Ocular impression-taking - which material is best?

Jennifer M Turner PhD[1], Christine Purslow PhD[1] and Paul J Murphy PhD[1,2]

[1]Cardiff University, School of Optometry and Vision Sciences, Cardiff, UK

[2]University of Waterloo, School of Optometry and Vision Science, Waterloo, Canada

Address for correspondence:

Prof Paul J Murphy

University of Waterloo

School of Optometry and Vision Science

200 Columbia Avenue West

Waterloo, N2L 3G1

Ontario, Canada

Email: pjmurphy@uwaterloo.ca

Tel: (1) 519 888 4567, ext 32020

Fax: (1) 519 725 0784

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Abstract

Objectives: To assess the efficacy and effect on clinical signs of a polyvinylsiloxane (Tresident™ (Shütz Dental Group GmbH, Germany) compared to an irreversible hydrocolloid (Orthoprint™, Zhermack SpA, Italy) for ocular impression taking.

Methods: Twenty subjects were recruited (13 female and 7 male), mean age 31.1±4.6 years [SD] (range 25.8 to 39.7). Subjects attended for 2 sessions, each of 1 hr duration, on 2 separate days. Each session was scheduled at the same time on each day. At each visit the subject underwent an ocular impression procedure, using either Tresident or Orthoprint, in random order and to one eye only. Investigator 2 was blind to this assignment. Two experienced practitioners carried out the study, Investigator 1 performed the ocular impression procedures and Investigator 2 observed and assessed the clinical signs: logMAR visual acuity (VA), ocular surface staining, tear break-up time (TBUT), and ocular hyperaemia.

Results: VA was unaffected by either material; TBUT was marginally disrupted by both materials, but was not clinically significant according to published criteria; ocular redness increased with both materials; corneal staining was significantly greater after Orthoprint impression. Less redness and clinically insignificant staining following impression-taking, with fewer clinical complications, was found following use of Tresident.

Conclusions: Tresident offers a quicker, more effective and clinically viable method of obtaining ocular impression topography compared to the traditional Orthoprint; and Orthoprint causes significantly more superficial punctuate staining of the corneal epithelium than Tresident.

Keywords: ocular impression, ocular surface, ocular prosthetics, materials

The purpose of taking an impression of any surface is to mould the negative dimensions of the structure and make a model of the 'positive' physical properties, which then provides an accurate representation of the shape, parameters and spatial relationships. Ocular impression taking is used in scleral contact lens fitting and ocular prosthesis manufacturing. In both situations, an accurate representation of the existing ocular surface is critical for success[1]. For example, in scleral contact lens fitting, the eye impression produced enables the manufacture of the lens to match with the patient's ocular surface topography. Alternative optical methods are now available, and used, for scleral lens fitting, but ocular impression-taking remains a vital component of the clinician's toolkit, and will also provide information over a larger scleral area. Ocular impression taking is also relatively inexpensive, can be used outside of the clinical office room, and are reproducible[1,2]. To our knowledge, no studies have been published that report on the effect of impression taking on the ocular surface, in a comparison between two established impression materials.

The characteristics of the 'ideal' ocular impression material include: minimal deleterious effects on the anterior ocular surface (AOS) or exposed ocular adnexa by the material; no lasting discomfort after the procedure (topical anaesthetic blocks the sensory corneal nerves during the procedure); high accuracy - the acceptable magnitude of error in impression taking is determined by its desired application, e.g. gas permeable contact lens manufacturing requires high accuracy (±0.05mm) to match the manufacturing tolerances of BS/EN/ISO/18369-2:2012[3]; excellent dimensional stability to ensure the material is not deformed by plaster pouring, or degraded by environmental conditions or physical manipulation; good flow characteristics and reasonable in-eye working time to allow sufficient time for the material to be applied to the impression tray and inserted without setting; rapid curing or setting time to reduce the amount of time required to maintain the material against the eye, thereby reducing artefacts incurred by random eye movements; and, excellent compatibility with gypsum dental stone (some impression materials are known to cause chemical degradation of the gypsum cast surface).

Cold, irreversible hydrocolloids or alginates (e.g. Orthoprint™, Zhermack SpA, Italy), which have been used for ocular impressions since the introduction of Ophthalmic Moldite[4], exhibit poor dimensional stability and poor tear

strengths, leading to inaccurate casts and the need for multiple impression-taking procedures[5,6]. The impressions formed are affected by: (1) the level of airflow around the impression, which causes evaporation of water from the gel, resulting in shrinkage; (2) by water, which causes the gel to expand by imbibition and absorption; (3) by high relative humidity, which induces syneresis and shrinkage; and (4) by in-organic salts, which affect the gel and cause physical changes that are dependent on their osmotic potential[7].

Orthoprint (Zhermack SpA, Italy) is a yellow, dust-free, alginate, irreversible, hydrocolloid impression material, which conforms to BS/EN/ISO/21563:2013[8], with origins in dental practice (Table 1). It provides good surface detail[9], is easy to use and mix, is cheap and has a long shelf-life, numbered in years[7]. The setting time can be controlled with water temperature and, as a gel, it is non-toxic and non-irritant[10]. However, it has relatively poor dimensional stability, compared with elastomers, and a low tear energy[11]. It is incompatible with Type 1 or 2 gypsum plaster[12,13], reacts to humidity, and has a very short on-eye setting time (45 secs). The mixing process is messy and dependent on operator handling. Automated mechanical mixing has been shown to increase speed and quality of alginate sol, eliminating casting imperfections[14]. For these reasons, the use of alginate for ocular impression-taking has been superseded by silicone rubber-based materials.

Polyvinylsiloxane polymers appear to allow reproduction of the greatest detail of all dental impression materials[15]. Indeed, the material provides sufficient detail to identify individuals by fingerprint analysis[16]. This level of accuracy is defined by BS/EN/ISO/4823:2015[17], which requires that all Type 3, light-bodied, elastomeric materials be able to reproduce a line 0.02mm in width. In addition, these materials have been found to have very low shrinkage (0.05-0.1%), during the polymerising process[18], and are well-matched to the setting expansion of Type 4 gypsum plaster, which is used to cast the impression[19].

Tresident™ (Shütz Dental Group GmbH, Germany) is a low viscosity, addition-polymerising, polyvinylsiloxane precision impression material with hydrophilic properties, which conforms to BS/EN/ISO/4823:2015[17] (Table 1). It is supplied in an auto-mix dual-cartridge, which requires a dispensing gun to automatically mix and advance equal

quantities of each siloxane-based component through a purpose-designed mixing cannula (Injector DS 50, Dreve Otoplastik GmbH, Germany). Tresident provides a working time of 1 min 15 secs, with a setting time of 2 mins 45 secs, giving a total setting time of 4 mins. During the setting time, the impression tray and material must be held against the ocular surface under gentle pressure. Plaster casts can be produced from the moulds, and can be poured from 1 hr to 14 days after the procedure. Further casts can be produced from each Impression, which are as accurate as the original, for up to 7 days[20], but to do so the impression material must be kept in a dry place at 18-25°C. Re-heating the impression to 37°C before pouring the plaster has been shown to improve accuracy of casting. However, it is doubtful if this is clinically significant[21].

The two components of the material are a polymethyl-hydrogen-siloxane copolymer of moderately low molecular mass, which contains silane terminal groups, and an accelerator material of a similar molecular weight, which contains vinyl-terminated polydimethyl siloxane. When mixed, the silane and vinyl groups react, catalysed by chloroplatinic acid (a homogenous, metal complex catalyst). The cross-linking that occurs during the polymerisation process causes minimal dimensional change and there are no by-products[22]. Both components contain fillers, amorphous silica and a low molecular weight retarder to delay the onset of polymerisation. Additionally, the base component has an emulsifying surfactant that improves the wettability of the impression. Colouring agents are added to distinguish between the two pastes and aid the evaluation of mixing process.

Polyvinylsiloxane materials have been found to have good long-term dimensional stability (up to 2 weeks), are not susceptible to changes in humidity, and do not undergo further chemical reactions or release by-products[15]. Tests carried out on intact rabbit skin concluded that the primary skin irritation of polyvinylsiloxane can be considered negligible[23]. For these reasons, it is considered a superior alternative to the irreversible hydrocolloids. Sydiskis and Gerhardt (1993)[24] also showed that while both polyvinylsiloxane and irreversible hydrocolloid materials have a cytotoxic effect on cell culture, the risk of producing an adverse reaction is low. However, the effects of the material on the tear film and adnexa, although considered clinically acceptable, have not previously been reported.

This study used a single-blind, randomised control trial to assess the efficacy and effect on clinical signs of a polyvinylsiloxane (Tresident) compared to an irreversible hydrocolloid (Orthoprint) for ocular impression taking. The hypotheses proposed are that: (1) Tresident offers a quicker, more effective and clinically viable method of obtaining ocular impression topography compared to the traditional Orthoprint; and (2) Orthoprint causes significantly more superficial punctuate staining of the corneal epithelium than Tresident.

Materials and Methods

Twenty subjects were included in the study, (13 female and 7 male), mean age was 31.1±4.6 years [SD] (range 25.8-39.7). Volunteers were recruited from staff and students of Cardiff University, and subjects were excluded if they were pregnant or breastfeeding; had any ocular or systemic condition known to affect the structure or characteristics of the AOS; were taking any medication known to affect the ocular surface; had worn rigid contact lenses in the preceding 6 weeks or soft contact lenses in the preceding 2 weeks. Ethical approval was sought and granted in accordance with the Tenets of the Declaration of Helsinki (2004) from the Cardiff School of Optometry and Vision Sciences Human Research Ethics Committee.

Subjects attended for 2 sessions, each of 1 hr duration, on 2 separate days. Each session was scheduled at the same time on each day. Two experienced practitioners carried out the study: one performed the ocular impression procedures (Investigator 1), and the other observed and assessed the clinical signs (Investigator 2). The practitioners carried out their investigations in separate rooms without any knowledge of the other's results. Each subject was randomly assigned to receive an ocular impression in one eye, using one of the two impression material, by a study administrator. Investigator 2 was blind to this assignment.

<u>Session 1</u>

The subject arrived and was assessed by Investigator 2 for suitability and baseline clinical assessment measurements. Both eyes were assessed, but the data analysed only for the eye assigned for treatment.

1. Best-corrected LogMAR distance acuity (Sussex Vision International Ltd, West Sussex, UK) at 3m direct viewing. Visual acuity was obtained by assigning 0.02 LogMAR units to each letter.

2. Instillation of fluorescein, using Fluoret strips (Chauvin, France) (each strip impregnated with approximately 1mg of fluorescein sodium BP) moistened with 0.9% physiological saline, to assess invasive tear break-up time. The subject was asked to blink and then hold their eye open as long as possible. The measurement was taken in seconds between the blink and the first appearance of a discontinuity in tear film coverage. Three values were recorded for each eye and the median used for comparison.

3. Tear break-up time using Tearscope Plus™ (Keeler Ltd, Windsor, UK), with fine grid insert. The measurement was taken in seconds between the blink and the first appearance of a discontinuity in tear film coverage. Three values were recorded for each eye and the median used for comparison.

4. Assessment of ocular integrity using CCLRU grading scales (Brian Holden Vision Institute (BHVI)), interpolated to 0.1 unit increments[25]: bulbar redness; limbal redness; lid redness; lid roughness; type, extent and depth of corneal staining with fluorescein.

Ocular impression was then performed in a separate room, where Investigator 1 carried out an impression procedure to one ocular surface (randomly-assigned) using one of the two materials. After impression taking, and saline wash-out to remove excess material, the subject returned to the room of Investigator 2 who repeated the clinical tests as above.

<u>Session 2</u>

When the subject arrived, Investigator 2 repeated the clinical tests carried out the day before, followed by Investigator 1 taking an ocular impression with the alternative material to a randomly-assigned eye. Investigator 2 repeated the clinical tests following a saline wash-out, post-impression procedure.

Ocular impression procedure

Each subject was positioned sitting upright and facing forward. A distant target was provided to align the visual axes, using the contralateral eye for fixation. The ocular surfaces of both eyes were anaesthetised with 0.5% Proxymetacaine HCL Minims eye drops (Chauvin, Kingston-upon-Thames, UK), and the procedure carefully explained to the subject. An impression tray was chosen from the set of 3 sizes, of maximum internal shell diameter 23, 24 or 25mm (Cantor and Nissel Ltd, Brackley, UK). These trays are moulded from acrylic with hollow stems, 32mm in length, marked with red circular indentations providing an anatomical registration at the 12 o'clock position (in relation to the cornea). The tray was selected by presenting the 3 sizes to the closed eye and choosing the largest in relation to the aperture and the global contour. Impression material was dispensed onto the internal surface of the shell covering the entire surface with 1.5-2.5mm[26] of either Tresident or Orthoprint (Figure 1).

The subject was instructed to 'look down' whilst remaining in the head upright position. The tray was inserted quickly under the top eyelid, and the subject was asked to 'look up' in order for the lower lid to be freed and the shell held between both eyelids. The tray was carefully positioned to locate the cornea at the centre of the shell; the investigator supported the stem and ensured that the subject maintained composure and optimal fixation (Figure 2).

After setting of the material, the tray and impression was removed by freeing the lashes of the upper lid and removing the material from the eye surface in one piece. Any material remnants were collected and the fornices irrigated with 0.9% buffered saline.

Statistical analysis

All data was collated with Excel 2007 (Microsoft, WA, US), and analysed within SPSS v13 (IBM, NY, US). The data distribution was evaluated for normality using the Kolmogorov-Smirnov statistical test. Comparisons were made of clinical signs assessed before and after each impression procedure, and paired t-tests used to determine statistical significance at the 95% level.

Results

A summary of the results is shown in Table 2. LogMAR acuity was found to be slightly reduced by 0.5 letters, on average, following impression using either material, but this was not statistically significant.

TBUT was found to be reduced following impression-taking with both materials, but was not clinically significant. Mean TBUT was 7.16±1.40 secs pre- and 6.68±1.27 secs post-Tresident impression, with a difference of -0.87±2.61 secs, which was not statistically significant ($p=0.383$). Mean TBUT was 7.42±1.55 secs pre- and 6.61±1.33 secs post-Orthoprint impression, giving a larger difference of -1.28±2.03 secs, but which did not reach statistical significance ($p=0.094$).

Ocular redness was found to increase following impression taking, with both impression materials. Bulbar redness increased following impression-taking with Tresident by +0.64±0.58 units ($p<0.001$), with a substantially greater change in redness observed following the use of Orthoprint +1.12±0.42 units ($p<0.001$). A statistical difference was found between the numerical values assigned to bulbar redness after Orthoprint compared to Tresident ($p=0.0231$). Similarly, limbal redness increased following impression-taking, +0.70±0.31 units ($p<0.005$) after Tresident use and +1.05±0.28 units ($p<0.005$) after Orthoprint. However, the mean difference between changes in limbal redness when comparing the two materials was not statistically significant ($p=0.072$). There was a small change in lid redness recorded after impression-taking. For Tresident this was 0.17 ±0.32units, which was statistically significant ($p<0.05$). However, the change was smaller after Orthoprint use (0.07 ±0.35 units) and was not statistically significant ($p=0.487$).

The clinical grading of lid roughness was found to increase following impression-taking with Tresident (0.03 ±0.25 CCLRU units), but this was not statistically significant ($p=0.459$). Orthoprint had no detectable effect on lid roughness.

Corneal staining with fluorescein was recorded following impression-taking with both materials. Staining type was micro-punctate and superficial after Orthoprint; 0.13 ±0.34 grade units (p=0.341), but tended to be macro-punctate after Tresident; 0.53 ±0.41 grade units (p=0.167). However, these changes were not statistically significant.

The extent of staining was found to increase substantially after Orthoprint impression to 2.33 ±0.46 grade units (p<0.001). These measurements indicate that, on average, 22% of the corneal surface (range 15-45%) was covered by staining. The recorded increase in extent of staining after Tresident was small (0.49 ±0.65 grade units), was not statistically significant (p=0.209) and the surface area stained was, on average, only 10% (range 1-22%). Changes in the depth of staining were found to be small (0.31±0.40 grade units after Orthoprint, 0.37±0.47 grade units after Tresident), which were statistically significant for Orthoprint, p<0.05, but not for Tresident (p=0.219).

Clinical summary

Visual acuity was unaffected by either material (clinically significant criterion Test-retest ±>2.4 letters)[27]. TBUT was marginally disrupted by both materials, but was not clinically significant according to published criteria)[28]. Bulbar redness increased with both materials. Orthoprint induced a clinically significant hyperaemic response in over half of the cohort, i.e. >2.6 CCLRU grade units[29,30], while Tresident was associated with increased bulbar redness within clinically acceptable limits. Both materials increased limbal redness, but this was within clinically acceptable limits (<2.4 CCLRU grade units[30]). Corneal staining was significantly greater after Orthoprint impression (clinically significant criterion >0.5 grade units)[31]. Orthoprint produced micro-punctate staining (type) over 15-45% (extent) of the cornea, fluorescein penetrated the superficial epithelium. Tresident produced macro-punctate staining (type) over 1-22% (extent) of the cornea, fluorescein penetrated the superficial epithelium.

Discussion

For the first time using clinical grading scales, the effects of Orthoprint and Tresident have been evaluated to determine the ocular surface disruption following ocular impression procedures, providing evidence to allow

practitioners to make an informed choice when deciding which material to use. The results from this study support the use of Tresident as the clinically safer impression material. It also requires less preparation time than Orthoprint. The use of Orthoprint was found to be associated with clinically significant (although superficial), micro-punctate staining of the corneal epithelium, leading to an increased bulbar hyperaemia response. In contrast, following the use of Tresident, ocular signs were within normal limits, with minimal corneal staining.

After the use of Orthoprint, 7 subjects reported a foreign body sensation accompanied by a slightly red eye, which persisted for up to 24 hrs after the procedure. These subjects were monitored carefully, provided with ocular lubricants and all symptoms resolved spontaneously. Inflammatory signs were not observed on the tarsal conjunctiva or the dermis of the lids, although both areas were also in contact with Orthoprint during the procedure. This, coupled with the hyperaemia response, suggests that there may be some toxicity response from the AOS. This could be due to: poor mixing of the alginate resulting in one or a combination of the chemical constituents causing damage to epithelial cell integrity. In particular, potassium fluorotitanate (chemical modifier) is listed as a hazardous component on the Orthoprint data safety sheet. Between 1-3% of the impression mix is made up of this chemical, and, if in contact with eyes, it advises to wash immediately with water for at least 10 mins. This effect might be prolonged if a chemical residue was left on the AOS after the gel was formed, which was not removed by irrigation.

It is commonly accepted that fluorescein staining of the cornea represents compromised epithelial integrity[32]. A red eye, accompanied by corneal staining, is intuitively taken as an unhealthy ocular situation and good practice advocates monitoring for signs of deterioration and treatment if necessary. In this study, a clinically significant increase in staining was observed after Orthoprint, but not Tresident (Dundas et al.,2001[31] suggests that a score of >0.5 should be considered unusual). Damage to corneal integrity caused by one, or a multitude of factors, during ocular impression-taking requires careful monitoring and consideration given that any denudation of epithelium increases the risk of infection[33]. A number of factors may have contributed to the superficial staining observed on the cornea.

The use of anaesthetic prior to ocular impression-taking may have contributed to the corneal staining – 0.5% Proxymetacaine HCl has been associated with increased corneal permeability to fluorescein[31]. However, this was applied equally for both impression methods, so it may be assumed that the differences in staining observed between the methods is a true difference.

The mechanism for observing corneal staining is typically to use surface fluorescein pooling or ingress around epithelial cells[32]. However, surface toxicity cannot be adequately explained in this manner. If Orthoprint does indeed cause a chemical interaction with tear mucins or membranes of the corneal and conjunctival epithelial cells, then fluorescein may be staining the affected cell complexes. Thus, the increased sensitivity reported by subjects after Orthoprint may be a result of the 'toxic' interaction that remains until the surface cells are sloughed off. The initial increased cell permeability by proxymetacaine anaesthesia may encourage the acute inflammatory response and increase subsequent corneal staining observed.

This effect may be emphasised by increased permeability of the cornea. Physical contact between the ocular surface and the setting alginate medium may cause the removal of multiple epithelial cells, allowing chemical contamination of the deeper layers of the epithelium. In addition, anaesthetic instillation can cause reduced corneal sensitivity, reduced blink frequency and can precipitate abnormal drying of the AOS[35], encouraging adherence of the impression material to the epithelium. Toxic interactions between anaesthetic and corneal epithelial cells have been found to cause loss or damage to surface microvilli and deposition onto the cell membranes[36].

Average bulbar redness using CCLRU scales in the normal population is reported to be 1.93 units, with scores of 2.6 units considered abnormal[29]. Eleven subjects had scores greater than this following the use of Orthoprint, with an average score of 3.14±0.37 grade units (range 2.7-3.8). This constitutes an abnormal level of hyperaemia

in over half the study cohort. In contrast, after using Tresident, only six subjects had scores above normal, with an average of 3.31±0.41 units (range 2.8 - 3.8).

The irritation of ocular tissues by irreversible hydrocolloids has been studied on white, adult, New Zealand rabbit eyes[37] and clinical observations in human eyes found a range of responses to the material, ranging from slight dehydration and irritation of the tissues to transient corneal abrasions[6]. Ocularists described capillary dilation, tissue oedema and prolific tearing. The study concluded that the impression material, similar in formulation to Orthoprint, elicited a significant, acute, inflammatory response in the rabbit conjunctiva on histological examination. The authors attributed the tissue insult to the granular alginate material rubbing against the corneal and conjunctival tissue interface, concurrent with blinking and eye movement. Additionally, they speculated, as in this study, that the chemical setting aids (bimetallic fluorides) may have had a toxic effect on the ocular tissues. The effects of the inflammatory response lasted 24-72 hours, leaving no permanent tissue damage[37].

Conclusion

The use of Orthoprint during ocular impression-taking caused an abnormal hyperaemic response to the bulbar conjunctiva, accompanied by significant superficial corneal staining. This may be attributed to a toxic reaction between the material and the eye surface, exacerbated by mechanical abrasion caused by eyelid movement and granular material apposition. However, further investigation would be necessary to establish the exact nature of this interaction.

Tresident was found to be the impression material of choice. This study observed less redness and clinically insignificant staining following impression-taking with fewer clinical complications. To manage any clinical complications from using Tresident, the following advice is given: provide lubricating drops post-impression; review the ocular surface integrity 24 hrs later; exclude dry eye patients and those with a comprised ocular surface, where possible; and, consider prophylactic treatment for patients with damaged or impaired ocular surface function.

These findings, combined with favourable handling and excellent physical properties, makes Tresident a superior material for taking ocular impressions.

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Table 1: Properties and characteristics of Orthoprint and Tresident.

	Tresident	Orthoprint
Material type	Silicone elastomer	Alginate
Reaction type	Addition polymerisation	Irreversible hydrocolloid
Components	Base paste: silicone polymer dispersion and reactive species, filler and surfactant to increase hydrophilic properties. Catalyst paste: silicone polymer dispersion and reactive species, catalyst, hydrogen scavenging agent, filler and pigments[20].	Soluble alginate reacts with calcium sulphate to produce insoluble calcium alginate gel, potassium fluotitanate to counteract interaction with gypsum setting, filler, retarder, pH modifier and glycol to reduce dust[35].
Smell	None	Vanilla odour and flavour
Detail reproduction	Reproduce lines <0.020mm Unknown effect of pH	Reproduce lines <0.75mm. Improved in alkaline pH[36]
Linear dimensional change	<1.5%	Variable with temperature and humidity
Elastic recovery	>99%	97.3%
Deformation	1.3-5.6%	11%
Tear strength	High 1640-5260g/cm	Low 380-700g/cm
Clinical history	First used Britain 1977: Ann Arnold-Silk[4]	First used America 1943: Theodore Obrig[37]
Mixing technique	Dual chamber cartridge using proprietary mixing canula and dispensing gun	By hand using rubber bowl and metal spatula. De-ionised water added to powder
Quantities	Quantities of each paste predetermined by means of cartridge and dispensing system	9g powder to 18ml water
Working time	1 min 15 secs	1 min 5 secs
On-eye time	2 mins 45 secs	45 secs
Setting time	4 mins	1 min 50 secs
Gypsum die pouring	After 1 hr, up to 14 days with no special conditions	Immediately or up to 48 hrs later if stored in hermetically sealed bag at 23°C
Number of casts	Up to 7	1
Environmental effects	0.2-1% shrinkage after 24 hrs. Higher temp reduces setting time, unaffected by humidity	Cold water retards setting time, shrinks up to 1.28% after 24 hrs if not stored at high humidity[38]

420 Table 2: Statistical comparisons of clinical outcomes between Tresident and Orthoprint.

Clinical Outcome	Mean differences in measurements pre- and post-impression procedure (mean±SD)		Statistical significance		
	Tresident	Orthoprint	Tresident pre- vs post-	Orthoprint pre- vs post-	Tresident vs Orthoprint
LogMAR acuity (Log Units)	-0.01±0.13	-0.01±0.21	p=0.414	p=0.082	p=0.593
Phenol red test (mm)	+5.06±6.22	+5.76±5.81	p=0.308	p<0.05	p=0.829
TBUT (secs)	-0.87±2.61	-1.28±2.03	p=0.383	p=0.094	p=0.265
Bulbar Redness (CCLRU units)	+0.64±0.58	+1.12±0.42	p<0.001	p<0.001	p<0.05
Limbal Redness (CCLRU units)	+0.70±0.31	+1.05±0.28	p<0.005	p<0.005	p=0.072
Lid Redness (CCLRU units)	+0.17±0.32	+0.07±0.35	p<0.05	p=0.157	p=0.487
Lid Roughness (CCLRU units)	+0.03±0.25	+0.00±0.40	p=0.459	p=1.00	p=0.506
Type of corneal staining (CCLRU units)	+0.53±0.41	+0.13±0.34	p=0.167	p=0.341	p=0.176
Extent of corneal staining (CCLRU units)	+0.49±0.65	+2.33±0.46	p=0.209	p<0.001	p<0.005
Depth of corneal staining (CCLRU units)	+0.37±0.47	+0.31±0.40	p=0.219	p<0.05	p=0.566

421

422

Figure 1: 25mm diameter impression tray holding Tresident material prior to insertion.

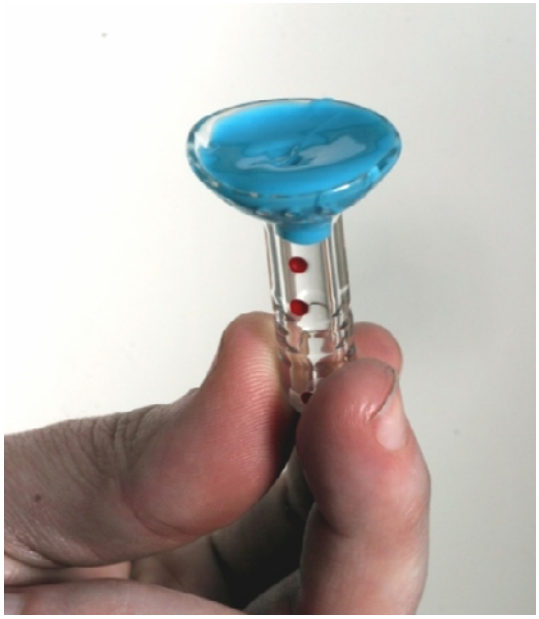

Figure 2: Position of tray and Tresident during impression procedure.