 30 minutes from the start of mixing. The impressions were allowed to polymerize approximately 5 times longer (30 minutes) than the time recommended by the manufacturer to ensure adequate polymerization occurred at room temperature, to compensate for delayed polymerization at room temperature rather than mouth temperature.

#### **Impression procedure**

Firstly, extrusion through the syringe tip, a little amount on a mixing pad, before placement around the impression copings. Part of the material was meticulously syringed around the impression copings to ensure complete coverage of the copings.

The remaining impression material was used to load the impression tray. The impression tray was lowered over the reference master model until the tray was fully seated and maintained in position throughout the polymerization time. Once in place, the tray was held with no pressure until it was completely set, and was then removed.

In the open tray impression technique, the guided pins were unscrewed and the trays were removed from the master model. In the closed tray impression technique, after removing the impression, the impression copings were manually repositioned in the impression and care was taken to avoid rotating the copings.

3. Material and Methods



*Fig. 27: Photos showing the prototype tray (K) in its holding element for the impression taking procedure and for the pouring of the gypsum.*

3. Material and Methods



*Fig. 28: Photos showing the custom tray (I) in its holding element for the impression taking procedure and for the pouring of the gypsum.*

3. Material and Methods

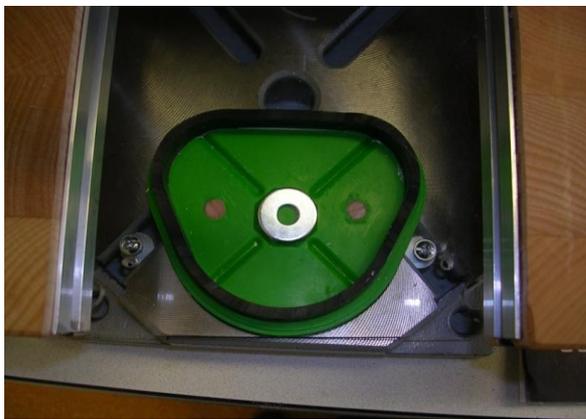


*Fig. 29: Photos showing the Miratray®Implant (M) in its holding element for the impression taking procedure and for the pouring of the gypsum.*

### 3.5 Pouring the casts

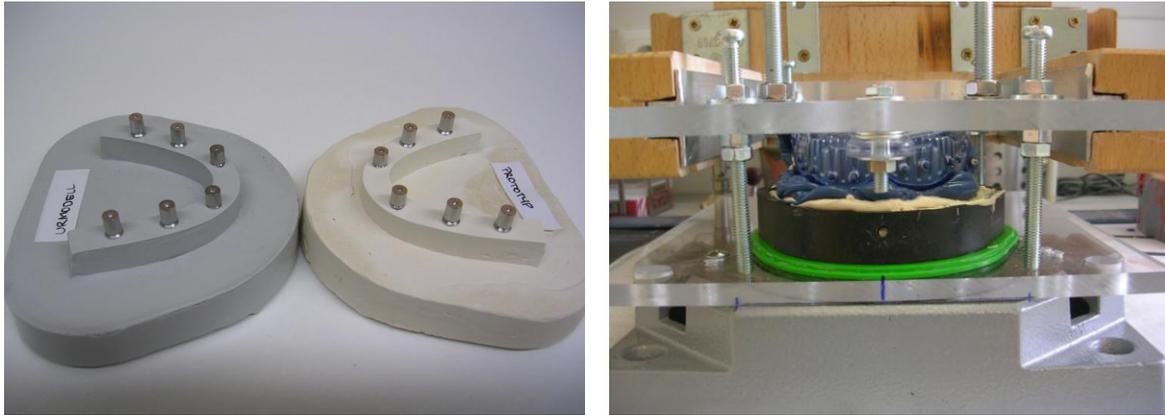
Impression taking and the production of casts are the two steps necessary to make a well-fitting restoration. Yet due to the quantity of comparisons made, it was also important for this study to ensure a standardized positioning during impression taking, gypsum pouring and the measurements of the casts.

For each impression a check was done to ensure that the laboratory analogues were in the correct position and that the components of the bur stand were always in the same position, and the heights to each tray type stayed constant as well.



*Fig. 30: The master-copy duplication system (breident GmbH & Co.KG) and the walls of the silicone sleeve (black in the photo above).*

The walls of the silicone sleeve from the Master-Copy duplication system (breident GmbH & Co.KG) fitted intimately to the master model walls, (the same silicone sleeve was used to produce the master model) in order to allow the same positioning and involvement to the base at all times, thus allowing afterwards, when the casts were made, that the same quantity of plaster could be used. The width of the retention grooves and the height and size of the base for the casts to be poured were identical with the corresponding master model.



*Fig. 31: Photo left: Far left the master model (grey) and on the right side the produced model of the prototype tray. Photo right: the pouring of a prototype tray filled with Identium impression material.*

After allowing the impression material to stand for 30 minutes, in the same constant environment as impression taking, the impressions were then poured with gypsum.

A class IV die stone (Exakto-Rock S ivory) was used, according to the manufacturer's instruction. To standardize the effect of the setting expansion of the stone, the powder and water was accurately pre-weighed using a digital scale and a product of a similar batch number was used to pour all the impressions.

Gypsum was allowed to set for 40 minutes before unscrewing the guide pins and removing the impression. All casts were stored at room temperature for a minimum of 72 hours before measurement.

Pouring the gypsum casts 30 minutes even up to 1 hour after the impression procedure may not be a clinical reality when impressions are sent to an external laboratory because they are often poured several hours later.

### **3.6 Measurements**

A Zeiss Prismo coordinate measuring machine was used.

The precision is in micrometers. A precision of 1  $\mu\text{m}$  (0,001 mm) can be achieved.

In order to have a comparison and programming the measuring process for these specific measurements, the master model and the casts needed cylindrical objects as reference points. The copings had too many patterns (whether it was for the open or for the closed impression tray) and so many variations were on the model. So guide screws provided by Straumann were used. The posterior 4 guide screws (049.083) were identical (46, 44, 36, 34) which fitted into the laboratory analogues in the posterior region.

The two anterior guide screws (026.4801) were slightly shorter, which were the correct guide screws for the anterior analogues (42, 32).

Ten impressions were made for every tray type, impression material and for each method.

The mean and standard deviation of 10 readings were calculated. The mean of the readings was used as an outcome measure. Only one single operator made all measurements.

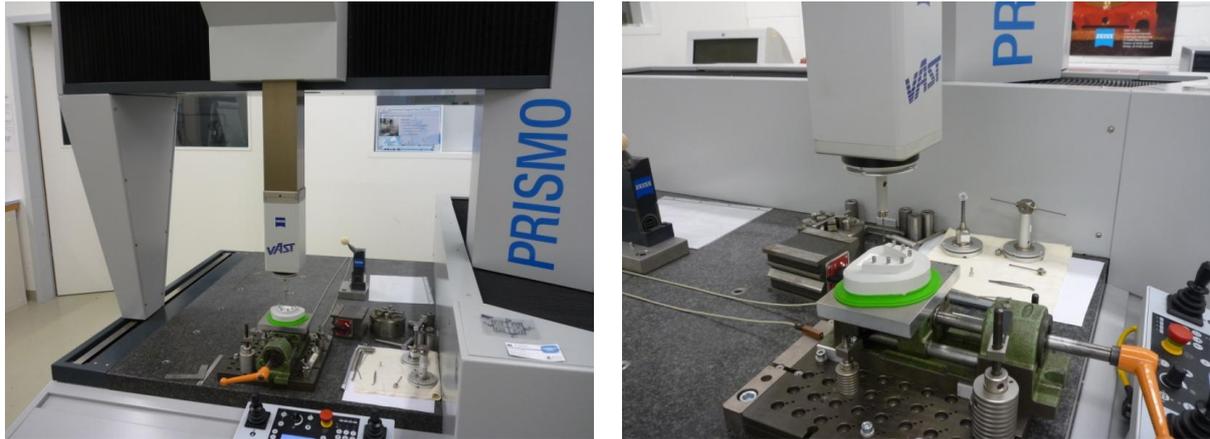
These measurements were compared to the measurements calculated on the reference master model which served as the control. The master model was also measured ten times and a mean value was calculated.

Name	K1-K10	K11-K20	I1-I10	I11-I20	M1-M10	M11-M20
Material	Impregum™	Identium®	Impregum™	Identium®	Impregum™	Identium®
Technique	open & closed	open & closed	open & closed	open & closed	open	open

*Table. 2: To explain the table lets have a look at an example.*

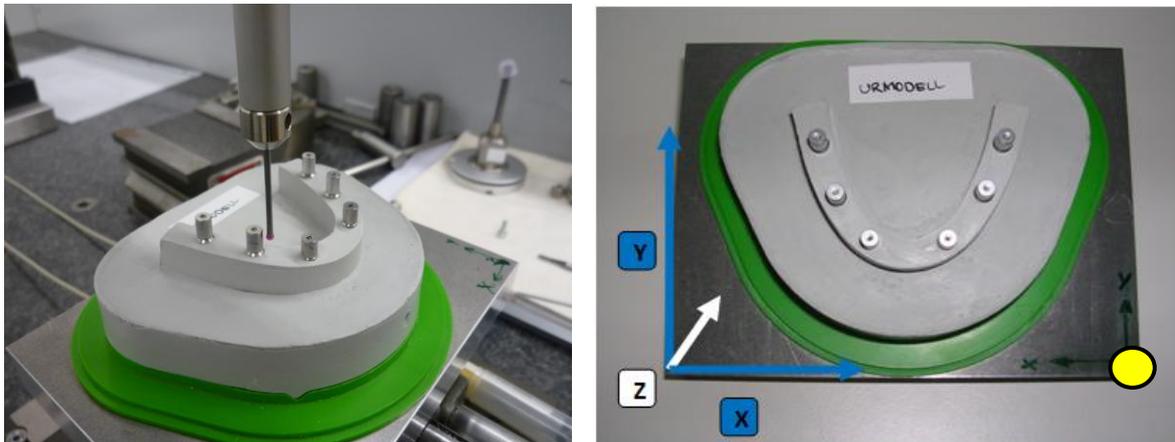
*For example: K1-K10. This means there were 10 times the prototype tray used, 10 times the material Impregum™ used and 10 times both methods used (open tray and closed tray).*

*K11-K20. This means there were 10 times the prototype tray used, 10 times the material Identium® used and 10 times both methods used (open tray and closed tray).*



*Fig. 32: Photo left: Frontal view of the Zeiss Prismo coordinate measuring machine with the master/refernece model being measured, which served as the control.*

*Photo right: A side view of the Zeiss Prismo.*



*Fig. 33: The base plate (green) was fixed on a square metal plate. The zero point (the point from where all measurements started) was at the bottom right side of the metal plate. Marked with a yellow circle on the photo above.*

To ensure the same seating for the master model and the casts that were produced, the same base plate was used during the measurement phase of the study, as it had been previously used for the impression taking and also for the gypsum pouring.

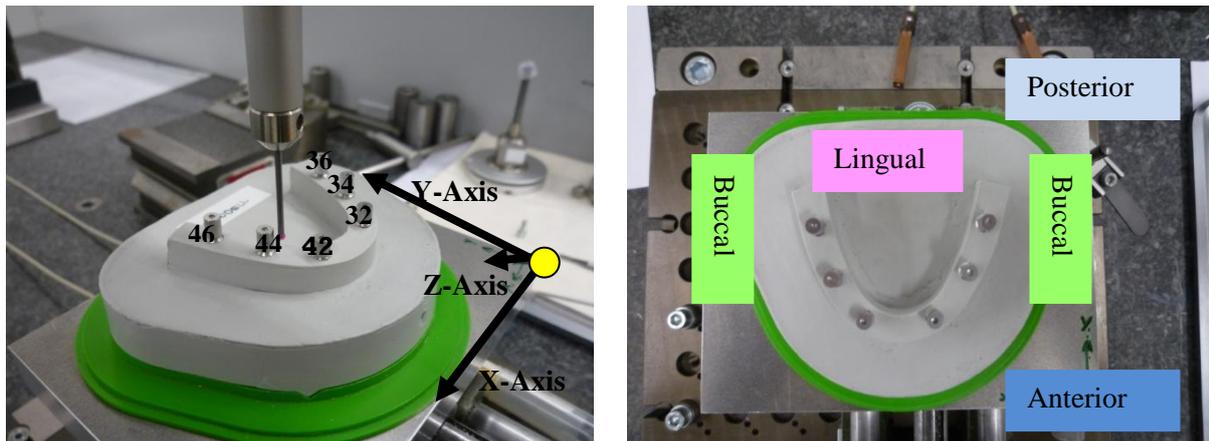
The master model and all casts produced, had magnets on the base, which allowed a constant positioning of all models on the base plate. (Green base plate on the photos).

The master model was measured. The 60 models produced where also measured from this point. The mean was calculated, how much the measurements varied to the master model.

### 3. Material and Methods

The computer software is designed amongst other to calculate linear changes and angular relationships for this study.

Measurements were done at a constant temperature and humidity, with only one operator measuring the models.



*Fig. 34: The photos representing the master model. The zero point (the point from where all measurements started is marked with a yellow dot).*

In the above diagram the X-axis, Y-axis and Z-axis are also shown.

The orientation to the mouth with lingual, buccal, posterior and anterior are also shown as these references will be needed later on when results will be compared and the discussion about the movements inside the mouth/inside the impression tray/impression material will follow.

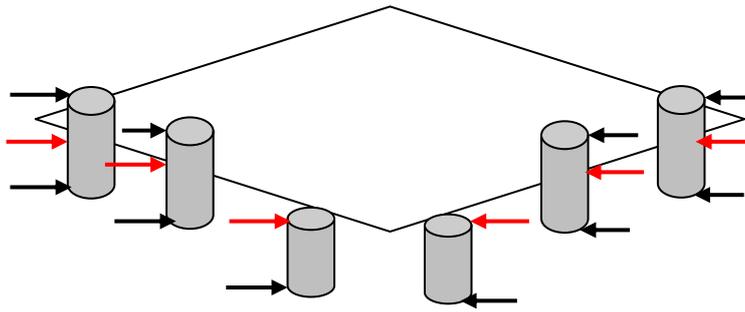
Posterior measurements left and right (34, 36, 44, 44) were measured circularly 3 times, at different heights in the X- and Y-axis for each model.

The measurements were made following the same procedure:

For example:

34 top X value, 34 middle X value, 34 bottom X value

Here the Zeiss Prismo went circularly three times around the screw guides. Once at the top, the middle and the bottom in the X-direction. Position 42 and 32 were measured circularly twice: bottom X value, top X value.



*Fig. 35: A diagram representing the measurement areas.*

*On the diagram the red arrow stands for the middle measurement of the position 46,44,36,34.*

*Position 42 and 32 the red arrow being the top measurement.*

*By connecting the red measurements a reference plane is achieved (square object in the diagram).*

The middle X values of the 2 posterior guide screws (44,46,34,36) and the top X values of the anterior guide screws (32,42) received a horizontal plane done by the Zeiss Prismo Program, in order to create an even reference plane. The plane was used to have a comparison of the measurements on this particular plane.

The function of the reference plane, was that the height, the horizontal measurements and hence the angulations can be compared to each other, at this specific level/reference plane. The mean of the angulation values were calculated to the horizontal plane.

A creation of a specific reference plane for such a precise machine was developed by the machine and its software.

34 top Y value, 34 middle Y value, 34 bottom Y value

Here the Zeiss Prismo went circularly 3 times around the screw guides. Once at the top, the middle and the bottom in the Y-direction.

34 top Z value, 34 middle Z value, 34 bottom Z value

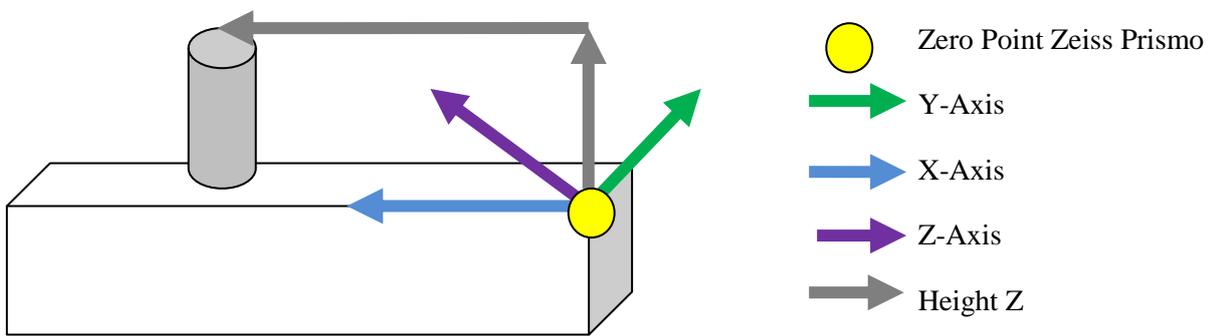
Here the Zeiss Prismo had to go vertically upwards – move upwards away from the Zero point, in order to reach the guide screws. The 3 Z values are the heights in Z, in which the Zeiss Prismo had to move in order to reach the 3 X- and Y- value measurements.

### 3. Material and Methods

One will notice, that the Z measurements towards the posterior region of the models, were slightly higher than anterior, because the mandible had a slight vertical increase towards the posterior region.

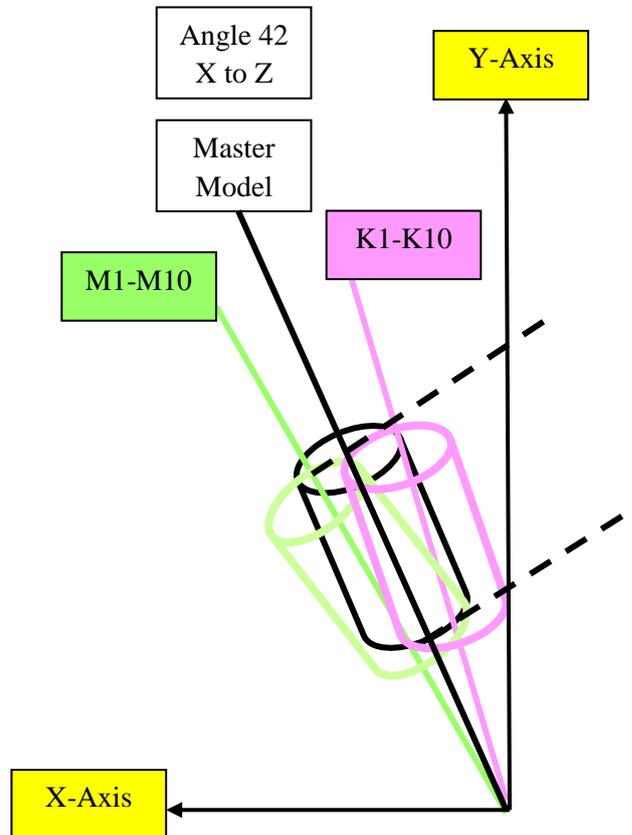
Height Z value.

This is the actual height measured for the guide screw. Slightly lateral from the middle point of the guide screws, as the middle point had a sinking of the height (where the screw went in order to remove the copings and guide screws).



*Fig. 36 Diagram representing the three dimensional measurements.*

All measurements were done in mm, except for the angles, these were measured/calculated in degrees. This was done for the Angle X to Z and Angle Y to Z.



*Fig. 37 Diagram representing for example Angle 42 X to Z*

*The above is an example of the master model (black cylinder) in comparison with the tray M1-M10 (greencylinder) and tray K1-K10 (pink cylinder).*

Between the two measuring points: the top X value 42 measurement and the bottom X value 42 measurement (interrupted black lines in the figure above) was an imaginary perpendicular line created (black line). From this line the degree of the screw guide was calculated/measured. The same was done with the Y values. And so the degrees were created. The figure above is an example of the master model (black cylinder) in comparison with the Tray M1-M10 (green) and K1-K10(pink). In order to try to explain the movements.

## 4. Results

### 4.1 The Mean Change and the Standard Deviation (SD)

	Master Model	Mean $\Delta$ Impregum K1-K10	SD Impregum K1-K10	Mean $\Delta$ Identium K11-K20	SD Identium K11-K20	Mean $\Delta$ Impregum I1-I10	SD Impregum I1-I10	Mean $\Delta$ Identium I11-I20	SD Identium I11-I20	Mean $\Delta$ Impregum M1-M10	SD Impregum M1-M10	Mean $\Delta$ Identium M11-M20	SD Identium M11-M20
42 X-value	-73,3538	-0,0452	0,3480	0,0037	0,2213	-0,0441	0,5356	-0,0049	0,2404	-0,2007	0,5136	-0,1008	0,2865
42 Y-value	33,9772	-0,0202	0,2044	-0,0402	0,0570	-0,0123	0,1308	-0,0801	0,0983	-0,0825	0,1733	-0,0490	0,0992
44 X-value	-81,3135	-0,0805	0,3300	-0,0124	0,2008	-0,0640	0,4901	-0,0315	0,2465	-0,1972	0,4826	-0,0964	0,2633
44Y-value	44,7973	-0,0297	0,2050	-0,0537	0,0696	-0,0282	0,1580	-0,0918	0,1028	-0,0566	0,1883	-0,0371	0,1093
46 X-value	-85,7214	-0,0754	0,3165	-0,0336	0,2001	-0,0679	0,4571	-0,0427	0,2382	-0,1869	0,4404	-0,0900	0,2356
46 Y-value	58,2576	-0,0115	0,2090	-0,0198	0,0752	0,0020	0,1560	-0,0618	0,0945	-0,0295	0,2141	-0,0063	0,1199
32 X-value	-55,4742	-0,0264	0,3517	0,0241	0,2135	-0,0446	0,5313	0,0056	0,2529				
32 Y-value	33,9255	-0,0140	0,1907	-0,0107	0,0860	0,0115	0,1172	-0,0577	0,0910				
34 X-value	-46,5374	-0,0247	0,3302	0,0183	0,2062	-0,0160	0,4964	0,0033	0,2360				
34 Y-value	45,9470	-0,0047	0,1831	0,0094	0,0957	0,0022	0,1247	-0,0280	0,0902				
36 X-value	-41,7183	-0,0238	0,3223	0,0274	0,1941	0,0024	0,4502	0,0166	0,2321				
36 Y-value	58,7398	0,0261	0,1898	0,0457	0,1003	-0,0033	0,1423	-0,0013	0,0946				

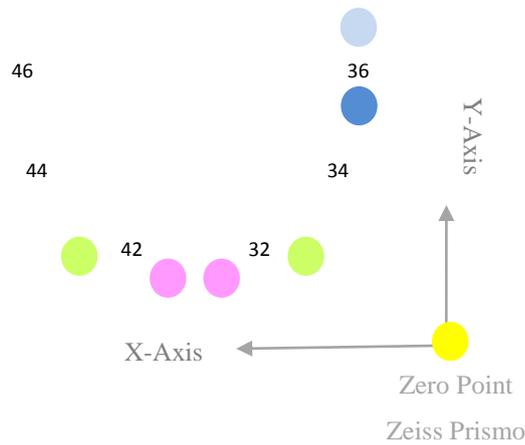
Table 3: The Mean Change (Mean  $\Delta$ ) and Standard Deviation (SD) of the master model and for the various casts in the X- and Y-values (mm)

4. Results

	Master Model	Mean Δ Impregum K1-K10	SD Impregum K1-K10	Mean Δ Identium K11-K20	SD Identium K11-K20	Mean Δ Impregum I1-I10	SD Impregum I1-I10	Mean Δ Identium I11-I20	SD Identium I11-I20	Mean Δ Impregum M1-M10	SD Impregum M1-M10	Mean Δ Identium M11-M20	SD Identium M11-M20
42 height_Z-value	34,6207	0,3746	0,1708	0,2289	0,0211	0,2613	0,0728	0,2369	0,0198	0,2155	0,0769	0,2307	0,0659
44 height_Z-value	36,6490	0,3601	0,2301	0,2067	0,0206	0,2292	0,0851	0,2331	0,0380	0,2241	0,0949	0,1998	0,0558
46 height_Z-value	37,1221	0,3620	0,2917	0,2193	0,0240	0,0297	0,5930	0,2521	0,0444	0,2689	0,1514	0,2014	0,0537
32 height_Z-value	35,1045	0,2774	0,1168	0,0991	0,0451	0,1280	0,0850	0,1021	0,0534				
34 height_Z-value	36,8131	0,2242	0,1159	0,1101	0,0314	0,1864	0,0715	0,1991	0,0431				
36 height_Z-value	37,1415	0,2569	0,1182	0,1643	0,0407	0,1860	0,0930	0,2164	0,0537				
angle 42_X to Z	-0,3803	0,1061	0,2084	0,0929	0,1018	0,0198	0,0994	0,0645	0,0807	-0,0186	0,2298	0,0508	0,1409
angle 42_Y to Z	-0,6766	-0,0645	0,1963	-0,1743	0,0936	-0,0284	0,0915	-0,1369	0,1170	-0,1096	0,2304	-0,1798	0,1335
angle 44_X to Z	1,0808	-0,0022	0,2959	0,1343	0,1679	0,0137	0,2042	0,0406	0,1652	0,0528	0,2712	0,1052	0,3650
angle 44_Y to Z	-0,5021	-0,1429	0,2586	-0,2174	0,2073	-0,3175	0,2063	-0,3557	0,1620	-0,2700	0,3377	-0,3393	0,1968
angle 46_X to Z	0,7251	0,2915	0,7604	0,0263	0,1752	0,0170	0,1912	-0,0316	0,1203	-0,0513	0,1704	-0,0305	0,2675
angle 46_Y to Z	-0,2129	0,1153	0,6068	-0,0694	0,2476	-0,1162	0,2402	-0,2370	0,2396	-0,2775	0,2798	-0,2024	0,1983
angle 32_X to Z	-1,1653	0,4269	0,2357	0,3290	0,2898	0,4071	0,2066	0,2901	0,3878				
angle 32_Y to Z	-0,8190	0,0130	0,2655	-0,0275	0,1391	0,1272	0,2461	0,1187	0,3509				
angle 34_X to Z	-0,8925	0,0000	0,2394	-0,1483	0,2036	-0,0893	0,0916	-0,1938	0,1191				
angle 34_Y to Z	-2,0531	0,0105	0,2037	0,0660	0,0972	0,0962	0,1839	0,1036	0,2481				
angle 36_X to Z	-0,1400	0,0921	0,2525	-0,0202	0,1828	-0,0399	0,1662	-0,0922	0,2656				
angle 36_Y to Z	-0,5654	0,6263	0,3233	0,4364	0,2236	0,3502	0,3426	0,4716	0,2134				

Table 4: The Mean Change (Mean Δ) and Standrad Deviation (SD) of the master model and for the various casts. (K1-K10, K11-K20, I1-I10, I11-I20, M1-M10, and M11-M20). Height Z-Values (mm) and Angulations X to Z and Y to Z (degrees).

4. Results

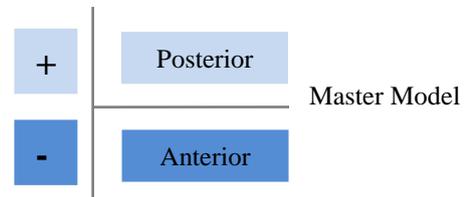


Master Model 36 middle Y value 58,7398

Mean  $\Delta$  K1-K10 0,0261  $\rightarrow$  moved posteriorly

Mean  $\Delta$  I1-I10 -0,0033  $\rightarrow$  moved anteriorly

In the graphical representations of the ***Y values in the Third Quadrant and Fourth Quadrant*** in comparison to the master model (being the zero point in the graph) the positive change indicates the posterior movement and negative change an anterior movement.

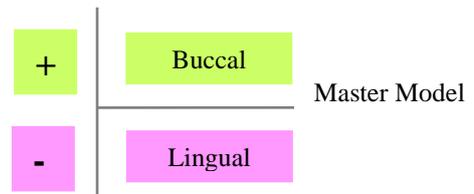


Master Model 32 upper X value -55,4742

Mean  $\Delta$  K1-K10 -0,0264  $\rightarrow$  moved lingually

Mean  $\Delta$  K11-K20 0,0241  $\rightarrow$  moved buccally

In the graphical representations of the ***X values in the Third Quadrant*** in comparison to the master model (being the zero point in the graph) the positive change indicates the buccal movement and negative change a lingual movement.



Master Model 42 upper X value -73,3538

Mean  $\Delta$  K1-K10 -0,0452  $\rightarrow$  moved buccally

Mean  $\Delta$  K11-K20 0,0037  $\rightarrow$  moved lingually

In the graphical representations of the ***X values in the Fourth Quadrant*** in comparison to the master model (being the zero point in the graph) the positive change indicates the lingual movement and negative change a buccal movement.

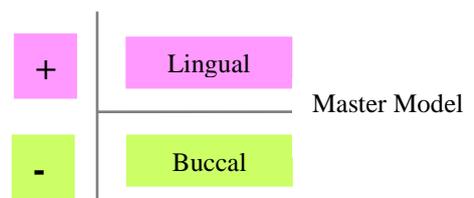
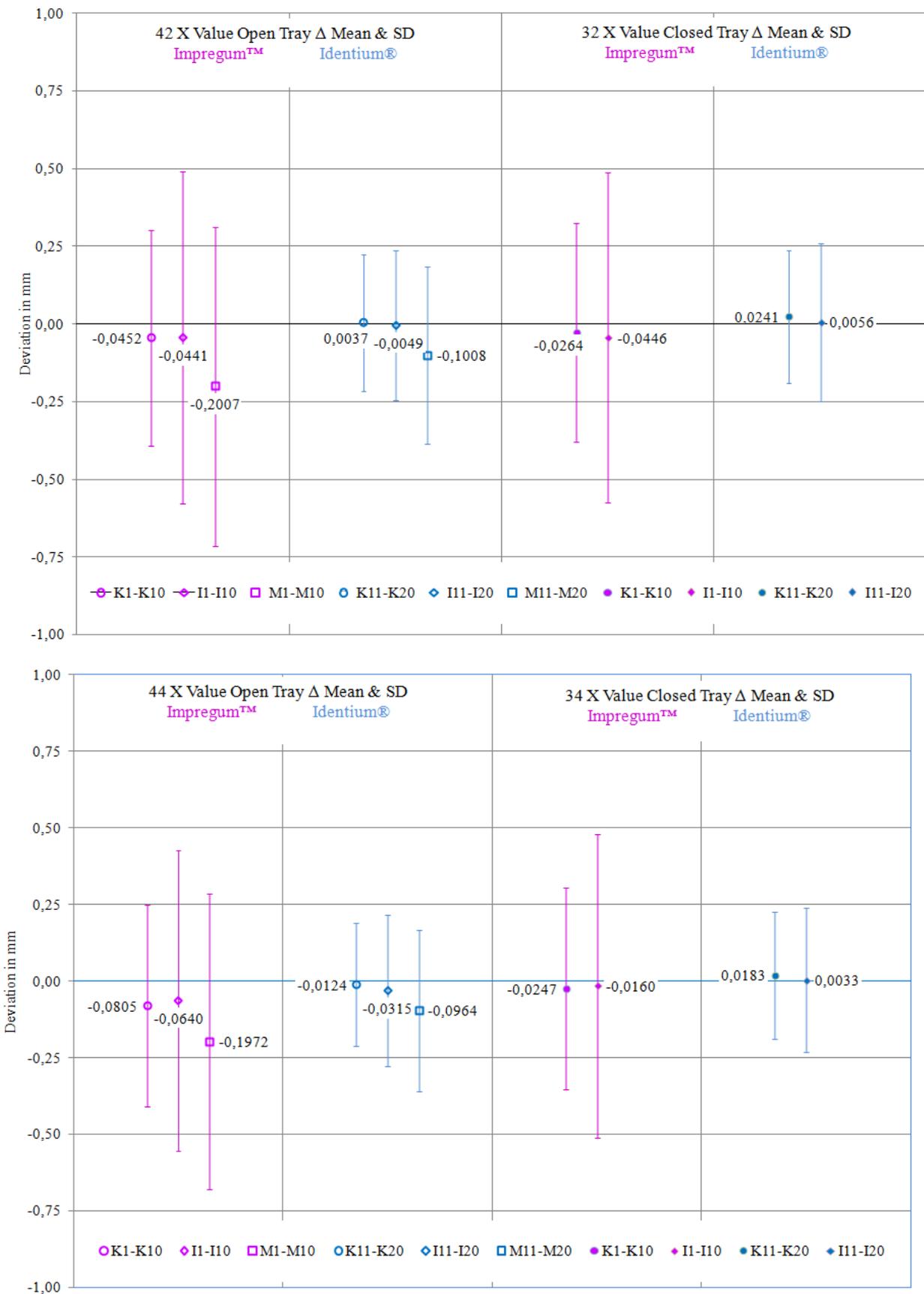
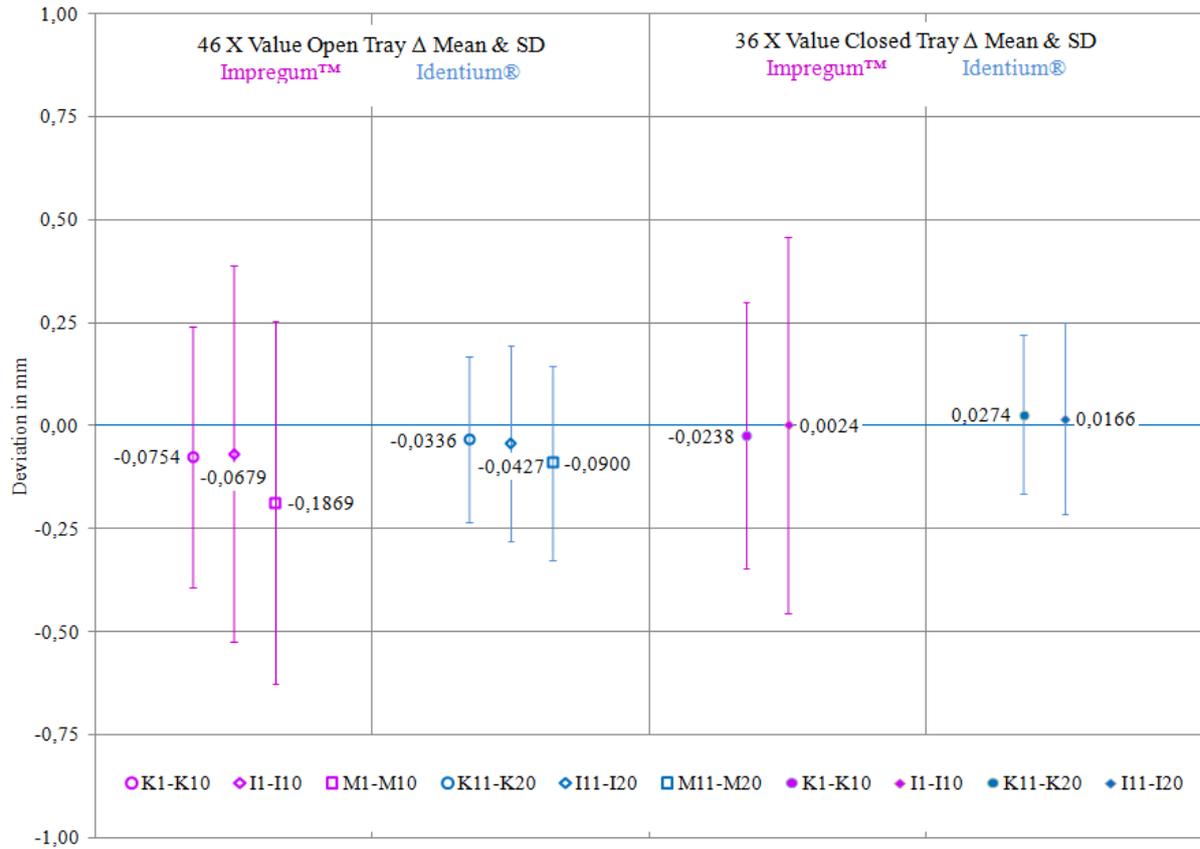


Fig. 38 Diagram explaining the Mean  $\Delta$  in the X- and Y-values

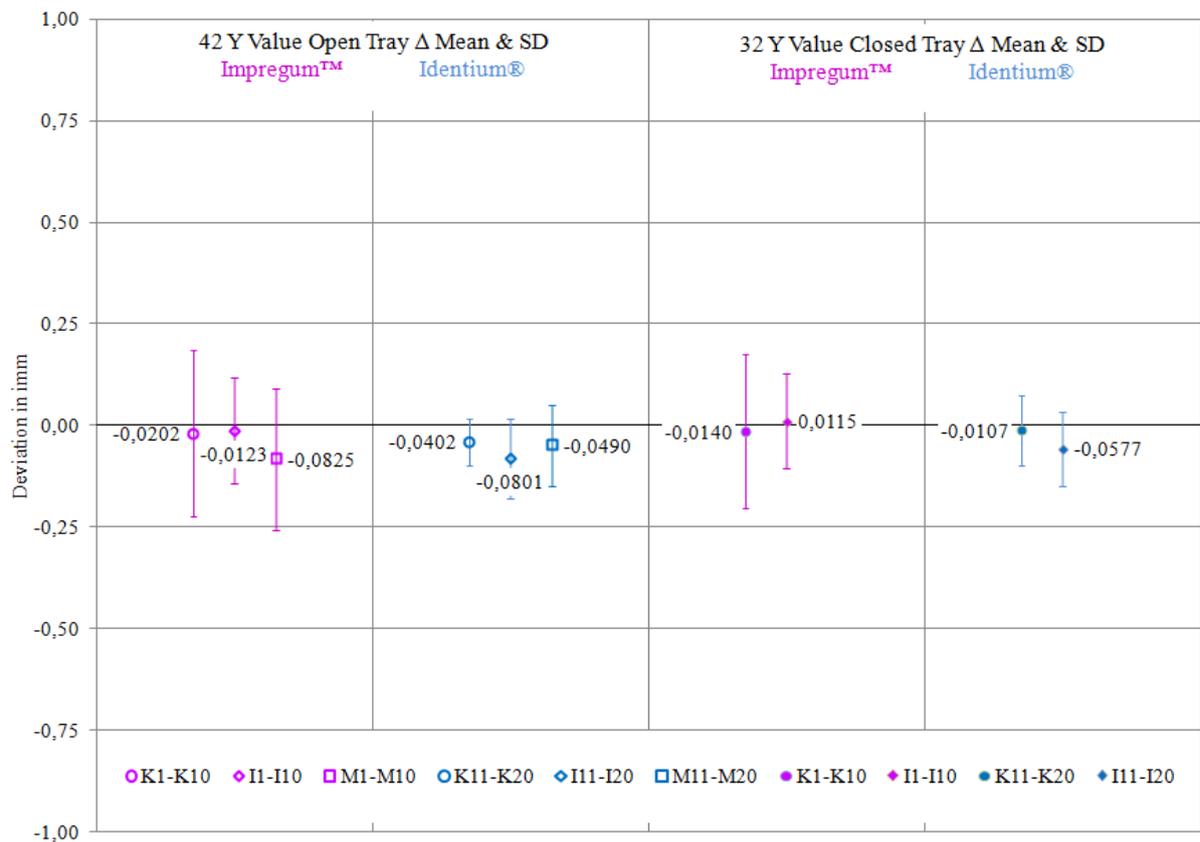
### 4.1.1 The Graphical representation of the Mean Change and Standard Deviation in the X Values for the Open and Closed Tray Impression Technique



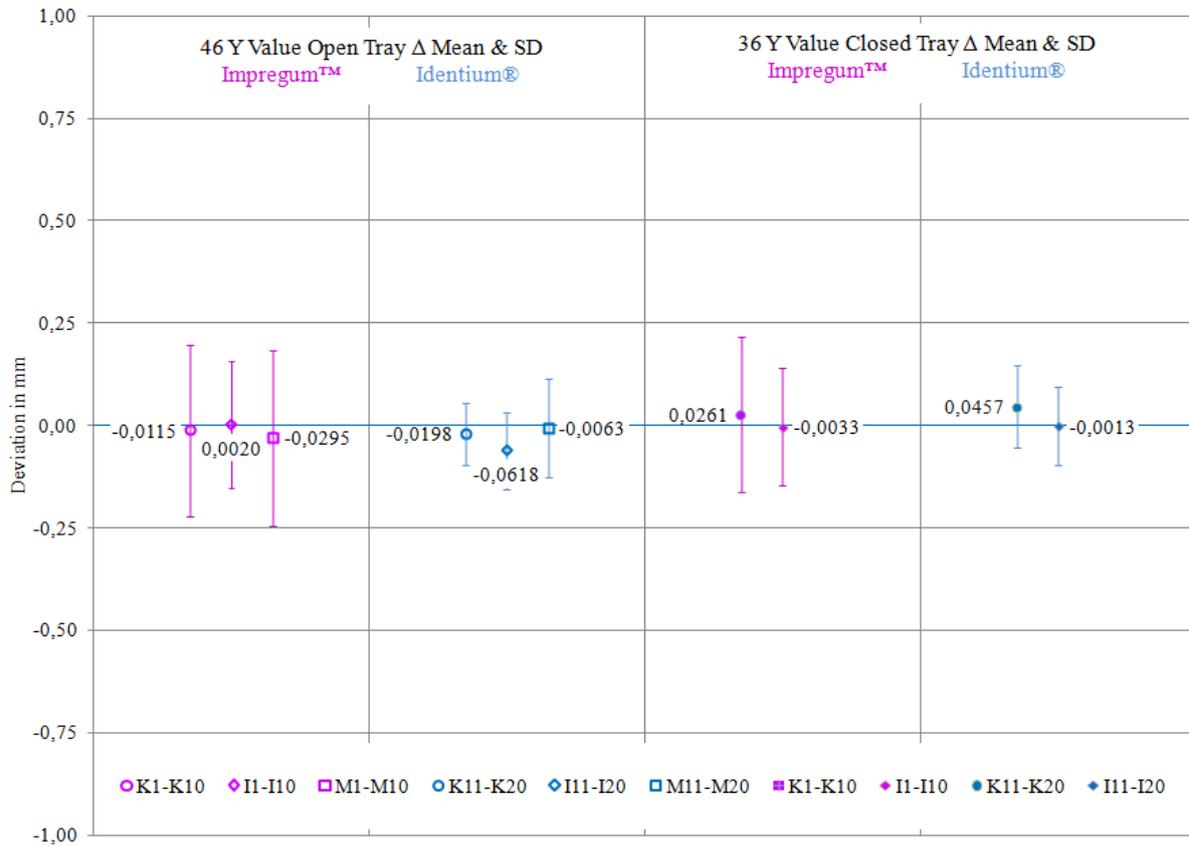
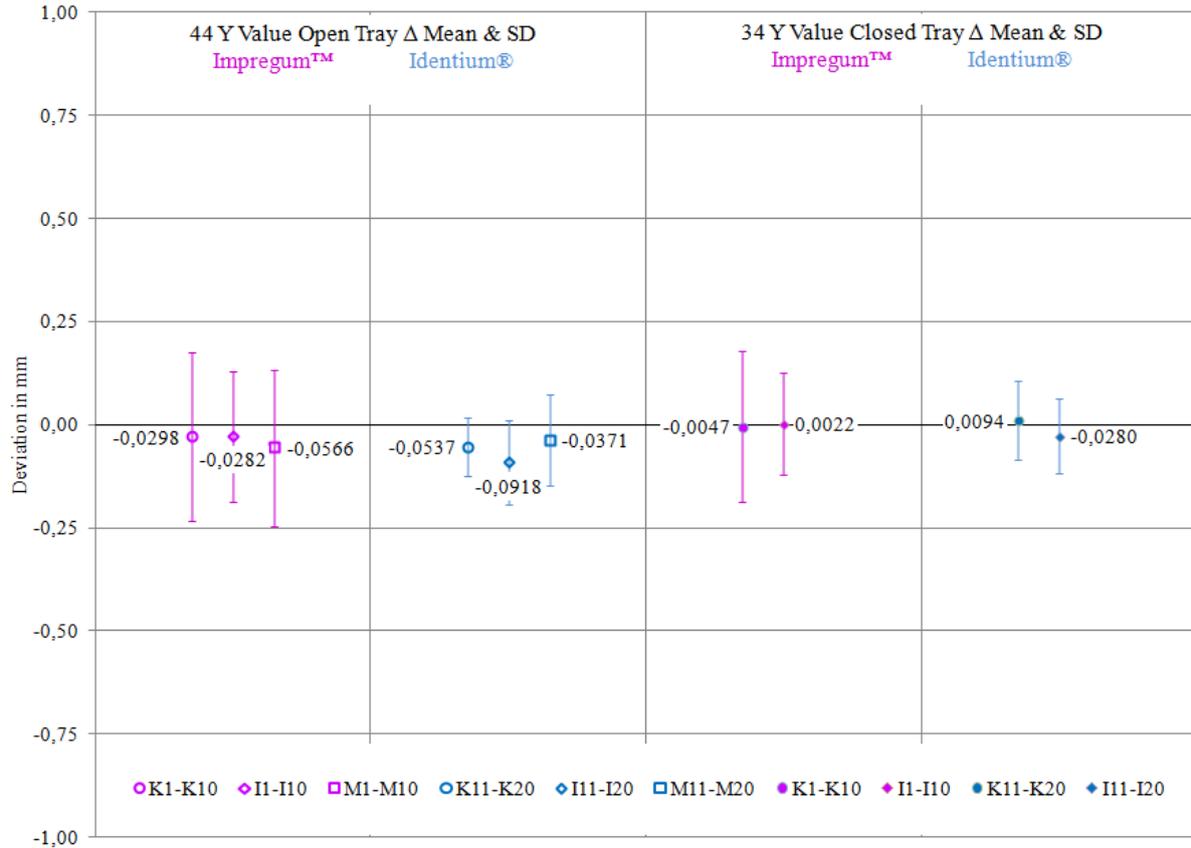
#### 4. Results



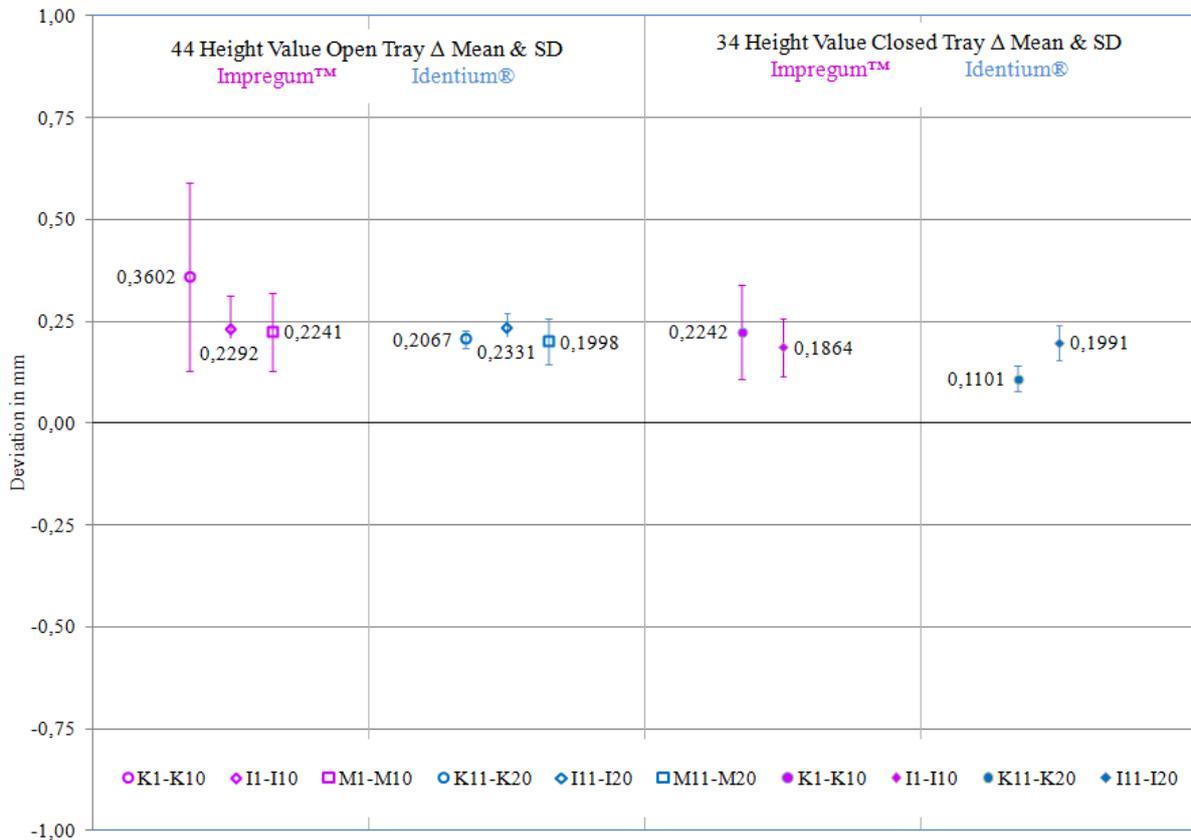
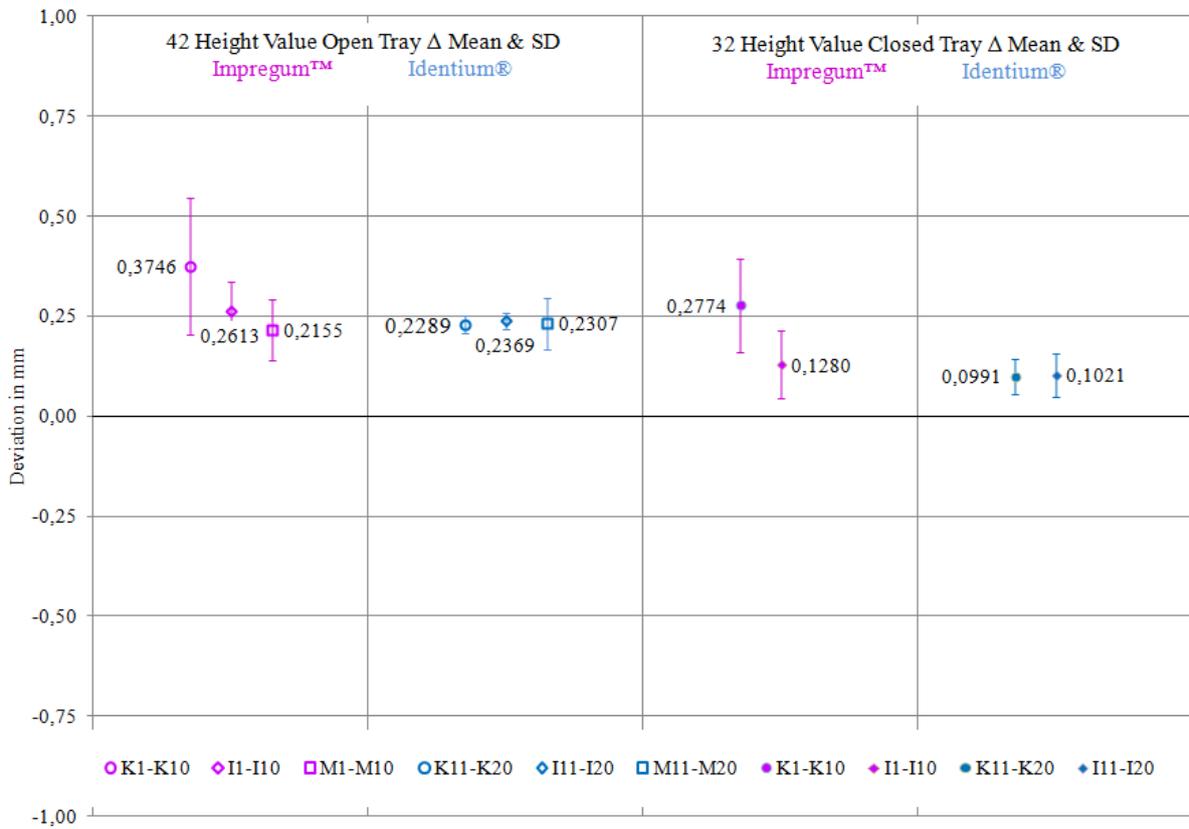
#### 4.1.2 The Graphical representation of the Mean Change and Standard Deviation in the Y Values for the Open and Closed Tray Impression Technique



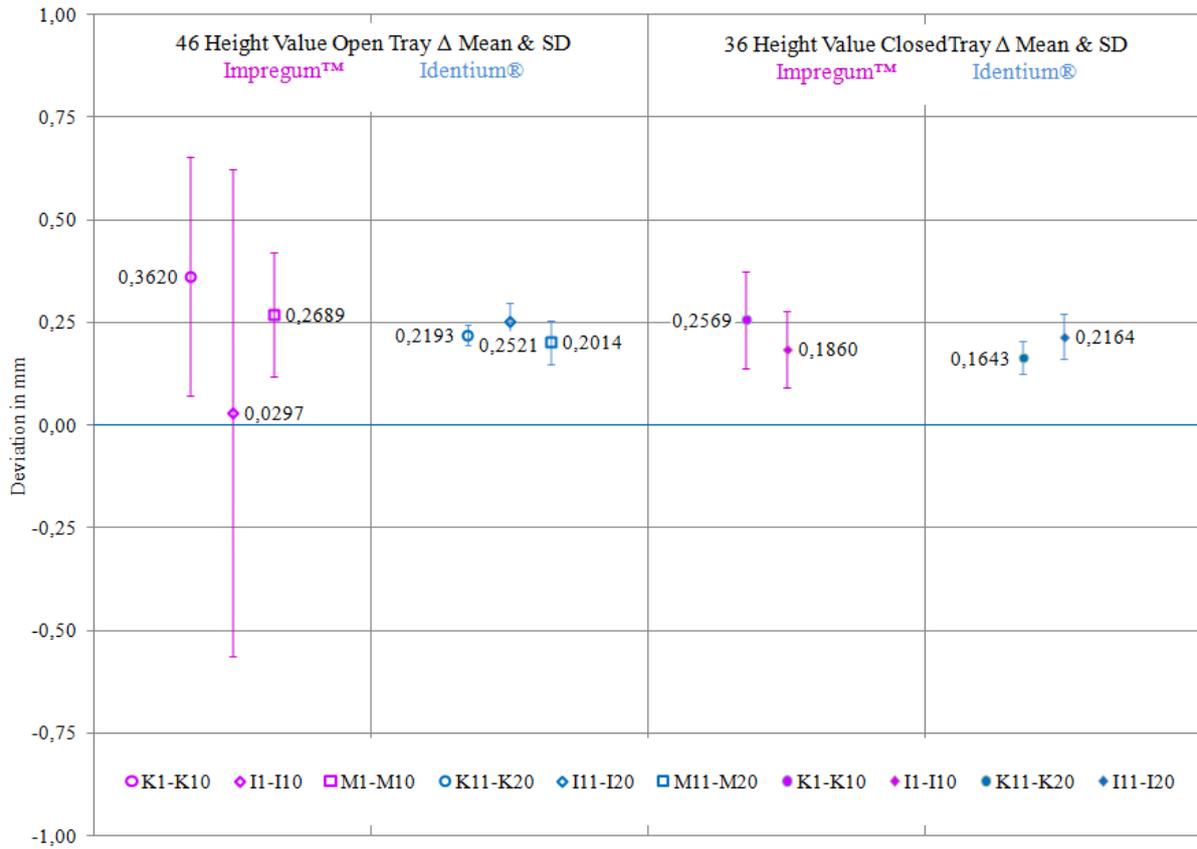
4. Results



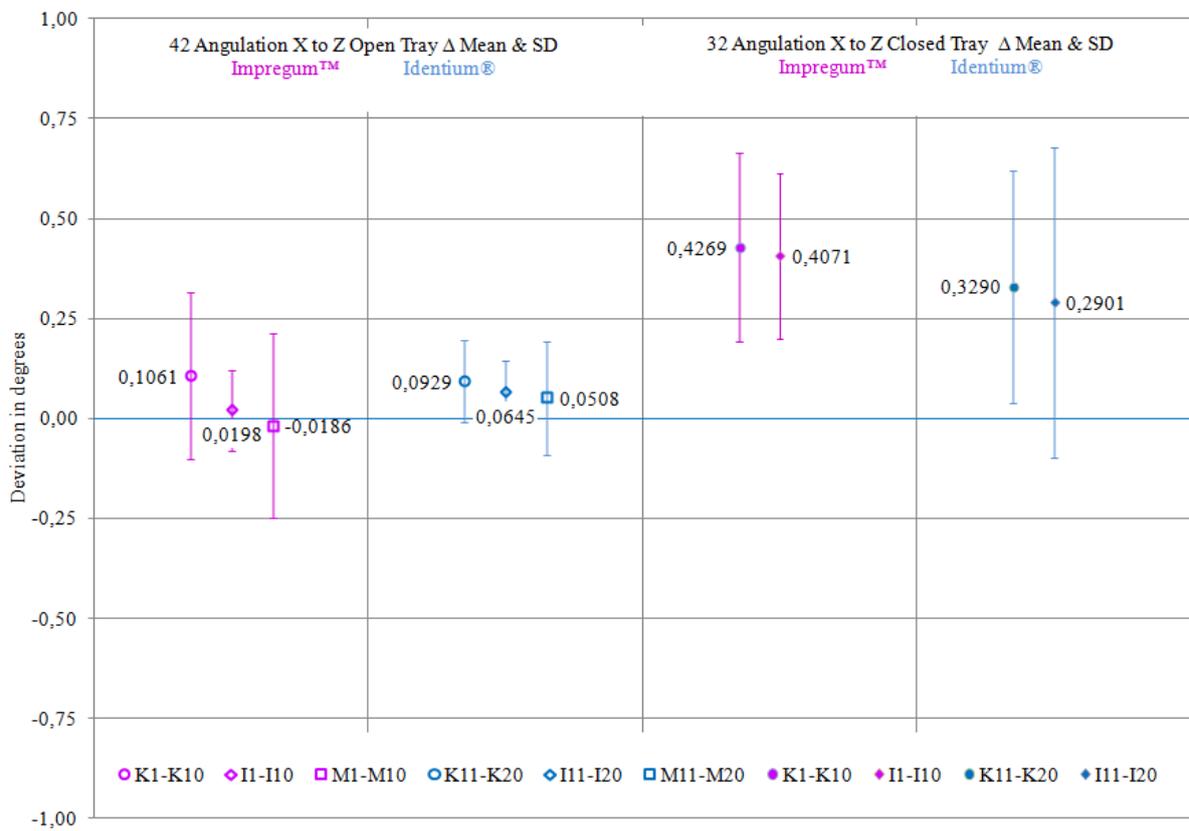
### 4.1.3 The Graphical representation of the Mean Change and Standard Deviation in the Height Z Values for the Open and Closed Tray Impression Technique



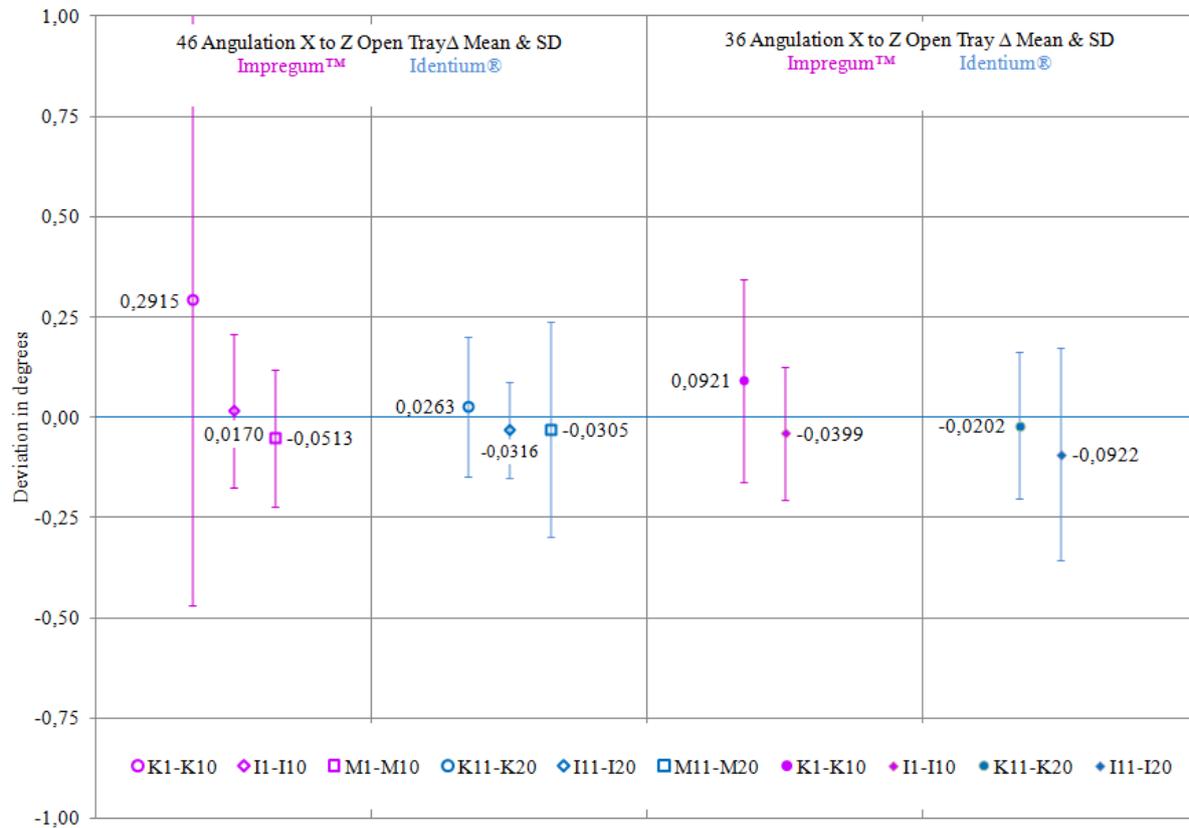
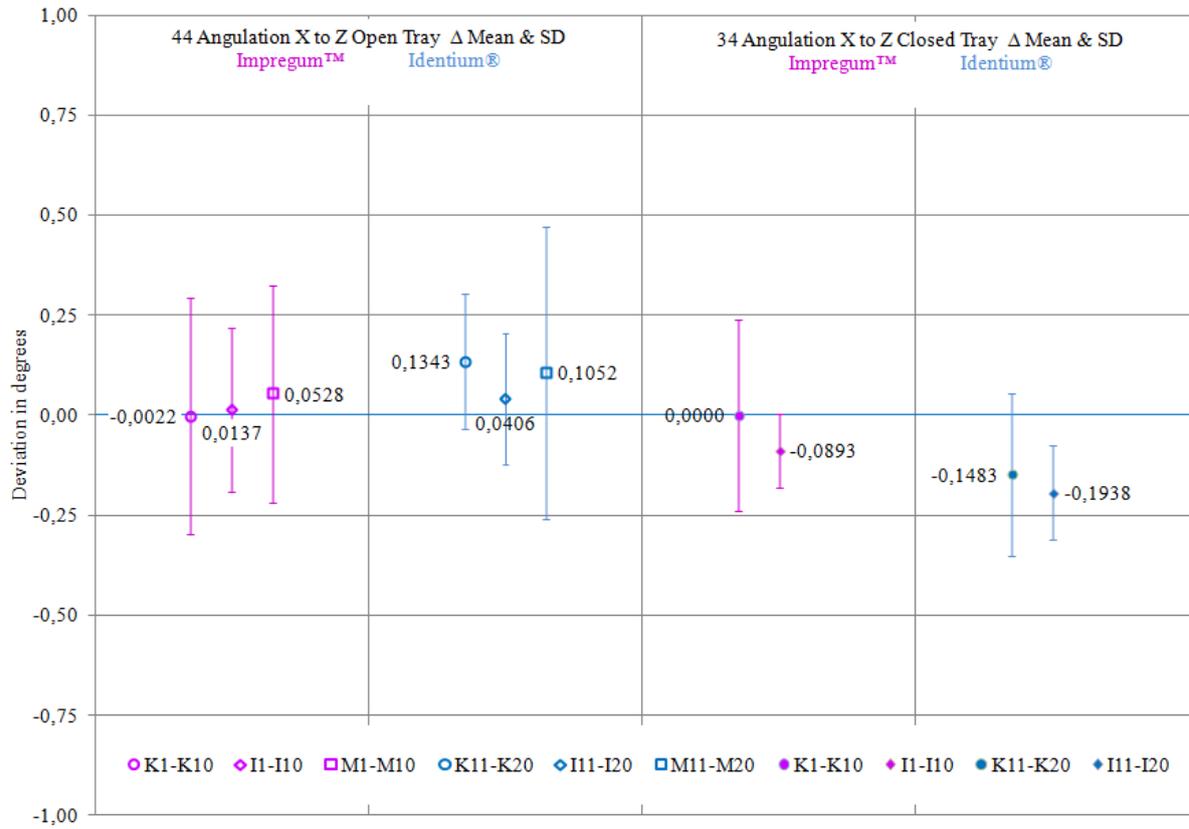
4. Results



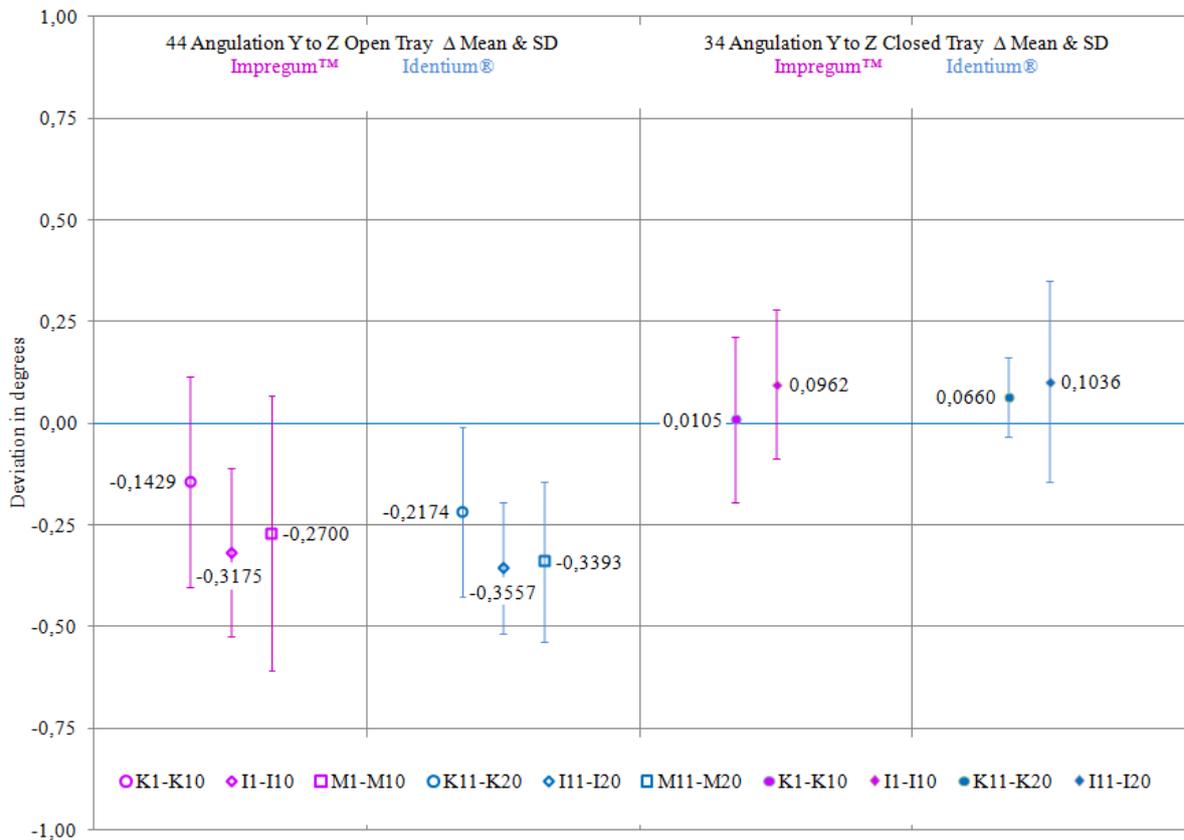
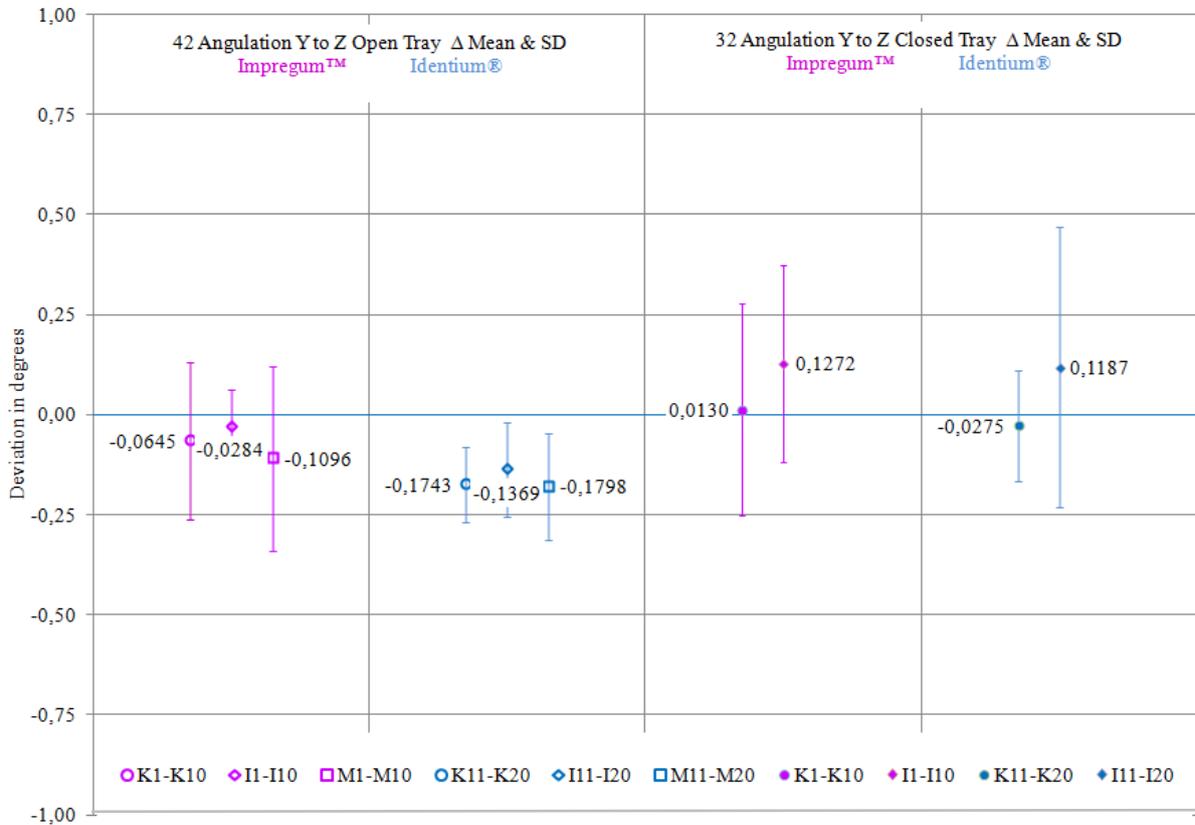
**4.1.4 The Graphical representation of the Mean Change and Standard Deviation in the Angulations X to Z Values for the Open and Closed Tray Impression Technique**



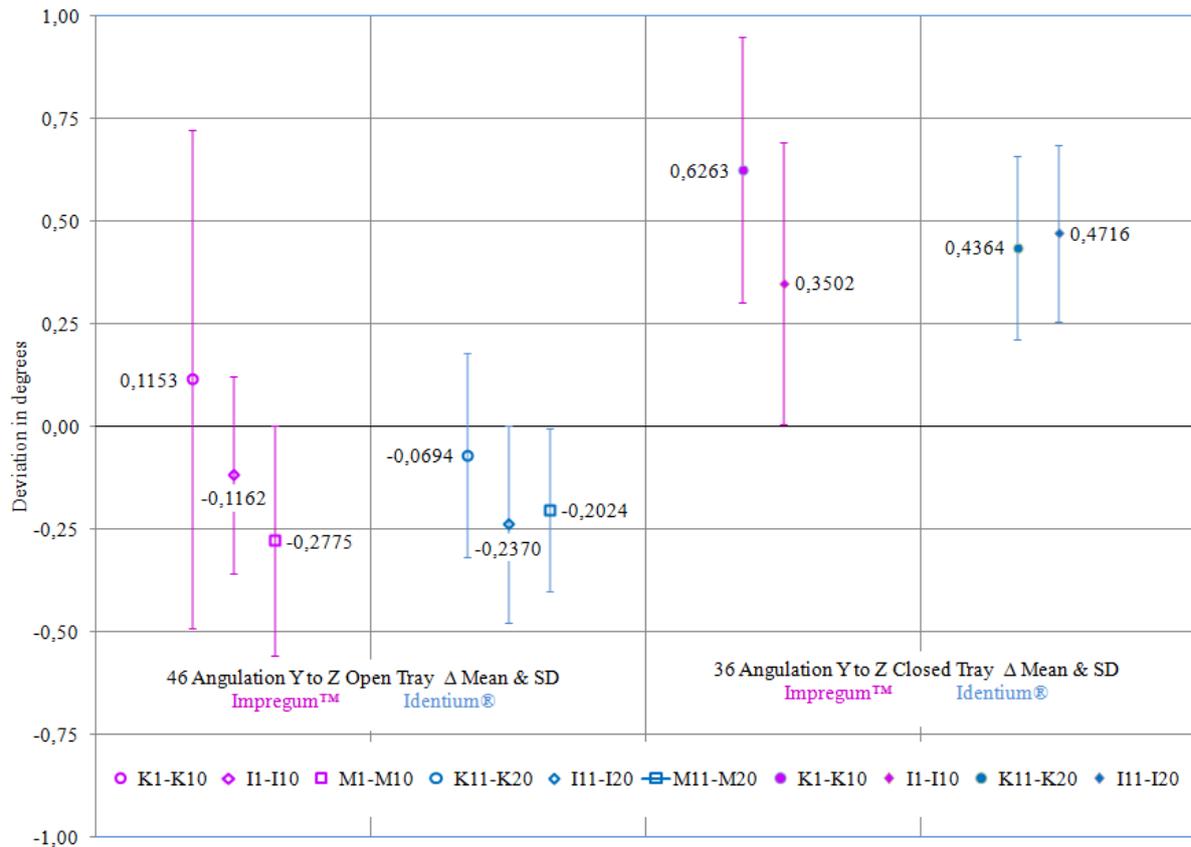
4. Results



### 4.1.5 The Graphical representation of the Mean Change and Standard Deviation in the Angulations Y to Z Values for the Open and Closed Tray Impression Technique



## 4. Results



## 4.2 The influence of the trays

### 4.2.1 Custom tray

The standard deviation by the custom tray was in certain results greater than the other two trays. For example:

X values 42 I1-I10 > K1-K10, 32 I1-I10 > K1-K10

X values 36 I11-I20 > K11-K20, 34 I1-I10 > K1-K10

The standard deviation was not much of a great difference in the Y values.

The Height Z value of implant 46 I1-I10 the custom tray gave a good mean result, but a high standard deviation.

For the closed or open tray impression technique for the custom tray in the X and Y values gave similar results.

#### 4. Results

Regarding the angulations and the custom tray, by looking at the graphs and values, one sees a pattern, that in the X to Z values, with the custom tray, the more posterior we look at the results (42, 32 going posterior to 46, 36) the better the results, especially in the closed tray impression technique.

In contrast, looking at the results Y to Z values, the more posterior we go (42,32 posterior to 46, 36) the weaker the results.

The custom tray performed poorly with Impregum™, but not with Identium® in the X value.

The custom tray performed in the Y values better with Impregum™ than the Identium® material.

In the angulations and height similar results were obtained regarding the custom tray and the two impression material, except for the previously addressed result regarding 46 height I1-I10.

#### **4.2.2 Prototype tray**

In the X values, compared to the Y values, the prototype tray has the same pattern as the custom tray. The standard deviations are higher in the X values than in the Y values.

The standard deviation in X and Y values seems to always be smaller with Identium® than with Impregum™.

In the X and Y values the prototype seems to have better mean results in the closed than in the open impression technique, as observed with the custom trays.

In the open impression technique, the prototype in comparison with the other stock tray, the Miratray® Implant, seems to generally have average better results.

Regarding the height measurements the prototype with Impregum™ shows weaker results in comparison to the other two tray systems.

In the open impression technique with Identium® the 3 trays seem to give similar results and in the closed tray, with Identium®, the prototype gives the better results.

A similar pattern with the angulations regarding X to Z values and Y to Z values as with the custom tray are achieved. A perfect results of 0,0000 in the  $\Delta$ mean achieved by 34 X to Z values of K1-K10. Another good result being the  $\Delta$ mean 44 X to Z for K1-K10 resulted at 0,0022. An almost perfect result is seen K1-K10 in 44 X to Z values.

A greater standard deviation in comparison to the other trays is seen in 46 K1-K10 X to Z values. A similar result with a high standard deviation is seen in 46 Y to Z values K1-K10.

The prototype performed poorly with polyether, but not with Identium®, in the X, Y and Z values.

#### **4.2.3 Miratray® Implant**

All trays were used for both impression techniques, except for the Miratray® Implant, which was used only for the open tray impression technique (according to manufacturer's instructions).

Unfortunately we cannot compare the closed impression technique with the Miratray® Implant. The comparison and discussions are only based on the open tray impression technique.

In the X and Y values, the same results are noted as the above two trays. The standard deviation was greater with Impregum™ than Identium® and generally the Miratray® Implant having weaker  $\Delta$ mean results in comparison to the custom tray and the prototype. In the height it had similar results to the other trays.

In the X to Z values, the angulations of 44 and 46, was interesting to see for the first time, that the standard deviation of Identium® was greater than that of Impregum™, with mostly weaker results in comparison to the custom trays.

In the Y to Z values, the standard deviation in Identium® was again smaller to Impregum™, with mostly weaker results in comparison to the prototype trays.

If we compare the X and Y values for all trays, one will notice that the greater mean values and the higher standard deviations were mostly in the X values.

### **4.3 The influence of the impression technique**

#### **4.3.1 The open tray impression technique (pick-up/ direct pick-up impression technique)**

46 X to Z values in Impregum™ K1-K10: The mean values and standard deviations are here greater than by Identium® K11-K20 open impression technique and in the closed tray impression techniques.

#### **4.3.2 The closed tray direct snap-on impression technique (snap-fit plastic impression technique).**

Looking at the graphs, the closed tray impression technique, had similar results as the open tray impression technique in the X, Y and Z values, with Impregum™ resulting in greater standard deviations than Identium®.

Differences can to be seen in 32 X to Z values. The mean values and standard deviations are here greater than the open tray impression technique.

34 X to Z values, the mean values are greater here in the closed impression technique using Identium®.

36 Y to Z values have greater mean in both materials in comparison to the open tray technique.

An overview of the movements, as taken from the X, Y and Angulations X to Z and Y to Z

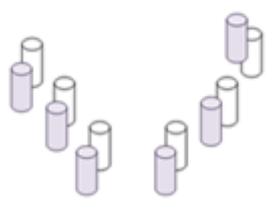
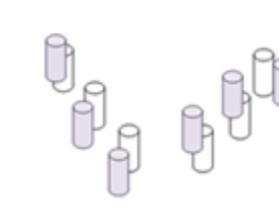
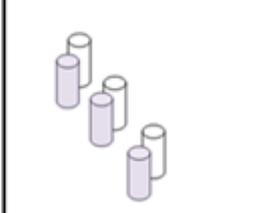
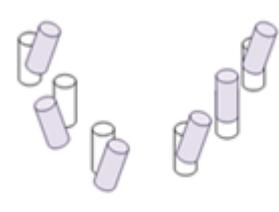
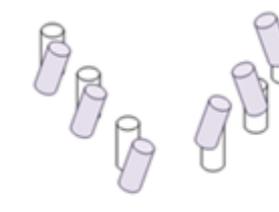
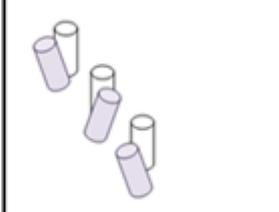
	K 1- K10	I 1- I 10	M 1 – M 10
Mean X values Mean Y values			
X to Z Y to Z			

Fig. 39: free hand figure representation of the Mean Change in X- and Y-values and in the Angulations X to Z and Y to Z values for the Open and Closed Tray Impression Technique for Impregum

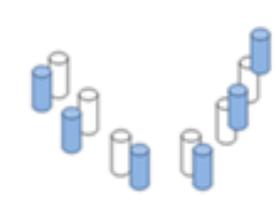
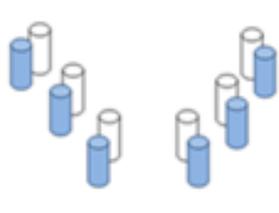
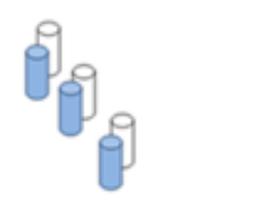
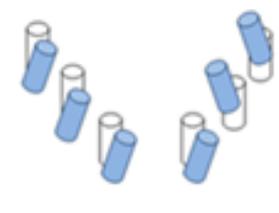
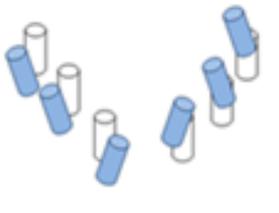
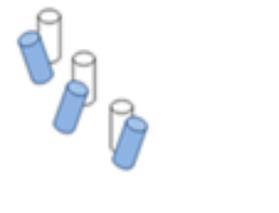
	K 11- K20	I 11- I 20	M 11 – M 20
Mean X values Mean Y values			
X to Z Y to Z			

Fig. 40: free hand figure representation of the Mean Change in X- and Y-values and in the Angulations X to Z and Y to Z values for the Open and Closed Tray Impression Technique for Identium

White cylinders representing the original position and the coloured cylinders representing the movements. For the open tray impression technique from the measurements (IV Quadrant) X-axis tendency towards the buccal wall, for Impregum™ and for the Identium®

Y-axis tendency movement anterior regardless whether it was Impregum™ or Identium®

Angulation X to Z: mostly in the lingual direction

Angulation Y to Z: mostly in the anterior direction

For the closed tray impression technique (III Quadrant)

X-axis tendency towards the buccal wall for Identium® and lingual wall for Impregum™

Y-axis more variations than in comparison to the open tray technique, some movements are anterior, other movements are posterior regardless whether it was Impregum™ or Identium®.

Angulation X to Z: more variations than in comparison to the open tray technique

Angulation Y to Z: mostly in the posterior direction.

## **4.4 The influence of the impression materials**

### **4.4.1 The polyether, Impregum™**

The standard deviation by Impregum™ was also most of the times higher than that of Identium®. With the only exception seen with the Miratray® Implant with the Angulation 44, 46 X to Z values.

Better mean values were achieved in the X values with the closed impression tray technique.

Looking at the Y values, good results were achieved with the open and closed impression tray technique.

In the X to Z better achievements can be seen in the open impression tray technique.

### **4.4.2 The vinylsiloxanether, Identium®**

In the X and Y values it certainly showed good mean results in the closed impression tray technique.

## 4.5 Statistical Analysis

The coordinates for the master model and the casts produced and their measurements (taken from the Zeiss Prismo) were exported to a spreadsheet (Excel 2007, Microsoft Office). The One-Sample t-Test and the Two-Sample f-Test were used.

The significance levels were set at  $p < 0.05$ . Data  $< 0.05$  was considered significant.

In order to test for significant differences between the trays and the materials, nonparametric statistical tests were conducted as a normal distribution is not given for all variables (proved by the Q-Q-plots) and as the sample size ( $n=10$ ) is small.

In the case of the three-group comparisons (tray K, I, M for the measurement points 42, 44, 46 – the open tray impression technique), the Kruskal-Wallis-test was conducted and for significant ( $p < 0.05$ ) main effects post-hoc pairwise comparisons were performed by means of the Mann-Whitney-test.

In the case of the two-group comparisons (tray K, I and for the materials, for the measurement points 32, 34, 36 – the closed tray direct snap-on impression technique), the Mann-Whitney-test was conducted. This is an exploratory analysis. Descriptive p-values  $< 0.05$  will be considered as statistically significant. All statistical tests were conducted in SPSS 21.

To look for the differences to the master model, the 95% confidence intervals for the mean were plotted (in SPSS 21) stratified by tray and material and one-sample t-tests were conducted (in Excel 2007). Again, p-values are interpreted descriptively.

In order to test for homogeneous variances the two-sample f-test was performed for all combinations of trays and materials (in Excel 2007).

## **4.6 An Overview of the Statistical Aspects to be discussed.**

### **4.6.1 The Significance of the Deviation from the Master Model & the casts produced**

#### **4.6.2 The 95% Coefficient Interval (SPSS)**

From these two aspects, we should keep in mind, that the master model will be compared to the casts produced.

In the graphs regarding these aspects, the zero line represents the master model. Here the analysis focuses on which group varies/resembles the master model.

### **4.6.3 The Significance of the Standard Deviation (Two-Sample f-Test) (Excel)**

#### **4.6.4 Nonparametric test (SPSS)**

From these two aspects, we should keep in mind, that the produced casts are compared to each other. Here the analysis focuses on which tray or which material had the most influence.

**4.6.1 The Significance of the Deviation from the Master Model and the casts produced**

	Master Model	One-Sample t-Test: Comparison of the Mean vs. Mean Master Model					
		K1-K10 vs. Master Model	K11-K20 vs. Master Model	I1-I10 vs. Master Model	I11-I20 vs. Master Model	M1-M10 vs. Master Model	M11-M20 vs. Master Model
42 X Value	-73,3538	0,6910	0,9591	0,8005	0,9498	0,2479	0,2949
42 Y Value	33,9772	0,7618	0,0527	0,7725	0,0298	0,1664	0,1523
44 X Value	-81,3135	0,4601	0,8496	0,6891	0,6959	0,2284	0,2766
44 Y Value	44,7973	0,6572	0,0373	0,5868	0,0198	0,3668	0,3114
46 X Value	-85,7214	0,4708	0,6084	0,6498	0,5844	0,2126	0,2580
46 Y Value	58,2576	0,8653	0,4264	0,9684	0,0686	0,6731	0,8709
32 X Value	-55,4742	0,8174	0,7298	0,7965	0,9461		
32 Y Value	33,9255	0,8212	0,7034	0,7623	0,0760		
34 X Value	-46,5374	0,8183	0,7855	0,9212	0,9661		
34 Y Value	45,9470	0,9373	0,7636	0,9564	0,3522		
36 X Value	-41,7183	0,8207	0,6661	0,9871	0,8258		
36 Y Value	58,7398	0,6736	0,1833	0,9428	0,9652		
42 Z Height	34,6207	0,0001	0,0000	0,0000	0,0000	0,0000	0,0000
44 Z Height	36,6490	0,0008	0,0000	0,0000	0,0000	0,0000	0,0000
46 Z Height	37,1221	0,0035	0,0000	0,8778	0,0000	0,0003	0,0000
32 Z Height	35,1045	0,0000	0,0001	0,0010	0,0002		
34 Z Height	36,8131	0,0002	0,0000	0,0000	0,0000		
36 Z Height	37,1415	0,0001	0,0000	0,0001	0,0000		
Angle 42 X to Z	-0,3803	0,1418	0,0180	0,5444	0,0326	0,8038	0,2838
Angle 42 Y to Z	-0,6766	0,3257	0,0002	0,3518	0,0049	0,1668	0,0021
Angle 44 X to Z	1,0808	0,9816	0,0322	0,8363	0,4571	0,5535	0,3857
Angle 44 Y to Z	-0,5021	0,1145	0,0090	0,0009	0,0001	0,0323	0,0004
Angle 46 X to Z	0,7251	0,2563	0,6463	0,7855	0,4285	0,3657	0,7269
Angle 46 Y to Z	-0,2129	0,5628	0,3988	0,1604	0,0122	0,0120	0,0104
Angle 32 X to Z	-1,1653	0,0003	0,0058	0,0002	0,0422		
Angle 32 Y to Z	-0,8190	0,8801	0,5476	0,1365	0,3125		
Angle 34 X to Z	-0,8925	0,9998	0,0467	0,0131	0,0006		
Angle 34 Y to Z	-2,0531	0,8739	0,0604	0,1324	0,2193		
Angle 36 X to Z	-0,1400	0,2784	0,7347	0,4670	0,3011		
Angle 36 Y to Z	-0,5654	0,0002	0,0002	0,0103	0,0001		

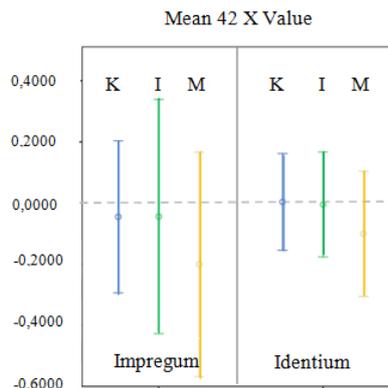
Table 5: The following table shows the One-Sample t-Test. Statistically significant values are marked with pink ( $P < .05$ ) these correspond with the significant differences with the 95% Confidence Interval, which will be discussed in the next section.

### 4.6.2 The 95% Confidence Interval (SPSS)

	Master Model	Mean Change Impregum K1-K10	SD Impregum K1-K10	Standard Error K1-K10	95%CI Lower K1-K10	95%CI Upper K1-K10
42 X Value	-73,3538	-0,0452	0,3480	0,1100	-0,2608	0,1705
42 Y Value	33,9772	-0,0202	0,2044	0,0646	-0,1469	0,1065
44 X Value	-81,3135	-0,0805	0,3300	0,1044	-0,2851	0,1240
44 Y Value	44,7973	-0,0297	0,2050	0,0648	-0,1568	0,0973
46 X Value	-85,7214	-0,0754	0,3165	0,1001	-0,2715	0,1208
46 Y Value	58,2576	-0,0115	0,2090	0,0661	-0,1411	0,1180
32 X Value	-55,4742	-0,0264	0,3517	0,1112	-0,2444	0,1915
32 Y Value	33,9255	-0,0140	0,1907	0,0603	-0,1322	0,1042
34 X Value	-46,5374	-0,0247	0,3302	0,1044	-0,2293	0,1799
34 Y Value	45,9470	-0,0047	0,1831	0,0579	-0,1182	0,1088
36 X Value	-41,7183	-0,0238	0,3223	0,1019	-0,2236	0,1760
36 Y Value	58,7398	0,0261	0,1898	0,0600	-0,0915	0,1437
42 Z Height	34,6207	0,3746	0,1708	0,0540	0,2687	0,4804
44 Z Height	36,6490	0,3601	0,2301	0,0728	0,2175	0,5028
46 Z Height	37,1221	0,3620	0,2917	0,0922	0,1813	0,5428
32 Z Height	35,1045	0,2774	0,1168	0,0369	0,2050	0,3497
34 Z Height	36,8131	0,2242	0,1159	0,0366	0,1524	0,2960
36 Z Height	37,1415	0,2569	0,1182	0,0374	0,1836	0,3301
Angle 42 X to Z	-0,3803	0,1061	0,2084	0,0659	-0,0231	0,2353
Angle 42 Y to Z	-0,6766	-0,0645	0,1963	0,0621	-0,1862	0,0572
Angle 44 X to Z	1,0808	-0,0022	0,2959	0,0936	-0,1856	0,1812
Angle 44 Y to Z	-0,5021	-0,1429	0,2586	0,0818	-0,3032	0,0174
Angle 46 X to Z	0,7251	0,2915	0,7604	0,2405	-0,1798	0,7628
Angle 46 Y to Z	-0,2129	0,1153	0,6068	0,1919	-0,2608	0,4914
Angle 32 X to Z	-1,1653	0,4269	0,2357	0,0745	0,2808	0,5730
Angle 32 Y to Z	-0,8190	0,0130	0,2655	0,0839	-0,1515	0,1776
Angle 34 X to Z	-0,8925	0,0000	0,2394	0,0757	-0,1483	0,1484
Angle 34 Y to Z	-2,0531	0,0105	0,2037	0,0644	-0,1157	0,1368
Angle 36 X to Z	-0,1400	0,0921	0,2525	0,0798	-0,0644	0,2486
Angle 36 Y to Z	-0,5654	0,6263	0,3233	0,1022	0,4259	0,8266

Table 6: The following table shows only part of The 95% Confidence Interval (CI). Values that did not achieve the 95% CI are marked with pink

### 4.6.2 The 95% Coefficient Interval



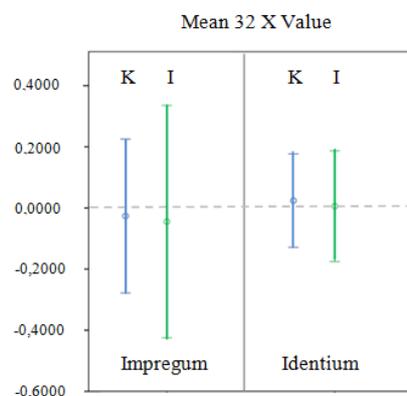
The Open Tray Impression technique (IV Quadrant 42,44,46) is represented with all 3 Trays.

- K Prototype
- I Custom Tray
- M Miratray@Implant

The left side of the diagram represents trays with Impregum™.

The right side of the diagram represents trays with Identium®.

The zero line represents the master model



The Closed Tray Impression technique (III Quadrant 32,34,36) does not include the Miratray@Implant Tray.

In both Impression techniques:

Values that did not achieve the 95% CI are marked with ●

Alone standing values achieving the 95% CI in a given situation are marked with ●

Fig.41: The figure above explains how to understand the 95% Confidence Interval Value Graphs.

In statistics, a confidence interval (CI) is a type of interval estimate of a parameter and is used to indicate the reliability of an estimate. It is an observed interval (i.e. it is calculated from the observations), how frequently the observed interval contains the parameter is determined by the confidence level or confidence coefficient [139].

Confidence intervals consist of a range of values (interval) that act as good estimates of the unknown parameter. The level of confidence of the confidence interval would indicate the probability that the confidence range captures this true parameter given a distribution of samples. It does not describe any single sample. This value is represented by a percentage, so when we say, "we are 95% confident that the true value of the parameter is in our confidence interval", we express that 95% of the observed confidence intervals will hold the true value of the parameter. After a sample is taken, the population parameter is either in the interval made or not; it is not a matter of chance [139].

#### 4. Results

In this study, we compare the mean values for a given group (e.g. K1-K10) and compare the confidence interval to the master model (the master model being the zero line in the graphs).

#### The X-direction

By comparing the cast models to the master model, no significant differences were found in the X-direction, for all trays, materials and for both impression techniques. All values achieved the 95% CI.

Looking at the one-sample t-Test table, one will notice, that all the X values, also do not show any significant values, all values being above  $>.05$ .

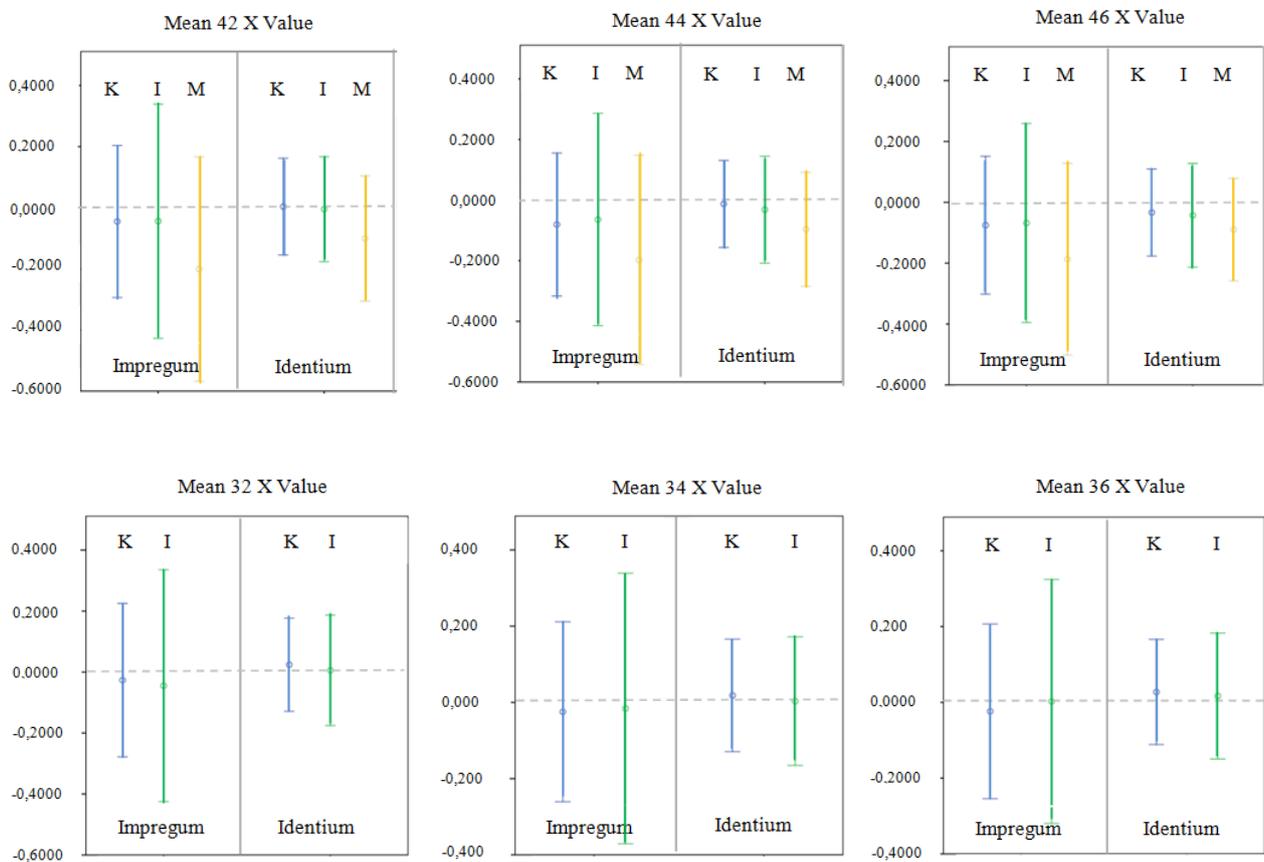


Fig.42: The 95% Confidence Interval Value Graphs with the Mean X Values

4. Results

**The Y-direction** For the Y-direction significant differences were found in:

(Marked with a pink point in the Diagram ● )

The custom tray using Identium® for open tray impression technique (42, 44, 46 Y value for I11-I20) and in the closed tray impression technique (32 Y value for I11-I20).

Using the prototype tray with Identium® also in the open tray technique (42, 44 Y value for K11-K20).

In the X- and Y-direction one notices that between the two impression materials, the Impregum™ having a greater standard of deviation than the Identium®.

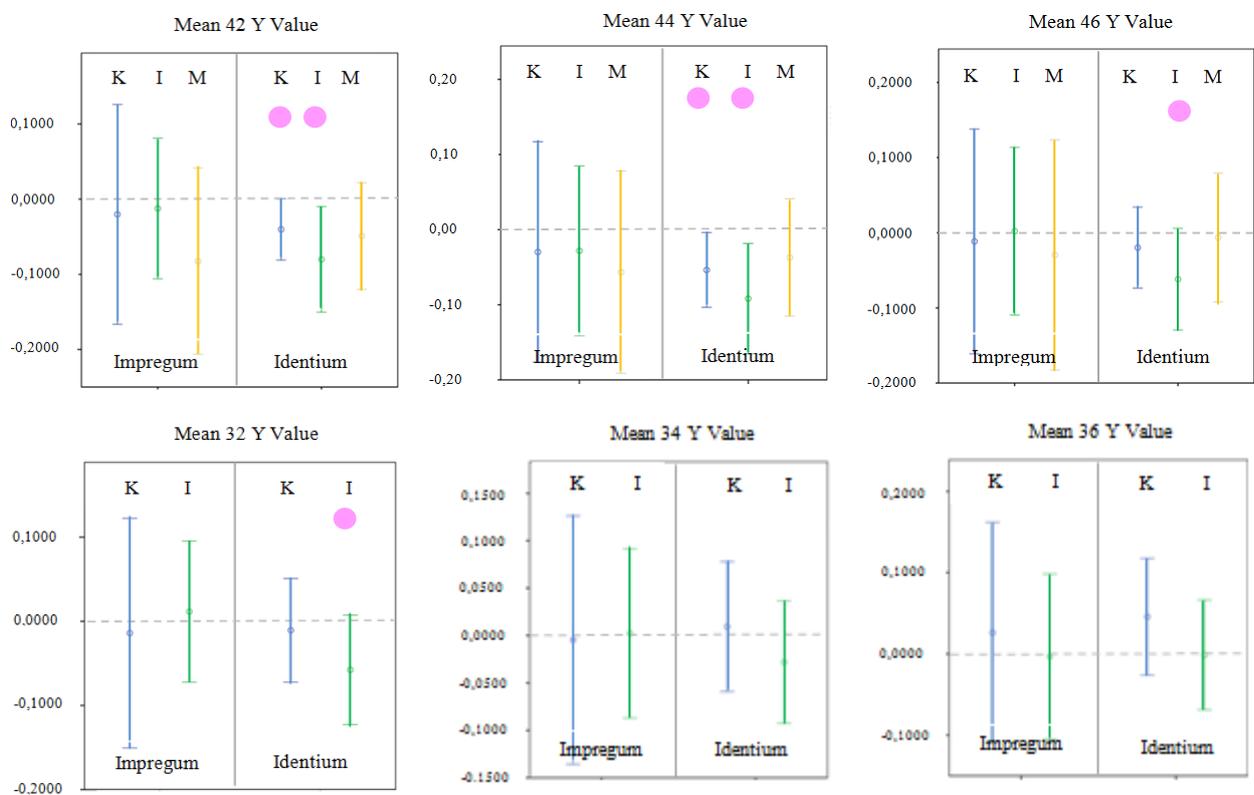


Fig.43: The 95% Confidence Interval Value Graphs with the Mean Y Values

### The Height Z Value

For the closed impression technique 32, 34, 36 showed significant differences for all trays and both materials. This corresponds with the one-sample t-Test.

For the open tray impression technique 42, 44, 46 showed significant differences for all trays and both materials, except for I1-I10 for the Height of 46. This too corresponds with the one-sample t-Test. (Marked with a green point in the Diagram ● )

Only I1-I10 achieved the 95% CI, yet having a high standard of deviation.

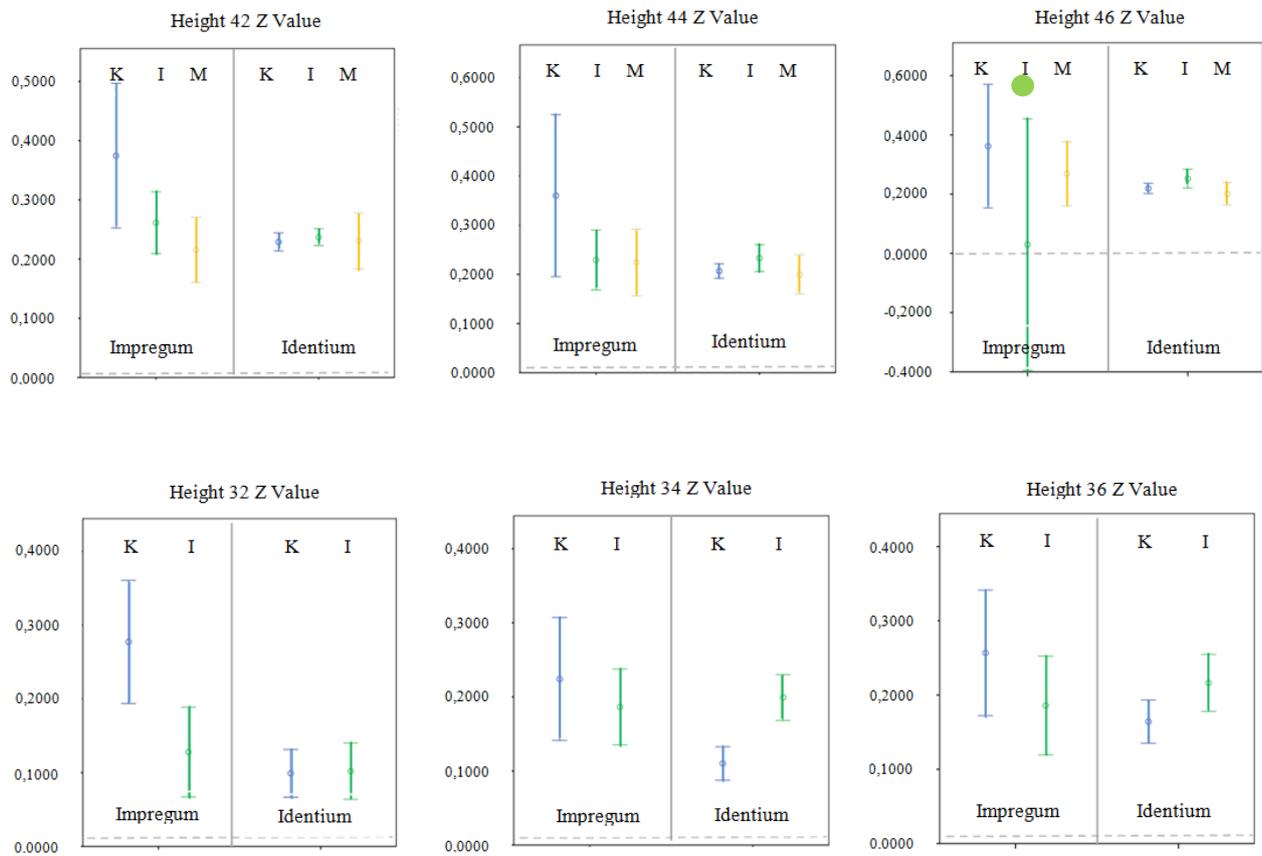


Fig.44: The 95% Confidence Interval Value Graphs with the Mean Height Z Values

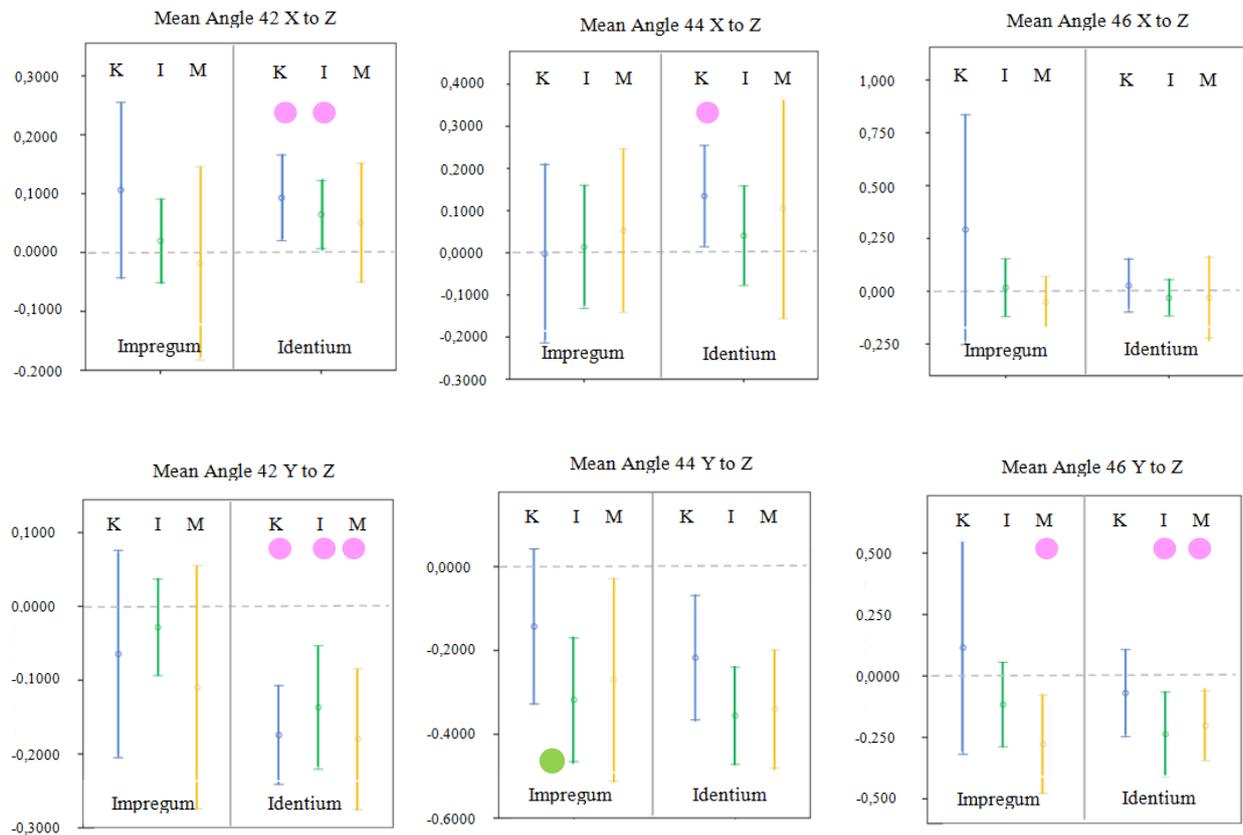
**The mean of angulation values to the crestal plane**

Significant differences were noted for the following:

**In the open tray impression technique (42, 44, 46),** significant differences were seen for 42 in the X to Z using Identium® and the prototype and the custom tray (K11-K20, I11-I20). For 42 in the Y to Z angulation using Identium® with all tray types (K11-K20, I11-I20, and M11-M20).

The 44 angulation X to Z for the prototype with Identium® showed significant differences (K11-K20). For 44 angulation Y to Z significant differences were seen with all trays and both materials, except for the prototype and Impregum™ (except K1-K10 marked ●).

No significant differences were noted with 46 in the X to Z angulation. Whereas the Y to Z angulation showed significant differences using the Miratray® Implant with both materials and the custom tray using Identium® (M1-M10, M11-M20, I11-I20).



*Fig.45: The 95% Confidence Interval Value Graphs with the Mean Angle X to Z Values and Mean Angle Y to Z in the Fourth Quadrant*

#### 4. Results

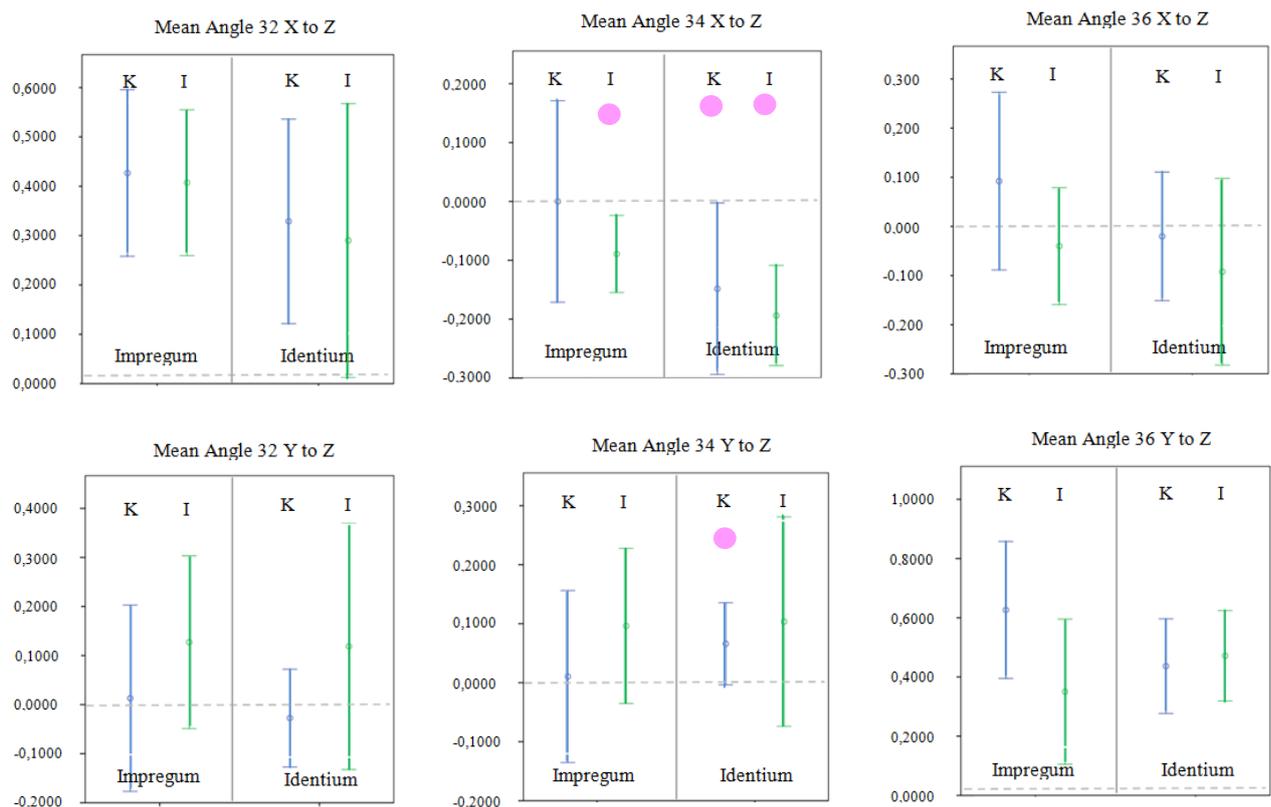
In the X to Z Angulation in the open tray impression technique, weaker results came from Identium® and the Prototype and custom tray.

In the Y to Z Angulation, weaker results were shown to be with Identium® and the Miratray® Implant and the custom tray.

Y to Z gave gave more significant differences than X to Z.

**For the closed impression tray technique** (32, 34, 36), significant differences were found for the prototype tray and custom tray with both materials in the X- and Y-direction. (In the Angulation 32 X to Z and 36 Y to Z for K1-K10, K11-K20, I1-I10, I11-I20 and in the Angulation 34 X to Z for K11-K20, I1-I10 and I11-I20. And in 34 Yto Z in K11-K20. (Note that the Miratray® Implant did not show any significant differences as it was not used for the closed impression tray).

32 X to Z and 36 Y to Z showed the weakest results. It seems as though as the posterior one moved with the Y to Z angulations the weaker the results (36) and the opposite being for the X to Z Angulations, the weaker results being in the front (32).



*Fig.46: The 95% Confidence Interval Value Graphs with the Mean Angle X to Z Values and Mean Angle Y to Z in the Third Quadrant*

**4.6.3 The significance of the Standard Deviation**

Master Model		Two-Sample f-Test (Comparing the Variance)								
		K1-K10 vs. K11-K20	I1-I10 vs. I11-I20	M1-M10 vs. M11-M20	K1-K10 vs. I1-I10	K1-K10 vs. M1-M10	I1-I10 vs. M1-M10	K11-K20 vs. I11-I20	K11-K20 vs. M11-M20	I11-I20 vs. M11-M20
42 X Value	-73,3538	0,1937	0,0257	0,0971	0,2149	0,2617	0,9025	0,8097	0,4535	0,6090
42 Y Value	33,9772	0,0008	0,4075	0,1118	0,1993	0,6303	0,4143	0,1205	0,1147	0,9790
44 X Value	-81,3135	0,1549	0,0528	0,0854	0,2544	0,2729	0,9643	0,5513	0,4320	0,8474
44 Y Value	44,7973	0,0036	0,2159	0,1208	0,4500	0,8043	0,6097	0,2611	0,1948	0,8571
46 X Value	-85,7214	0,1878	0,0654	0,0764	0,2887	0,3394	0,9134	0,6117	0,6338	0,9749
46 Y Value	58,2576	0,0055	0,1516	0,0992	0,3969	0,9435	0,3594	0,5073	0,1811	0,4894
32 X Value	-55,4742	0,1533	0,0376		0,2349			0,6221		
32 Y Value	33,9255	0,0265	0,4628		0,1629			0,8694		
34 X Value	-46,5374	0,1771	0,0372		0,2402			0,6947		
34 Y Value	45,9470	0,0666	0,3486		0,2683			0,8641		
36 X Value	-41,7183	0,1468	0,0614		0,3339			0,6029		
36 Y Value	58,7398	0,0711	0,2395		0,4040			0,8642		
42 Z Height	34,6207	0,0000	0,0006	0,6527	0,0182	0,0262	0,8738	0,8550	0,0023	0,0014
44 Z Height	36,6490	0,0000	0,0248	0,1289	0,0067	0,0145	0,7509	0,0822	0,0066	0,2685
46 Z Height	37,1221	0,0000	0,0000	0,0050	0,0461	0,0640	0,0004	0,0807	0,0249	0,5810
32 Z Height	35,1045	0,0092	0,1819		0,3580			0,6258		
34 Z Height	36,8131	0,0006	0,1489		0,1662			0,3565		
36 Z Height	37,1415	0,0040	0,1174		0,4861			0,4233		
Angle 42 X to Z	-0,3803	0,0442	0,5447	0,1612	0,0381	0,7755	0,0201	0,5006	0,3471	0,1126
Angle 42 Y to Z	-0,6766	0,0378	0,4753	0,1194	0,0327	0,6411	0,0111	0,5162	0,3047	0,7007
Angle 44 X to Z	1,0808	0,1065	0,5379	0,3898	0,2841	0,7995	0,4103	0,9628	0,0301	0,0271
Angle 44 Y to Z	-0,5021	0,5202	0,4830	0,1233	0,5115	0,4387	0,1582	0,4747	0,8793	0,5722
Angle 46 X to Z	0,7251	0,0002	0,1842	0,1954	0,0003	0,0001	0,7380	0,2780	0,2236	0,0261
Angle 46 Y to Z	-0,2129	0,0135	0,9948	0,3201	0,0109	0,0306	0,6566	0,9238	0,5191	0,5822
Angle 32 X to Z	-1,1653	0,5482	0,0746		0,7008			0,3985		
Angle 32 Y to Z	-0,8190	0,0677	0,3053		0,8251			0,0110		
Angle 34 X to Z	-0,8925	0,6378	0,4463		0,0086			0,1257		
Angle 34 Y to Z	-2,0531	0,0383	0,3856		0,7654			0,0102		
Angle 36 X to Z	-0,1400	0,3500	0,1787		0,2289			0,2809		
Angle 36 Y to Z	-0,5654	0,2870	0,1745		0,8654			0,8918		

Table 7: The above table showing a Two-Sample f-Test  
 Statistically significant values are marked with pink ( $P < .05$ )

#### 4. Results

Least significant differences between all measurements were seen in the comparison group of K11-K20 vs. I11-I20, (same material, tray varied) this was the single group, where the most values were below 30  $\mu\text{m}$  and the only group where all the Heights (32, 34, 36, 42, 44, 46) in comparison were below 30  $\mu\text{m}$ . Significant differences in this comparison group was found by the Y to Z angulation in 32 and 34.

The 30  $\mu\text{m}$  measurement will be discussed in Section 5.1 and 5.2.

The group M1-M10 vs. M11-M20 (same tray, material varied). Showed only one significant difference in the 46 Height Z value between their measurements. Keeping in mind that in the Miratray® Implant no III Quadrant impressions (closed impression technique) took place.

A high amount of significant differences between the various groups were found between the following group comparisons.

K1-K10 vs. K11-I20 (same tray) here one notices that the angulation Y to Z showed no significant differences (except 34 Y to Z) and that the X-direction values for 42, 44, 46 also showed no significant values, as with the 34 and 35 X-and Y-directions.

Generally looking at the table one notices significant differences amongst all groups regarding the heights being the III or IV Quadrant, except for as mentioned previously the Group K11-20 vs. I11-I20.

More significant differences were noted in the Y vales when compared with the X values. And more significant differences were noted regarding the angualtions in the IV Quadrant than in the III Quadrant.

### 4.6.4 Nonparametric test

#### When comparing the trays to each other

a) The Kruskal-Wallis-Test (for 42,44,46).

Test for significant main effects concerning the factor tray (K,I,M) and the material Impregum™

(Material = imp(1-10) and tray= K,I,M (three groups))

Significant differences are to be seen in:

42 Z Height (for the Trays K,I,M for the Material Imp 1-10)

	42 X Value	42 Y Value	44 X Value	44 Y Value
Chi-Quadrat	,947	2,098	,519	,286
df	2	2	2	2
Asymptotische Signifikanz	,623	,350	,772	,867

	46 X Value	46 Y Value	42 Height Z Value	44 HeightZ Value
Chi-Quadrat	,699	,312	6,862	1,742
df	2	2	2	2
Asymptotische Signifikanz	,705	,855	,032	,419

	46 HeightZ Value	Angle 42 X to Z	Angle 42 Y to Z	Angle 44 X to Z
Chi-Quadrat	1,876	2,674	1,401	,531
df	2	2	2	2
Asymptotische Signifikanz	,391	,263	,496	,767

	Angle 44 Y to Z	Angle 46 X to Z	Angle 46 Y to Z
Chi-Quadrat	3,301	2,403	4,885
df	2	2	2
Asymptotische Signifikanz	,192	,301	,087

- a. material = imp(1-10)
- b. Kruskal-Wallis-Test
- c. Gruppenvariable: tray

Table 8: The above table showing The Kruskal-Wallis-Test for Impregum™ with trays as the variable

Significant differences are seen in the 42 Height Z values for the Material Impregum® for Tray K,I,M. (Three groups). To determine between which trays the significant differences lie, the post-hoc pairwise comparisons are made.

b) For significant main effects, post-hoc pairwise comparisons are conducted by means of the Mann-Whitney test

#### 4. Results

##### Mann-Whitney-Test

material = imp (1-10), tray = K, I

	42 Height Z Value
Mann-Whitney-U	26,000
Wilcoxon-W	81,000
Z	-1,814
Asymptotische Signifikanz (2-seitig)	,070
Exakte Signifikanz [2*(1-seitig Sig.)]	,075 <sup>c</sup>

- a. material = imp(1-10)  
 b. Gruppenvariable: tray  
 c. Nicht für Bindungen korrigiert.

material = imp (1-10), tray = K, M

	42 Height Z Value
Mann-Whitney-U	17,500
Wilcoxon-W	72,500
Z	-2,458
Asymptotische Signifikanz (2-seitig)	,014
Exakte Signifikanz [2*(1-seitig Sig.)]	,011 <sup>c</sup>

- a. material = imp(1-10)  
 b. Gruppenvariable: tray  
 c. Nicht für Bindungen korrigiert.

material = imp (1-10), tray = I, M

	42 Height Z Value
Mann-Whitney-U	38,000
Wilcoxon-W	93,000
Z	-,907
Asymptotische Signifikanz (2-seitig)	,364
Exakte Signifikanz [2*(1-seitig Sig.)]	,393 <sup>c</sup>

- a. material = imp(1-10)  
 b. Gruppenvariable: tray  
 c. Nicht für Bindungen korrigiert.

Table 9: The above table showing Mann-Whitney-Test, to determine between which trays the significant differences lies

Significant differences are to be seen in 42 Z Height (K1-K10 vs. M1-M10)

This significant difference will later be found in a table marked with 

a) The Kruskal-Wallis-Test (for 42,44,46). Test for significant main effects concerning the factor tray (K,I,M) and the material Identium®

(Material = ide(1-10) and tray = K,I,M (three groups))

Significant differences are to be seen in:

46 Z Height (for the Trays K,I,M for the Material Ide 11-20)

Statistik für Test<sup>a,b,c</sup>

	42 X Value	42 Y Value	44 X Value	44 Y Value
Chi-Quadrat	,506	2,960	,217	2,836
df	2	2	2	2
Asymptotische Signifikanz	,777	,228	,897	,242

Statistik für Test<sup>a,b,c</sup>

	46 X Value	46 Y Value	42 Height Z Value	44 Height Z Value
Chi-Quadrat	,072	2,519	3,455	5,585
df	2	2	2	2
Asymptotische Signifikanz	,965	,284	,178	,061

Statistik für Test<sup>a,b,c</sup>

	46 Height Z Value	Angle 42 X to Z	Angle 42 Y to Z	Angle 44 X to Z
Chi-Quadrat	7,930	,343	,424	1,030
df	2	2	2	2
Asymptotische Signifikanz	,019	,842	,809	,598

Statistik für Test<sup>a,b,c</sup>

	Angle 44 Y to Z	Angle 46 X to Z	Angle 46 Y to Z
Chi-Quadrat	3,425	1,133	2,836
df	2	2	2
Asymptotische Signifikanz	,180	,568	,242

- a. material = ide(11-20)  
 b. Kruskal-Wallis-Test  
 c. Gruppenvariable: tray

Table 10: The table on the left shows The Kruskal-Wallis-Test for Identium®

with trays as the variable

#### 4. Results

Significant differences are seen in the 46 Height Z values for the Material Identium™ for Tray K,I,M. (Three groups)

To determine between which trays the significant differences lie, the post-hoc pairwise comparisons are made.

b) For significant main effects, post-hoc pairwise comparisons are conducted by means of the Mann-Whitney test

**Mann-Whitney-Test**  
material = ide (11-20), tray = K, I

	46 Height Z Value
Mann-Whitney-U	20,000
Wilcoxon-W	75,000
Z	-2,268
Asymptotische Signifikanz (2-seitig)	,023
Exakte Signifikanz [2*(1-seitig Sig.)]	<b>,023<sup>c</sup></b>

a. material = ide(11-20)  
b. Gruppenvariable: tray  
c. Nicht für Bindungen korrigiert.

material = ide (11-20), tray = K, M

	46 Height Z Value
Mann-Whitney-U	28,000
Wilcoxon-W	83,000
Z	-1,663
Asymptotische Signifikanz (2-seitig)	,096
Exakte Signifikanz [2*(1-seitig Sig.)]	,105 <sup>c</sup>

a. material = ide(11-20)  
b. Gruppenvariable: tray  
c. Nicht für Bindungen korrigiert.

material = ide (11-20), tray = I, M

	46 Height Z Value
Mann-Whitney-U	21,000
Wilcoxon-W	76,000
Z	-2,192
Asymptotische Signifikanz (2-seitig)	,028
Exakte Signifikanz [2*(1-seitig Sig.)]	<b>,029<sup>c</sup></b>

a. material = ide(11-20)  
b. Gruppenvariable: tray  
c. Nicht für Bindungen korrigiert.

*Table 11: The above table showing Mann-Whitney-Test, to determine between which trays the significant differences lies*

Significant differences are to be seen in 46 Z Height (K11-K20 vs. I11-I20 and I11-I20 vs. M11-M20) This significant difference will later be found in a table marked with 

4. Results

Mann-Whitney-Test (for 32, 34, 36), tray=K, I (two-group comparison as no values for tray M) Significant differences are to be seen in:

material = Imp(1-10), tray=K, I

Statistik für Test <sup>a,b</sup>				
	32 X Value	32 Y Value	34 X Value	34 Y Value
Mann-Whitney-U	38,000	44,000	40,000	48,000
Wilcoxon-W	93,000	99,000	95,000	101,000
Z	-.907	-.454	-.756	-.302
Asymptotische Signifikanz (2-seitig)	.364	.650	.450	.762
Exakte Signifikanz [2*(1-seitig Sig.)]	.399 <sup>c</sup>	.684 <sup>c</sup>	.481 <sup>c</sup>	.796 <sup>c</sup>

Statistik für Test <sup>a,b</sup>				
	36 X Value	36 Y Value	Angle 32 X to Z	Angle 32 Y to Z
Mann-Whitney-U	39,000	43,000	47,000	41,000
Wilcoxon-W	94,000	96,000	102,000	96,000
Z	-.832	-.529	-.227	-.680
Asymptotische Signifikanz (2-seitig)	.406	.597	.821	.496
Exakte Signifikanz [2*(1-seitig Sig.)]	.436 <sup>c</sup>	.631 <sup>c</sup>	.853 <sup>c</sup>	.529 <sup>c</sup>

Statistik für Test <sup>a,b</sup>				
	Angle 34 X to Z	Angle 34 Y to Z	Angle 36 X to Z	Angle 36 Y to Z
Mann-Whitney-U	40,000	31,000	37,000	22,000
Wilcoxon-W	96,000	96,000	92,000	77,000
Z	-.756	-1.436	-.963	-2.117
Asymptotische Signifikanz (2-seitig)	.450	.151	.326	.034
Exakte Signifikanz [2*(1-seitig Sig.)]	.481 <sup>c</sup>	.165 <sup>c</sup>	.353 <sup>c</sup>	.039 <sup>c</sup>

Statistik für Test <sup>a,b</sup>				
	32 Height Z Value	34 Height Z Value	36 Height Z Value	
Mann-Whitney-U		15,000	42,000	29,000
Wilcoxon-W		70,000	97,000	84,000
Z		-2.646	-.605	-1.587
Asymptotische Signifikanz (2-seitig)		.008	.545	.112
Exakte Signifikanz [2*(1-seitig Sig.)]		.007 <sup>c</sup>	.579 <sup>c</sup>	.123 <sup>c</sup>

a. material = Imp(1-10)  
 b. Gruppenvariable: tray  
 c. Nicht für Bindungen korrigiert.

material = Ide(11-20), tray=K, I

Statistik für Test <sup>a,b</sup>				
	32 X Value	32 Y Value	34 X Value	34 Y Value
Mann-Whitney-U	50,000	32,000	49,000	42,000
Wilcoxon-W	105,000	87,000	104,000	97,000
Z	.000	-1.361	-.076	-.605
Asymptotische Signifikanz (2-seitig)	1,000	.174	.940	.545
Exakte Signifikanz [2*(1-seitig Sig.)]	1,000 <sup>c</sup>	.190 <sup>c</sup>	.971 <sup>c</sup>	.579 <sup>c</sup>

Statistik für Test <sup>a,b</sup>				
	36 X Value	36 Y Value	Angle 32 X to Z	Angle 32 Y to Z
Mann-Whitney-U	50,000	38,000	40,000	36,000
Wilcoxon-W	105,000	93,000	96,000	91,000
Z	.000	-.907	-.756	-1.058
Asymptotische Signifikanz (2-seitig)	1,000	.364	.450	.290
Exakte Signifikanz [2*(1-seitig Sig.)]	1,000 <sup>c</sup>	.393 <sup>c</sup>	.481 <sup>c</sup>	.315 <sup>c</sup>

Statistik für Test <sup>a,b</sup>				
	Angle 34 X to Z	Angle 34 Y to Z	Angle 36 X to Z	Angle 36 Y to Z
Mann-Whitney-U	43,000	44,000	38,000	47,000
Wilcoxon-W	96,000	99,000	93,000	102,000
Z	-.529	-.454	-.907	-.227
Asymptotische Signifikanz (2-seitig)	.597	.650	.364	.821
Exakte Signifikanz [2*(1-seitig Sig.)]	.631 <sup>c</sup>	.684 <sup>c</sup>	.393 <sup>c</sup>	.853 <sup>c</sup>

Statistik für Test <sup>a,b</sup>				
	32 Height Z Value	34 Height Z Value	36 Height Z Value	
Mann-Whitney-U		50,000	.000	18,000
Wilcoxon-W		105,000	55,000	73,000
Z		.000	-3.780	-2.420
Asymptotische Signifikanz (2-seitig)		1,000	.000	.016
Exakte Signifikanz [2*(1-seitig Sig.)]		1,000 <sup>c</sup>	.000 <sup>c</sup>	.019 <sup>c</sup>

a. material = Ide(11-20)  
 b. Gruppenvariable: tray  
 c. Nicht für Bindungen korrigiert.

Table 12: The above table showing Mann-Whitney-Test, two-group comparison.

Left side Impregum™ Tray K. vs. Tray I and the right side Identium® Tray K vs. Tray I

The Material Imp 1-10 for the angulation 36 Y to Z (K1-K10 vs. I1-I10) and 32 Z Height (K1-K10 vs. I1-I10). This significant difference will later be found in a table marked with 

The Material Ide 11-20 significant differences were seen in the 34, 36 Z Height (K11-K20 vs. I11-I20). This significant difference will later be found in a table marked with 

4. Results

**When comparing the impression materials to each other** nonparametric tests were used. Pairwise comparison of the two materials stratified by tray-group by means of the Mann-Whitney-Test.

For Tray K significant differences were seen:

42,44,32,34,36 Z Height (K1-K10 vs. K11-K20)

This significant difference will later be found in a table marked with 

	42 Height Z Value	44 Height Z Value	46 Height Z Value	32 Height Z Value
Mann-Whitney-U	11,000	19,000	43,000	1,000
Wilcoxon-W	66,000	74,000	98,000	56,000
Z	-2,948	-2,343	-,529	-3,704
Asymptotische Signifikanz (2-seitig)	,003	,019	,597	,000
Exakte Signifikanz [2*(1-seitig Sig.)]	<b>,002<sup>c</sup></b>	<b>,019<sup>c</sup></b>	,631 <sup>c</sup>	<b>,000<sup>c</sup></b>

	34 Height Z Value	36 Height Z Value	Angle 42 X to Z	Angle 42 Y to Z
Mann-Whitney-U	15,000	19,000	50,000	26,000
Wilcoxon-W	70,000	74,000	105,000	81,000
Z	-2,646	-2,343	,000	-1,814
Asymptotische Signifikanz (2-seitig)	,008	,019	1,000	,070
Exakte Signifikanz [2*(1-seitig Sig.)]	<b>,007<sup>c</sup></b>	<b>,019<sup>c</sup></b>	1,000 <sup>c</sup>	,075 <sup>c</sup>

Table 13: The above table showing Mann-Whitney-Test, to determine between which materials the significant differences lies

For Tray I and Tray M using the pairwise comparison showed no statistical differences.

#### 4. Results

The following represents the table showing a Two-Sample f-Test

Statistically significant values are marked with pink ( $P < .05$ ) for the f-Test.

From the nonparametric tests, the significant difference are marked with

- When comparing the trays to each other  Tray K, I, M with Impregum™ (K1-K10, I1-I10, M1-M10). Significant differences are to be seen in  
42 Z Height (K1-K10 vs. M1-M10)  
32 Z Height (K1-K10 vs. I1-I10)
- When comparing the trays to each other  Tray K, I, M with Identium® (K11-K20, I11-I20, M11-M20). Significant differences are to be seen in  
46 Z Height (K11-K20 vs. I11-I20 and I11-I20 vs. M11-M20)  
34, 36 Z Height (K11-K20 vs. I11-I20)
- Comparing the impression materials to each other  Material Impregum™ and Identium® with the 3 trays (K1-K10 vs. K11-K20 and I1-I10 vs. I11-I20 and M1-M10 vs. M11-M20)

For Tray K significant differences were seen:

42,44,32,34,36 Z Height (K1-K10 vs. K11-K20)

For Tray I and Tray M there were no significant differences.

Here the Impression Material was not a significant factor for the measured variables for the same tray/impression technique.

4. Results

Master Model		Two-Sample f-Test (Comparing the Variance)								
		K1-K10 vs. K11-K20	I1-I10 vs. I11-I20	M1-M10 vs. M11-M20	K1-K10 vs. I1-I10	K1-K10 vs. M1-M10	I1-I10 vs. M1-M10	K11-K20 vs. I11-I20	K11-K20 vs. M11-M20	I11-I20 vs. M11-M20
		K11-K20	I11-I20	M11-M20	I1-I10	M1-M10	M1-M10	I11-I20	M11-M20	M11-M20
42 X Value	-73,3538	0,1937	0,0257	0,0971	0,2149	0,2617	0,9025	0,8097	0,4535	0,6090
42 Y Value	33,9772	0,0008	0,4075	0,1118	0,1993	0,6303	0,4143	0,1205	0,1147	0,9790
44 X Value	-81,3135	0,1549	0,0528	0,0854	0,2544	0,2729	0,9643	0,5513	0,4320	0,8474
44 Y Value	44,7973	0,0036	0,2159	0,1208	0,4500	0,8043	0,6097	0,2611	0,1948	0,8571
46 X Value	-85,7214	0,1878	0,0654	0,0764	0,2887	0,3394	0,9134	0,6117	0,6338	0,9749
46 Y Value	58,2576	0,0055	0,1516	0,0992	0,3969	0,9435	0,3594	0,5073	0,1811	0,4894
32 X Value	-55,4742	0,1533	0,0376		0,2349			0,6221		
32 Y Value	33,9255	0,0265	0,4628		0,1629			0,8694		
34 X Value	-46,5374	0,1771	0,0372		0,2402			0,6947		
34 Y Value	45,9470	0,0666	0,3486		0,2683			0,8641		
36 X Value	-41,7183	0,1468	0,0614		0,3339			0,6029		
36 Y Value	58,7398	0,0711	0,2395		0,4040			0,8642		
42 Z Height	34,6207	0,0000	0,0006	0,6527	0,0182	0,0262	0,8738	0,8550	0,0023	0,0014
44 Z Height	36,6490	0,0000	0,0248	0,1289	0,0067	0,0145	0,7509	0,0822	0,0066	0,2685
46 Z Height	37,1221	0,0000	0,0000	0,0050	0,0461	0,0640	0,0004	0,0807	0,0249	0,5810
32 Z Height	35,1045	0,0092	0,1819		0,3580			0,6258		
34 Z Height	36,8131	0,0006	0,1489		0,1662			0,3565		
36 Z Height	37,1415	0,0040	0,1174		0,4861			0,4233		
Angle 42 X to Z	-0,3803	0,0442	0,5447	0,1612	0,0381	0,7755	0,0201	0,5006	0,3471	0,1126
Angle 42 Y to Z	-0,6766	0,0378	0,4753	0,1194	0,0327	0,6411	0,0111	0,5162	0,3047	0,7007
Angle 44 X to Z	1,0808	0,1065	0,5379	0,3898	0,2841	0,7995	0,4103	0,9628	0,0301	0,0271
Angle 44 Y to Z	-0,5021	0,5202	0,4830	0,1233	0,5115	0,4387	0,1582	0,4747	0,8793	0,5722
Angle 46 X to Z	0,7251	0,0002	0,1842	0,1954	0,0003	0,0001	0,7380	0,2780	0,2236	0,0261
Angle 46 Y to Z	-0,2129	0,0135	0,9948	0,3201	0,0109	0,0306	0,6566	0,9238	0,5191	0,5822
Angle 32 X to Z	-1,1653	0,5482	0,0746		0,7008			0,3985		
Angle 32 Y to Z	-0,8190	0,0677	0,3053		0,8251			0,0110		
Angle 34 X to Z	-0,8925	0,6378	0,4463		0,0086			0,1257		
Angle 34 Y to Z	-2,0531	0,0383	0,3856		0,7654			0,0102		
Angle 36 X to Z	-0,1400	0,3500	0,1787		0,2289			0,2809		
Angle 36 Y to Z	-0,5654	0,2870	0,1745		0,8654			0,8918		

Table 14: The table showing a showing a Two-Sample f-Test and Statistically Significant values are marked with pink ( $P < .05$ ) for the f-Test.

From the nonparametric tests, the significant difference are circled with purple for Impregum™, blue circle for Identium® and significant difference in the trays are circled yellow

4. Results

<b>K1-K10 vs. K11-K20</b>	<b>I1-I10 vs. I11-I20</b>	<b>M1-M10 vs. M11-M20</b>
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Comparing the impression materials to each other:  
nonparametric tests were used. Pair wise comparison of the two materials stratified by tray-group by means of the Mann-Whitney-Test.

<b>K1-K10 vs. I1-I10</b>	<b>K1-K10 vs. M1-M10</b>	<b>I1-I10 vs. M1-M10</b>	<b>K11-K20 vs. I11-I20</b>	<b>K11-K20 vs. M11-M20</b>	<b>I11-I20 vs. M11-M20</b>
------------------------------	------------------------------	------------------------------	--------------------------------	--------------------------------	--------------------------------

Comparing the trays to each other :

nonparametric tests were used.

The material Impregum® (Material = imp (1-10) and tray = K,I,M)

The material Identium™ (Material = ide (11-20) and tray = K,I,M)

For the open tray impression technique (42, 44, 46)

a) Kruskal-Wallis-Test was used (three groups K,I,M)

b) For significant main effects, post-hoc pair wise comparisons (K,I and K,M and I,M) are conducted by means of the Mann-Whitney-Test.

For the closed tray impression technique (32, 34, 36)

The Mann-Whitney-Test tray = K,I (two group comparison as no value for tray M)

Pairwise comparisons of the two materials stratified by tray-group by means of The Mann-Whitney-Test (imp (1-10) Tray K,I and ide (11-20) Tray K,I) were used.

## 5. Discussion

Thoroughly impression taking and the production of stone casts are the two main steps necessary to make a well-fitting restoration. To achieve mechanical adaptation and a biological seal of the mating implant components are two major prerequisites for the fabrication of well-fitting implant-supported fixed prostheses [54, 80].

This study, like the most observed studies regarding the accuracy of implant impression techniques was evaluating the dimensional changes of the casts produced in relation to the reference master model using an indirect measurements set up [6, 9, 21, 37, 47, 54, 58, 137].

For practical clinical purposes, an understanding of the magnitude and variability of distortion when employing certain methods and materials helps the clinician to determine which procedures provide the best chance for accuracy [15].

The aim was to investigate the deviations of the implant positions of the casts produced when using different tray systems and impression materials.

The setting expansion of the impression plaster, the shrinkage of the impression materials and the rigid fixation of the impression transfer copings may have distorted the interabutment relationship from that of the master cast.

## 5.1 Some numerical data

In order to have more understanding what relevance the data we have provided has to clinical aspects some numerical data may be interesting to know.

Research in periodontometry has shown that teeth can move in the bucco-lingual direction 56  $\mu\text{m}$  - 108  $\mu\text{m}$ . Teeth can have an intrusion of up to 28  $\mu\text{m}$ . Therefore a tooth can move up to 100  $\mu\text{m}$  within its periodontal ligament [25, 71].

The slight mobility of osseointegrated implants is ascribed to the “elasticity” of the investing bone [71]. An osseointegrated implant has extremely limited movement in the range of only 10  $\mu\text{m}$  [25].

In a good impression, there is a possibility of finding a discrepancy of 50  $\mu\text{m}$  in any axis. Distortion of a polyether and an A-Silicone can be up to ca. 100  $\mu\text{m}$  [47].

When comparing the cemented restorations to the screw type restorations one can say, that the cemented restorations can at least close the microgaps and prevent bacteria from entering the marginal gap, perhaps this may be a way to limit the vertical problems.

Measurements with accuracy of 4  $\mu\text{m}$  can be made directly on impression materials with implant components under ambient conditions [43].

A minimal discrepancy (22–100  $\mu\text{m}$ ) exists between impression copings and either the prosthetic abutment or the abutment replica [91, 116, 128].

Gypsum stones cannot reproduce detail much smaller than 20  $\mu\text{m}$  because their crystal size ranges from 15 to 25  $\mu\text{m}$ . Epoxy and polyurethane resins can reproduce detail down to 1 to 2  $\mu\text{m}$  making them highly compatible with the detail capture possible with polyvinyl siloxane impressions [94].

The expansion of the plaster setting may have a negative influence on positioning the analogues and consequently be a negative factor added to the basic requisites for achieving a passive fit [79,136].

The setting expansion of the type IV improved dental stones ranged from 0.14% to 0.21%. In an article by KIM ET AL, it is stated that type IV dental stone, has a linear setting expansion of 10% at most. A stable, low-expansion master cast material would be advantageous if multi-unit implant prosthesis were fabricated [44, 61].

The tolerable discrepancy of a framework over several implants is not known, but because discrepancies of less than 30µm in the fit of an implant-retained framework on multiple abutments cannot be detected clinically by experienced operators, therefore this figure could serve as a criterion between acceptable and unacceptable frameworks [6].

KLINEBERG AND MURRAY suggested that frameworks with gap widths up to 30 µm across 90% of the abutments cylinder area can be considered to have a good passive fit. [139]. They did not specify whether this was in the horizontal or vertical axis.

In the horizontal axis, some of these techniques in our study would satisfy this criteria, as the technique for example closed impression, prototype/custom tray using Identium® would fall within this 30 µm area.

If this criterion represents the vertical axis, then none of these techniques in our study would satisfy this criteria fully, as none of the techniques fall within this 30 µm area. With the exception of the 46 Z values with Open Tray, Impregum™ and a custom tray.

### **5.1.1 Results achieving less than 30µm**

From the results (for values of less than 30 µm) it seems as though the results being less than 30 µm, are more commonly found in the X and Y values. Less in the angulations and are only once achieved in the Z values.

Results achieving measurements under the 30 µm in the X values were found in:

Tray: closed prototype Impregum™ in position 32, 34, 36

Tray: closed custom Impregum™ in position 36

Tray: closed prototype and custom Identium® in position 32, 34, 36

Tray: open prototype Impregum™ in position 44.

Results achieving measurements under the 30 µm in the Y values were found in:

Tray: closed prototype and custom Impregum™ in position 32, 34, 36

Tray: closed Identium® in position 32, 34 prototype and in position 34, 36 custom

Tray: open prototype Impregum™ in position 44.

Tray: open prototype and custom Impregum™ in position 42, 44, 46 and for Miratray® Implant in position 46.

Tray: open Identium® prototype and Miratray® Implant in position 46.

#### In the Height Values

One result achieving a measurement of under the 30 µm in the Z values was found in:

Tray: open custom Impregum™ in position 46, with a high standard of deviation.

Results achieving measurements under the 30 µm in the X to Z Angulation Values were found in:

Tray: closed prototype Impregum™ in position 34

Tray: closed prototype Identium® in position 36

Tray: open Impregum™ in position 44 prototype and in position 42, 44, 46 custom and in position 42 for Miratray® Implant

Mostly in the open tray, Impregum™ and the custom tray for 42,44,46

Results achieving measurements under the 30 µm in the Y to Z Angulation Values were found in:

Tray: closed prototype Impregum™ in position 32, 34

Tray: closed prototype Identium® in position 32

Tray: open custom Impregum™ in position 42

### **5.1.2 Discussion regarding the various directions, the range < 30 µm and the 95% CI**

#### **The X- and Y-Direction**

For the X-direction, it seems as though more results were achieved < 30 µm for the closed impression technique, for both the prototype and custom tray and for both impression materials.

For the Y-direction, Impregum® with the prototype and the custom tray with the open impression tray achieved mostly good results and also for the closed impression technique using both the materials and the prototype and custom tray.

Three significant differences were noted between the master model to the various groups. These being in the Y-direction for I11-I20 (42, 44) and 44 for K11-K20. Comparing the various groups in their mean change to each other yielded in both the X- and Y-direction no other significant differences.

The standard deviation in the X-direction has a tendency of being higher than in the Y-direction. This can be due to the fact, that the inter-coping space is constant and smaller than the bucco-lingual direction, where the relation of material volume to space may be greater, leading to greater shrinkage, especially in the custom tray.

### **The Height**

For both techniques (closed and open tray impression technique), both materials and all three impression trays, showed that the laboratory analogues were at an increased distance from the occlusal plane, indicating that the final restoration was more likely to be in the supra-occlusion upon fitting (Height Z value increased).

In the closed impression technique, this could be due to the adhesive having a stronger bond into the direction of the tray lid.

In the open impression technique, this could be due to the bulk of material, even though the opening was kept to a minimal, the shrinkage was towards the opening, as most material (bulk) is found at that particular site.

In theory another reason could be that in the open tray impression technique, a failure of complete repositioning of the impression coping might have occurred.

Another explanation can be that in the closed tray impression technique, the re-insertion of the copings into the impression caps might also not have been fully repositioned. Even though utter most care was taken, that the impression copings were correctly seated or re-inserted.

However, finger tightening, can also cause inconsistencies. These can lead to vertical indiscrepancies. (The cautions taken to avoid these discrepancies are discussed in the Materials and Methods Section).

The assessment with regard to the vertical measurements, it is difficult to say which results are superior to the other. Whether one tray, material or method being here superior to the other. The mean change 46 Impregum™ and the custom tray gave a measurements of <30 µm. Yet the standard deviation was so high, that it is difficult to interpret as this method being the superior choice.

Comparing the master model with the various groups and the comparison of the groups themselves (95% CI, f-Test) most significant differences lay within the Height Zone.

The prototype with Impregum™ shows weaker results in comparison to the other two tray systems. Perhaps the prototype has a weaker compatibility with Impregum™ than with Identium®. Perhaps Identium® gave the prototype more elastic recovery.

In the Z Height values, one may assume that no ideal choice of tray/material/technique can be suggested for good height results from this study.

### **The Axial Inclination**

Small angular deviations are more disastrous for a multi-unit prosthesis than for a single-tooth restoration [7].

In the axial inclination, similar results were recorded within the open tray technique group and demonstrating more variable variations in the closed tray technique group.

This may indicate that in the closed tray impression technique group one may have less control of the movements of the impression caps in the impression material, and also perhaps the difficulty in the repositioning of the impression caps.

In the X to Z values, better results were achieved for both materials, techniques and all trays in the posterior region when compared to the anterior region (46, 36 vs. 42,32).

In the Y to Z values, better results were achieved for both materials, techniques and all trays in the anterior region when compared to the posterior region (42, 32 vs. 46,36).

The reason for this may be that in the anterior region one has a greater volume of material between 42 and 32 than between the tray walls and the implant 46 in the bucco-lingual direction. And the same reason being that between 42 and 44 Y to Z values, less volume of impression material lies in the region 42, 44, 32, 34 than distally to 46/36 in Y to Z values.

Or perhaps the greater differences in values between X to Z anterior for example may be caused by the removal of the tray. Distortions may have occurred, by removing the impression one has a bucco-lingual movement and once a loosening of the tray occurs then an anterior posterior movement occurs, hence anterior angulations being greater in X to Z and angulations being greater in Y to Z in the posterior region, due to less elastic recovery in this region.

One has to state, that a perpendicular removal was done, but slight movements had to occur, as the removal of the tray filled with impression material from the master cast and removing the impression from the gypsum, was quite difficult, even though no undercuts from the master model were present, but retentive patterns in the snap-fit plastic impression caps are present, as these caps have to be retained in the impression material.

The most difficult removals were from Impregum™, the closed tray impression technique and the custom tray. Easy handling was with the Identium® and the Miratray® Implant. The prototype fell between the two above.

## **5.2. Influence of the material**

In our study there is no pattern showing us that a certain material using a specific impression technique or tray is superior to the other.

One also has to keep in mind that where impression materials are compared, there is always a compatibility question regarding the material of the tray and the compatibility with the impression material or its adhesive.

According to the statistical analysis the impression material was not a significant factor for the measured variables for the custom tray and Miratray® Implant.

Significant differences were seen for Tray K 42, 44, 32, 34, 36 Z Height (K1-K10 vs. K11-K20).

Which means that these readings differed significantly when using the Tray K and between the two materials. So the choice of material for this tray played a significant role.

The Tray K is rigid. It may be that with a rigid tray and a rigid material, as Impregum™, there was not enough elastic recovery offered. And hence the opposite being for the material Identium® allowing for example enough elastic recovery and hence the values being significantly different for the two materials for the tray K. And for both impression techniques.

There is something one has to keep in mind regarding the elastic recovery. The DIN 13 945 Test shows the following: A cylinder of a diameter 12,5mm is filled with the impression material (elastomer) to 20mm.

Pressure is applied and the material is allowed to compress 2mm (10%), 4mm (20%) and 6mm (30%). Thereafter the elastic recovery is recorded with the measurement of the remaining measurement after the pressure measurements minus the initial measurement. The compressed thickness stresses the importance of tray space [81].

Discrepancies detected for both polyvinyl siloxane and polyether materials may result, among other reasons, from the incomplete elastic recovery or from the residual polymerization, resulting in the shrinkage of the impression [98].

During polymerization, new covalent bonds are formed within the molecules, reducing the volume occupied by them. Thus, the shrinkage resulting from material polymerization will contribute to the loss of accuracy over time [98].

Removing the copings can cause less than ideal elastic recovery from the deformation and may cause an inaccurate relationship of working cast implants [15].

### **5.2.1 The polyether, Impregum™**

The polyethers show their strong points with their hydrophilicity, flowability, precision and dimensional stability [28]. This in-vitro-study offered dry conditions for Impregum™, yet

other studies showed that the material rendered the best detail under slightly moist conditions [126].

Traditional polyether impression materials have been considered to be the least flexible on setting and evidenced by a low strain in compression or low instantaneous elastic creep compliance and higher surface hardness [121].

Removing the copings can cause less than ideal elastic recovery from the deformation and may cause an inaccurate relationship of working cast implants [15].

Polyether has been suggested as the material of choice for implant impression procedures, a more elastic impression material could hypothetically reduce the permanent deformation of the impression [18, 37].

The standard deviation by Impregum™ was also most of the times higher than that of Identium®. With the only exception seen with the Miratray® Implant with the angulation 44, 46 X to Z values.

The greater amount of the higher standard deviations may be due to the fact, that Impregum™ is very rigid and by impression tray removal, eventually causing more distortion and maybe have a less than ideal elastic recovery. A higher standard deviation (SD) may indicate a greater variation in replacement of the copings/greater variations of results and hence a greater SD.

Better mean values were achieved in the X values with the closed impression tray technique. Looking at the Y values, good results were achieved with the open and closed impression tray technique.

In the X to Z values, better achievements can be seen in the open impression tray technique. This may be due to the fact that in the opening less material volume is present then in the bucco-lingual direction as in the closed tray impression technique.

Slightly better results are seen in the Y to Z values in the closed impression tray technique.

### **5.2.2 The vinylsiloxanether, Identium®**

Although polyether has been suggested as the material of choice for implant impression procedures [18], a more elastic impression material could hypothetically reduce the permanent deformation of the impression material determined by the stress between the material and impression copings created when an impression with the copings is removed from internal connection implants [37].

The lower standard deviation seen by Identium® may be due to the following:

The elastic recovery of Identium® is almost at 100% [Kettenbach]. (The physical properties of an A-Silicone are responsible for this physical property).

Recovery i.e. it is flexible enough during the removal, in order not to cause any tearing of the fine detail reproduced in the impression. And not cause any breakage of the gypsum model upon removal of the impression [81].

The shark fin test done by Kettenbach shows that the flowability of Identium® stays constant over the entire working time. (Discussed under the section Thixotropic). A balance is achieved with the elasticity and the flowability.

The main objective is to try to keep the copings in their original exact position. Therefore with the pick-up impression technique, a rigid material should inhibit rotation [137].

Materials with a high dimensional stability should not shrink/contract or swell [110].

In the X and Y values it certainly showed good mean results in the closed impression tray technique. The physical properties, may allow the copings to be kept in place, have a good elastic recovery, and hence minimize distortion.

The standard deviation in X and Y values seems to always be smaller with Identium® than with Impregum™. There seems to be a good compatibility regarding the prototype and Identium®.

### 5.3 Influence of the tray

Looking at the comparisons which trays were accompanied with the  $< 30 \mu\text{m}$  measurements, that the Miratray® Implant had the least measurements below  $30 \mu\text{m}$ . There were two readings where Miratray® Implant gave acceptable results. Using Impregum™ & Identium® in the open tray impression technique with the measurements of 46 Y values. And using Impregum™ in the measurement 42 X to Y, perhaps indicating that Impregum™ gave enough rigidity for the copings with this tray, during this particular situation in the Y to Z angulation.

Otherwise it seems as though the prototype and the custom tray had similar results, irrespective which material or technique was used.

In a study done by THONGTHAMMACHAT, found that the custom tray produced better results with an A-Silicone than with a polyether [53]. This is not the case in this study, as the custom tray also performed well with Identium® as well as with Impregum™. And so did the prototype.

According to the statistical analysis the choice of tray for using Impregum™ had statistically significant differences in

42 Z Height (K1-K10 vs. M1-M10)

32 Z Height (K1-K10 vs. I1-I10)

Impregum™ being rigid and looking at the differences in the Height between the K1-K10 vs. M1-M10, one may assume, that the tray lid of M1-M10 was not as rigid/stable as K1-K10.

The differences may lie within the K1-K10 trays in combination with Impregum™. This group having the 42 Height values more similar to the master model more than the M1-M10 group.

According to the statistical analysis the choice of tray for using Identium® had statistically significant differences in

46 Z Height (K11-K20 vs. I11-I20 and I11-I20 vs. M11-M20)

34, 36 Z Height (K11-K20 vs. I11-I20)

### 5.3.1 Custom tray

The primary purpose of the custom tray is to provide an even thickness of the layer of impression material. Dimensional changes that occur during the setting of elastomeric impression materials are proportional to the thickness of the material [127]. Polymerization shrinkage occurs in areas of greater bulk of material. Dimensional changes are minimized when the thickness is held constant between 2 mm to 3 mm [125, 127].

Even though the custom tray is subjected to standardization, it is still handmade and each custom tray could have varied a minimal. Hence internal spaces for the impression material might have also varied to a minimal. As a result, the impression material thickness cannot be fully controlled, which may lead to increased variability among the dental casts produced.

This could explain (as the material volume varies) why the standard deviation by the custom tray was in certain results greater than the other two trays.

For example:

X values 42 I1-I10 > K1-K10, 32 I1-I10 > K1-K10

X values 36 I11-I20 > K11-K20, 34 I1-I10 > K1-K10

The standard deviation was not much of a great difference in the Y values. An explanation for this may be due to the distances (the volume of the impression material) between the impression copings between each tray type stays constant.

The custom tray, made up of a light-curing pink acrylic tray material (bredent GmbH & Co. KG) performed poorly with Impregum™, but not with Identium® in the X value. This might be due to the tray material might not be compatible with the polyether impression material adhesive used.

And hence, the X values might have altered more (the X-direction), as the volume of the material might have altered a bit more from the custom trays in the bucco-lingual direction, causing a greater mean value and higher standard deviations.

The custom tray performed in the Y values better with Impregum™ than the Identium® material. But in the Y values the influence would rather be the inter-copings spaces and not the tray walls, as in the X value.

When deciding whether to use a custom tray rather than a stock tray, the dentist must decide if the advantages outweigh the disadvantages. The advantages of using a custom tray include a more accurate impression, manipulation of the impression material, reduced costs, and improved restoration fit. The disadvantages of using a custom tray, is: material compatibility, fabrication costs and time expenditure, as well as increased health concerns if a monomer is used in fabricating the tray.

### **5.3.2 Prototype tray**

In the open impression technique with Identium® the three trays seem to give similar results and in the closed tray, with Identium®, the prototype gives the better results. This could also be due to the elastic recovery that Identium® offers yet the material being rigid enough to hold the impression caps in place. But offering enough elastic recovery to inhibit distortions

A greater standard deviation in comparison to the other trays is seen in 46 K1-K10 X to Z values. Perhaps the tray wall flexibility could play a role. It may be that for this particular posterior region Impregum™ did not offer enough elastic recovery.

The prototype performed poorly with polyether, but not with Identium®, in the X, Y and Z values. In this situation, the prototype might not be compatible with the polyether impression material used. Or Impregum™ not offering elastic recovery for the prototype tray.

Perhaps with the prototype tray and the closed tray impression technique, the control of the impression material volume was slightly better than with the open tray impression technique. As seen when one compares the 42 X values for K1-K10 closed with the K11-K10 open impression tray technique's values.

Most stock trays are open distally. One can assume, that here, Impregum™ did not offer enough elastic recovery for 36 in the Y to Z value. In comparison 36 Y to Z values K11-K20 had better results than I11-I20 36 Y to Z, even though I11-I20 the custom tray was distally

closed. This is another indication, that for the prototype Identium® gave enough elastic recovery.

In contrast to the above mentioned, 36 Y to Z, K1-K10 performed weaker to I1-I10 with Impregum™. (As mentioned above with Identium® it was the opposite).

This is somewhat difficult to explain, but the material consistency of Identium® may be better suited for the prototype tray with limited side support compared to the custom tray. And that the Impregum™ may be better suited for a custom tray, as the side support is better in this situation, as the periphery of a custom tray is longer and offers more cover of the structures.

However, the sides of prototype tray are more extensive and support the impression material to a greater extent than the Miratray® Implant, as seen in the results of the Y to Z values Miratray® Implant vs. prototype, yielding the Miratray® Implant with weaker results.

In the X values, compared to the Y values, the prototype tray has the same pattern as the custom tray. The standard deviations are higher in the X values than in the Y values.

The same argument can be used, regarding material volume being greater in the bucco-lingual direction than the inter-coping spaces. Hence linear polymerization shrinkage occurs in areas of greater impression material bulk, therefore in this case, in the buccal-lingual direction.

The advantages of a stock tray, is that the trays are ready availability, easy to handle, low in costs, time saving and the elimination of the need for fabrication. Perforations in the prototype tray increases mechanical retention and hence also reducing distortion.

Disadvantages are the wastage of impression material and the necessity of modifying the stock tray to ensure proper fit to the patient's mouth.

In the past, a custom tray was considered to be a must. These days materials are so good, that a stock tray should be sufficient.

### **5.3.3 Miratray® Implant**

For the first time it was interesting to see that in the X to Z values, the angulations of 44 and 46, the standard deviation of Identium® was greater than that of Impregum™, with mostly weaker results in comparison to the custom trays.

Perhaps in comparison to the other two trays, the Miratray® Implant being the least rigid, did not work as good in conjunction with the Identium®.

Here it is seems as though the Identium® and the Miratray® Implant would not be a good choice, if the angulations or a multiple implant prosthesis was being planned. It may be that Identium® did not offer enough rigidity between the impression coping and the tray wall and hence the standard deviation being greater than Impregum™.

The tray does not seem to have too much rigidity. The foil has an advantage of being able to see very well, it seems as though one can produce a clean impression, but the tray seems to be rather flexible.

If we compare the X and Y values for all trays, one will notice that the greater mean values and the higher standard deviations were mostly in the X values.

It may be that the physical property of the tray allowing tray flexure. Even when the tray material recovered, the impression material was permanently deformed. Many reports suggest that tray flexure may be the cause of the impression and cast distortion [76, 111, 132].

If the tray wall flexes, then when seated one can expect an outward flexure, residual stress remains in the tray wall. This causes recoil and deforms the impression upon removal [112].

WASELL AND IBBETSON identified poor fitting stock trays and consequent tray wall flexure as the greatest concern for inaccuracy.

The last tooth in the arch has the disadvantage of being the region with the greatest tray flexibility and a complex flow of impression material.

Irregularities in stock trays could be related to the difficulty in accurate orientation of the impression coping and abutment replica assembly in the final impression.

In a study by SPECTOR ET AL, sectioned the impressions and often demonstrated air entrapment and incomplete seating of the impression tray, which may have impeded accurate placement of the transfer impression coping assembly [22].

## **5.4 Influence of the impression technique**

Looking at the comparisons as well as the mean change and the standard of deviation, it seems as though both impression techniques revealed similar results, irrespective which material or tray was used.

Discrepancies might mean that, there may be a need for adjustments or in some cases even a remaking of the final restoration.

One may suppose that both methods could be used. In certain situations, as a lack of interarch space or a gag reflex, a snap-fit impression technique could be useful.

It seems as though the impression technique was not a significant factor of any of the measured variables. Where weak values were found, then both techniques were involved, as for example the height measurements.

### **5.4.1 The open tray impression technique (pick-up/direct pick-up impression technique)**

For this procedure it is important to avoid movements of the impression copings inside the impression material throughout the procedure associated with fabrication of casts.

The problem in this procedure is that there may be an accidental rotation of the impression copings. Unscrewing the guide pins from the impression copings when the tray is removed from the mouth or screwing the matching abutment replicas in the impression, may cause minor movements and thus influence the cast accuracy [71].

When looking at the graphs, for example at Implant 46 Height K1-K10. No good mean values is achieved and a large standard deviation is present.

It could be, that there was no proper seating of the impression coping. Or perhaps incorrect positioning of the laboratory analogue into the coping, leading to this larger standard deviation.

46 X to Z values in Impregum™ K1-K10: The mean values and standard deviations are here greater than by Identium® K11-K20 open impression technique and in the closed tray impression techniques. Perhaps indicating, that Identium® gave more elastic recovery to the

impression coping and prevented movements of the coping 46, or that Impregum™ was too rigid and added to the greater standard of deviation.

Perhaps with the manipulation of unscrewing the coping may have lead to a great standard of deviation.

#### **5.4.2 The closed tray direct snap-on impression technique (snap-fit plastic impression technique).**

Errors here are probably introduced during the re-insertion of the copings into the snap-fit plastic impression copings situated in the impression. A similar error is seen by the research of SPECTOR ET AL. There the error is suspected to be with the re-insertion of the tapered copings into the impression.

It seems simple and easy to handle, however care must be taken that the three-dimensional positioning of the cylinders with the impression caps in the impression may be a problem during the removal of the impression [54]. The removal of the impression tray can cause distortions in the impression.

The resin cap remaining in the impression should improve the accuracy of repositioning the transfer copings and the resulting cast [17, 58].

Perhaps due to the re-insertion of the copings into the snap-fit impression cap, some lateral discrepancies occurred. Or perhaps by removing the impression material distortion occurred.

34 X to Z values, the mean values are greater here in the closed impression technique using Identium®.

Identium® might be rigid enough, but in this case, due to the difficulties in the removal of the custom trays, and Identium® being easier to remove, yet in this case perhaps not offering enough rigidity for the snap-fit impression caps and causing distortions.

36 Y to Z values have greater mean in both materials in comparison to the open tray technique.

Here, again the removal of the tray after impression taking or re-insertion of the copings into the snap-fit plastic impression copings, causing distortion in the angulation values. Also 36 Y

to Z being in the last tooth in the arch of this master model and therefore having the greatest tray flexibility and a complex flow of impression material taking place in this region.

## 5.5 The clinical relevance

The clinical relevance of these statistically significant differences and or the measurements < 30 µm is questionable and the application of these findings to clinical situations could be a complex task. Despite the differences found, the outcomes using both techniques and impression materials and the trays appear to be comparable.

Several studies reported the superiority of the open tray impression technique [9, 15, 55]. Similar to this study, other studies reported that both impression techniques provided comparable results [6, 21, 73].

In studies by AKÇA ET AL, LIOU ET AL. as well as WEE ET AL., found that the accuracy of casts produced by direct and indirect impressions technique for implants were similar, similar outcomes have been found in this study.

In a study by STOBER, the results for the VSE (Vinylsiloxanether, Identium®) were similar as to PE (Polyether) and VPS (polyvinyl siloxane).

Some studies found no significant differences between PE and PVS [47, 55, 84, 99, 124]. Regarding the comparison with VSE, one must keep in mind the studies regarding the VSE, are on prepared teeth. More studies are perhaps needed in the implantology section.

As far as the trays are concerned, in a study by BURNS [30] showed that casts from the stock trays were statistically significantly less in the mean fit of accuracy of than the mean fit of accuracy of the casts produced from the custom trays. Best maintained accuracy was achieved in a study by LACY [102], by using a custom tray.

In our study similar results were found for the prototype (stock) tray as for the custom tray, as other studies have shown [27, 30, 31, 76, 101].

This similarity in outcome between the two impression techniques, two materials and trays, may imply that the snap-on pick-up impression technique used with a stock tray and a vinylsiloxanether impression material is an effective method, and that the “Golden Standard” using an open tray impression technique, with a custom tray and the use of Impregum™ [15, 45, 54], may be something of the past. We may widen our horizon as materials and trays and impression techniques keep on developing.

Whether or not certain horizontal  $\mu\text{m}$  measurements will have an influence on the implants and superstructures, or the changes in degrees, and what amount of change is clinically relevant, may be answered by future studies that evaluate the fit of a framework on the casts using an electronic microscope (to measure the size of the gap) or strain gauges. Strain could be measured and then correlated to misfit in the prosthesis [74].

Developing a method to test strain clinically would be a valuable objective tool for clinicians to evaluate framework fit [74].

### **5.6 Possible reasons for the inaccuracies during the study**

Numerous precautions were taken to reduce the possible impact of extraneous factors.

All handling and mixing procedures of impressions and die stone materials were either carried out according to manufacturers' instructions or subjected to standardization. And all procedures were carried out by one operator.

In order to achieve optimal results for this in-vitro-study, pre-impression taking and practicing with the impression material, the trays, the implant system and the pouring of the plaster and some pre-measurements with the Zeiss Prismo were done prior to the actual study.

To improve the accuracy of impressions and cast fabrication, one has to take caution with every step during the procedure. One has to have knowledge about dimensional changes in the materials, inaccurate repositioning of the copings and improper connection of the components.

Finger tightening, can also cause inconsistencies. These can lead to vertical indiscrepancies. The analogues were not tightened carried out with the torque control unit at 10 Ncm.

In daily work, the technician and clinician use different closure torques and tightening sequences.

Thus, it would seem logical to apply the same torque and tightening sequences throughout the fabrication process, starting with the abutment analogues to the impression copings, the removal of the impression from the oral cavity and continuing through all the laboratory procedures.

### **5.7 The limitations of this study**

The impressions were made from a resin master cast. These conditions differ from those of teeth in the natural oral environment, since soft tissue was not present, nor was saliva or sulcular fluid, and the intraoral temperature would be different. Also the disinfection of the impressions taken from the resin master model did not take place.

The resin master model die does not have the same behaviour as oral tissue.

It does not absorb liquids; it contains no surface free energy of proteinaceous surfaces of prepared teeth and tissue. Keeping in mind, that the surface energy will affect how well impression will wet the surface.

Intraoral situations can have undercuts, exostoses, angulations of teeth or of the abutments and buccal pressure. This makes the removal of the impression material much more difficult. Other intraoral aspects as unbalanced occlusion and parafunctional habits are of course also excluded in an in-vitro-study.

A lack of parallelism between implants and implant and teeth is commonly encountered in implant prosthodontics and may create an undesirable path of withdrawal and subsequently distortions of the impression [2]. Smaller angular deviations are more disastrous for the multiple-unit prosthesis than for the single-tooth restoration [7].

The displacement of the impression copings during impression taking and the displacement of the abutment replicas while fabricating the definitive casts were not measured. The total amount of displacement from the impression and cast fabrication was measured.

A difficult part of this study was to design a master model to fit all trays. This could be a slight limitation to all trays, but a good comparison could not have been made if three different models to fit each tray would have been used.

It is uncertain what long-term effect strains of the magnitude recorded in this investigation may have on the bone and the prosthesis.

Considering the limitations of this in-vitro-study, it was shown that vinylsiloxanether and polyether monophase impressions display acceptable accuracy for clinical use, since the results for vinylsiloxanether were comparable to the results for polyether.

Significant statistically differences were observed among the two impression materials for the tray K regarding the heights. Three various impression trays were compared to each other using Impregum™ and using Identium® regarding the heights as well.

The clinical impact of these differences is difficult to assess, as all combinations showed some weaknesses but also some strengths.

## **5.8 Conclusion**

It seems as though the clinician has to choose which errors he prefers.

An ideal impression technique would require minimal time, be easy to use, inexpensive, and comfortable for the patient and gives the best results [57].

Under the conditions of this study, the following conclusions can be drawn with respect to the accuracy of transfer techniques for implant impression taking:

1. The outcomes achieved with the two impression techniques were similar.

Our study shows that both impression techniques could be used. In certain situations, as a lack of interarch space or a gag reflex, a snap-fit impression technique could be more useful.

2. The outcomes achieved with the two impression materials were similar.

## 5. Discussion

Although polyether has been suggested as the material of choice for implant impressions, our study shows that a vinylsiloxanether can also be an effective implant impression material as it shows comparable results to the polyether.

3. The outcomes achieved with the three impression trays K, I, M with Impregum™ were similar. We can assume from our study that the two materials were so good, that the two stock trays were sufficient, because the custom tray did not achieve better results.

4. The outcomes achieved with the three impression trays K, I, M with Identium® were similar. Custom trays are considered to be a must but our study shows that the prototype tray and the Miratray® Implant offered good results and could be used for daily routine. It has to be regarded that under clinical points of view the positioning and motionless keeping in place of a custom tray might be easier.

5. When comparing the master model to the casts produced, the best results were achieved in the X-direction. We can assume that the material thickness varied the least in this direction or the least abutment movements took place in this direction.

6. The weakest results when comparing the master model to the casts produced were seen in the Height Z.

Even though most care was taken with standardized methods, one may assume that unfortunately no ideal choice of tray/material/technique can be suggested for good height results from this study. The restorations produced would be too high intraorally which means that there would be a need for adjustments or in some cases even a remaking of the final restoration.

In our study the exact, that means one hundred percent equal reproduction of implant positions in a cast obtained from an impression was not possible even under idealized and standardized conditions.

One would need to compare this study with a digital method and see what outcomes would and could have been achieved in this given situation.

A passively fitting prosthesis is fabricated to prevent prosthodontic complications and loss of fixture integration.

## 5. Discussion

Discrepancies of less than 30  $\mu\text{m}$  on multiple abutments cannot be detected clinically by experienced operators so this figure could serve as a criterion between acceptable and unacceptable frameworks. We can ask ourselves whether this was achieved in this study.

Even though there were a few measurements below 30  $\mu\text{m}$ , yet from this study we can presume that we would have not reached a gap-free and tension-free dental structure, if we were to fabricate them.

Unfortunately, not in a single impression method (one tray, one impression technique and one material) offered continuous measurements throughout the various values (x, y, height and angulation) of measurements lower than 30 $\mu\text{m}$ .

If we look at the study from the SAE technology perspective, where a maximum gap of 5  $\mu\text{m}$  can be achieved allowing a gap-free and tension-free precision fit of the dental structures on implants and implant-abutments.

Even though we used conventional impression methods, we even achieved a few measurements below 5  $\mu\text{m}$  but there are not enough measurements in order to obtain a tension-free situation.

For the purpose of our study, we can conclude that the comparison of impression methods, materials and trays gave similar results and therefore offering a possible alternative for conventional implant impression taking.

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