

## Study Protocol

### **Evaluation of effect of incorporating 0.5% Chloramine-T as disinfectant in type III gypsum product on its setting time and abrasion resistance.**

#### **Abstract:**

**Background:** Disinfection of dental cast is very important because it can cause cross-infection from patients to clinicians and lab personnel. This study aimed to evaluate the effect of addition of 0.5% of chloramine-T as disinfectant in type III gypsum product on its setting time and abrasion resistance. **Objectives:** 1. To evaluate the effect of Chloramine-T on **setting time** of type III gypsum product. 2. To evaluate the effect of Chloramine-T on **abrasion resistance** of type III gypsum product. 3. To compare the mentioned properties with control group of type III gypsum product without Chloramine-T. **Methodology:** This is an invitro study, sample size is 140. We will be testing for setting time with the help of Vicat needle apparatus and abrasion resistance will be tested with the help of two body wear testing apparatus. This study will be conducted under 4 groups: Group1- Control group for setting time, Group2- Experimental group for setting time, Group3- Control group for abrasion resistance, Group 4- Experimental group for abrasion resistance. **Expected result:** It is expected that this study would result in forming a type III gypsum product incorporated with Chloramine-T, thus eliminating the need for any additional steps for disinfecting casts and ultimately preventing cross-infection. **Conclusion:** Incorporating Chloramine-T can be an efficient method of disinfecting gypsum without adversely affecting the product's mechanical and physical properties.

**Keywords:** Disinfection, Chloramine-T, Type III gypsum product, Setting time, Abrasion resistance.

#### **Introduction:**

The field of dentistry comprises of patient and the clinician being exposed to saliva which may act as communicable infectious agent. Patients who need prosthodontic treatment are typically a risky group of population with respect to the ability to spread as well as to acquire the infectious diseases.(1)Thus infection control is very necessary to be followed to prevent cross infection. Disinfection of impression material and dental cast is important because infection can be transmitted from dental patient to lab technician.(2)

Impression materials and prosthesis which are contaminated are the most significant route for infectious communication from patients to the lab technician.(3) These pollutants may be carried to casts used in dentistry by keeping the cross-contamination and infection contamination cycle ongoing. Currently impression material is disinfected by spraying method or by immersion method before pouring the impression with dental stone. In addition to this gypsum material should also be disinfected.

Even after disinfection of the impression material, it is possible that dental cast is infected which can lead to cross contamination. Dental cast can also be reinfected while processing of the prosthesis. Example, when the record base of acrylic resin is placed in the oral cavity and then replaced on the dental casts cross-contamination can occur. Hence, to avoid cross-contamination, the casts used in dentistry must be disinfected.

Gypsum products may be directly added with the chemical disinfectant. Adding disinfectant to gypsum products, on the other hand, has been documented to affect important gypsum properties like dimensional accuracy, setting time and compressive strength. The aim of this research was to create a gypsum product containing disinfectant with suitable physical and mechanical properties. Studies have been done where powdered form of Chlorhexidine Hydrochloride(4), Calcium Hypochlorite(5), Silver Nitrate and Copper Sulphate(6) have been added to gypsum product, but these were incorporated at the time of mixing

Tosylchloramide or N-chlorotosylamide, commonly known as **Chloramine-T**, it is widely used in a number of fields, including medicine, dentistry, veterinary medicine, agriculture, and food processing as a antimicrobial agent. It is used to clean instruments and surfaces as a disinfectant.(7). **Chloramine-T** has been chosen as the disinfectant in this study because of its potent disinfecting properties and stability. Literature on usage of **Chloramine-T**, especially in its powdered form, in amalgamation with type III gypsum product is very scarce, hence this study will be undertaken to explore new avenues in cast disinfection technique

**Aim:** To evaluate effect of incorporating 0.5% Chloramine-T as disinfectant in type III gypsum product on its setting time and abrasion resistance.

**Objectives:**

- 1.To evaluate the effect of Chloramine-T on **setting time** of type III gypsum product.
- 2.To evaluate the effect of Chloramine-T on **abrasion resistance** of type III gypsum product.
- 3.To **compare** the mentioned properties with control group of type III gypsum product without Chloramine-T.

**Material and Methods:**

**SETTING:** This study will be conducted in the Department of Prosthodontics and Crown & Bridge in Sharad Pawar Dental College.

**Sample Size Calculation:**

Based on mean hardness values given in table no. 4 of the reference article the minimum sample size calculated is 35 in each of the 3 groups with  $\alpha$ -value = 5%,  $\beta$ -value and 95% power of the study. You can take 40 in each group to further minimise errors or loss in data.

Table 1: Sample Size Calculation

Sample Size		Study Parameters	
Group 1	35	Mean, group 1	9.41
Group 2	35	Mean, group 2	8.68
<b>Total</b>	<b>70</b>	Alpha	0.05
		Beta	0.05
		Power	0.95

$$k = \frac{n_2}{n_1} = 1$$

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2/K)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$$n_1 = \frac{(0.85^2 + 0.85^2/1)(1.96 + 1.64)^2}{0.73^2}$$

$$n_1 = 35$$

$$n_2 = K * n_1 = 35$$

$\Delta = |\mu_2 - \mu_1|$  = absolute difference between two means  
 $\sigma_1, \sigma_2$  = variance of mean #1 and #2  
 $n_1$  = sample size for group #1  
 $n_2$  = sample size for group #2  
 $\alpha$  = probability of type I error (usually 0.05)  
 $\beta$  = probability of type II error (usually 0.2)  
 $z$  = critical Z value for a given  $\alpha$  or  $\beta$   
 $k$  = ratio of sample size for group #2 to group #1

**\*Reference Article:** Ahmad S, Tredwin C, Nesbit M. Moles DR. Effect of immersion disinfection with Perform-ID on alginate, an alginate alternative, an addition-cured silicone and resultant type III gypsum casts. Br Dent J 2007;202 <https://doi.org/10.1038/bdj.2006.120>.

**Study Design:** It is a experimental cross-sectional study, a total of 70 samples will be tested for each physical property. The groups are as follows:

- Group I: For Setting Expansion: Control (type III gypsum product without disinfectant) group. Sample size will be 35.
- Group II: For Setting Expansion: Experimental (type III gypsum product with disinfectant) group. Sample size will be 35.

- Group III: For Abrasion Resistance: Control (type III gypsum product without disinfectant) group. Sample size will be 35.
- Group IV: For Abrasion Resistance: Experimental (type III gypsum product with disinfectant) group. Sample size will be 35.

**DURATION: 2 years**

**SAMPLE SIZE: 140**

**MATERIALS USED IN STUDY:**

- Material: -
  - Type III gypsum product
  - Chloramine T powder
- Instruments: -
  - Bowl and spatula
  - Mold for testing abrasion resistance
  - Metal matrix for testing setting time
- Equipment: -
  - Two body wear test apparatus
  - Vicat needle apparatus

**METHOD:**

**Fabrication of sample: -**

For Setting time:

A cylindrical metal mould of size 50mm height and 35mm internal diameter will be used. Chloramine-T will be weighed 50mg Chloramine-T per 100grams of gypsum product type III. For control group, type III gypsum product will be mixed with bowl and spatula. For experimental group admix of type III gypsum product and 0.5% of chloramine-T will be mixed with bowl and spatula. The mix will be poured separately in the mould.

For Abrasion Resistance:

A circular metal mould of size 15mm in diameter and 3mm in depth will be used. (Fig. no.:1). Chloramine-T will be weighed 50mg Chloramine-T per 100grams of type III gypsum product. For the control group type III gypsum product will be mixed with a bowl and spatula. For experimental group admix of type III gypsum product and 0.5% of chloramine-T will be mixed with bowl and spatula. The mix will be poured separately in the mold.



**Mold for testing abrasion resistance**  
**(Fig. no:1)**

**Method for testing Setting time:**

Cylindrical metal mould of vicat apparatus (Fig. no.: 2) of dimensions 50 mm height and 35mm internal diameter will be filled with the mixture and smoothed with spatula. Mould is placed in the apparatus in its position. Prior to setting of the gypsum product valve screw will be loosened to allow the needle tip to just touch the surface of the gypsum product. Then needle will be released to penetrate the mix, needle should reach up to the bottom of the mould. This entire process is to be repeated every 30 seconds, each time mould is slightly repositioned and needle is to be cleaned. Every time valved screw is tightened when needle will be penetrate the mix and degree shown in the stylus is to be recorded. This process is repeated until needle cannot penetrate up to the bottom of the mould.



**Vicat needle apparatus**  
**(Fig. no.2)**

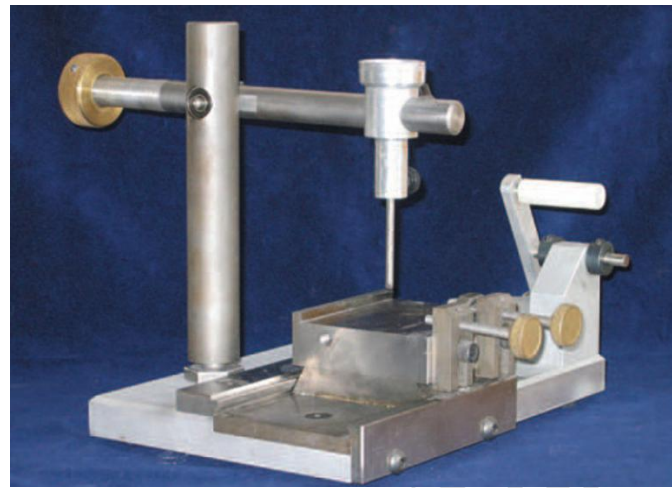
**Method for testing abrasion resistance: -**

Two body wear test apparatus:

This apparatus consists of a chisel which is perpendicular to the specimen, when it is abraded. It is known as two body wear because the abrasion occurs when one hard surface is rubbed on another surface. In this case, chisel will act as the abrading device for the specimen. Weight of 50grams is applied on the chisel for stabilization. Specimen size should be 15 mm diameter and 3 mm depth and pre-testing weight of sample will be recorded. Secure specimen in the apparatus and stylus should be perpendicular to the specimen 50 grams of weight is applied over it. Reciprocating table will be driven at 350 rpm for 5000 cycles and the specimen will be abraded then the specimen will be cleaned to remove all the abraded particles and post testing weight will be recorded.



(a)



(b)

**Two body wear test apparatus  
(Fig. no.:3)**

### **STATISTICAL ANALYSIS:**

Descriptive and analytical statistics will be done. The normality of data will be tested by Shapiro-Wilk test. If the data followed normal distribution parametric tests (ANOVA test with Tukey's post hoc test) will be used and if the data does not follow normal distribution non-parametric test (Kruskal Wallis Test with Dunn post hoc test) will be used.

**Software:** SPSS (Statistical Package for Social Sciences) Version 20.1 (IBM Corporation, Chicago, USA)

**Expected outcome:** It is expected that this study would result in forming a type III gypsum product incorporated with Chloramine-T, thus eliminating the need for any additional steps for disinfecting casts and eventually preventing cross-infection.

### **Discussion:**

It is expected that this study would result in a disinfected type III gypsum product which will be incorporated with chloramine-T which will result in elimination of any need for disinfection of cast and eventually preventing cross-infection.

Implication of this study is prevention of cross-infection from patients to dental clinicians, laboratory technicians and vice-versa without additional steps of cast disinfection by pre-mixing the type III gypsum product with disinfectant.

Disinfection of the cast is a very important step in dentistry as its disinfection will prevent patient as well as clinician and lab personnel.

Schutt R. W in the year 1989 had conducted a study on the bactericidal effect of irreversible hydrocolloid impressions and stone casts which were made by disinfected dental stone. This research concluded that the bactericidal property of a dental gypsum substance integrated with 0.25 percent chloramine-T in stone casts and oral irreversible hydrocolloid impressions was increased. Adding disinfectants in dental stone would likely provide a way to disinfect dental impressions and stone cast which will avoid cross contamination(8)

In the year 1998, Breault G.L et al investigated die stone disinfection using sodium hypochlorite. The findings revealed a Significantly improved rigidity and compressive strength, as well as a reduction in setting time. The rest of the property was untouched.(9)

The effect of disinfectants on the mechanical properties of gypsum products was studied by Khalid M.A. et al in 2002. They discovered that when chemically disinfected gypsum is mixed with water alternatives, it loses strength. Calcium hydroxide and gum arabic additives make for a lower liquid/powder ratio, which can aid in balancing this deterioration.(10)

In 2006, S. Ahmad et al investigated the impact of three different impression materials when widely used immersion disinfectants were used, as well as any subsequent effects on surface detail replication, stiffness, and abrasion resistance of gypsum casts. They came to the conclusion that disinfection with Perform-ID (Potassium peroxymonosulphate) and strong surface information of impression(11)

In the year 2008, Lucas MG et al investigated the impact of adding disinfectant solution on detailed reproduction, linear dimensional stability, and setting time in dental stone casts. They discovered that sodium hypochlorite was added to two dilutions, which greatly altered all of the properties tested. However, adding chlorhexidine and glutaraldehyde had no noticeable impact.(12)

In 2013, Zarakani H et al compared the compressive pressure, setting expansion and setting time of gypsum casts made with distilled water or 0.05 percent sodium hypochlorite and gypsum powder. The results of this study showed that compressive strength, setting expansion, or setting time of dental stone casts had no negative impact when using sodium hypochlorite instead of distilled water(13). Studies on similar aspects of disinfection of various dental materials were reported(14,15).

The efficacy of disinfecting agents on certain mechanical and physical properties of gypsum product type IV was investigated by Khalaf H.A and Mohammed M.R in 2014. The findings revealed that silver nitrate and copper sulphate powder significantly sped up the setting time of type IV dental stone.(6)

Limitation for this study would be: Many parameters of type III gypsum product which influence its usability like setting expansion and impact resistance are also to be considered and a more extensive and longitudinal study is required to provide more statistically significant data.

#### **Conclusion:**

Substituting Chloramine-T can be an efficient and sufficient method of disinfecting gypsum without adversely affecting the product's mechanical and physical properties.

#### **COMPETING INTERESTS DISCLAIMER:**

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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