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Title: Effect of mouthguard design on retention and potential issues arising with usability in sport.

Key words: custom mouthguards, retention, thickness, sport

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Abstract: *Background/Aims:* Mouthguard retention could potentially increase an athlete's motivation to wear the device, due to potential improvements in physical comfort. The aim of the present study was to examine the retentive properties of selected customised mouthguard designs, during normal conditions (dry) and within the presence of artificial saliva (wet). Additionally, the correlation between thickness and retention was investigated. *Material and Methods:* Six different custom mouthguard designs (MG1 – MG6) reported in previous studies, were pressure-formed with 2 mm and 4 mm blanks accordingly. Thickness was measured ten times at seven anatomical points and the mean (\pm SD) was recorded. A novel rig was fabricated to connect the mouthguards to a Hounsfield H10KS Tensometer, which was used to fully displace each device from the model at a constant rate of 50 mm/min. The test was repeated under both dry and wet conditions. *Results:* Retention forces recorded at the anterior region demonstrated higher measurements under conditions than dry ($p < 0.001$). The total retention of the mouthguards was influenced by alterations in their design ($p < 0.015$). Trend analysis indicated that 64% of MG retention could be explained by their thickness under dry conditions and 55% when wet. *Conclusions:* Design and thickness of mouthguards are key factors in retention. Mouthguard fabrication techniques should be considered in order to minimise dislodgment of the devices as well as potentially increasing the wearability of mouthguards during sport.

Introduction

The highest incidence rates of dental trauma are seen within contact sports such as boxing, martial arts, rugby and hockey. Hence, the importance of wearing mouthguards (MGs) should be further emphasised to prevent such traumas within these types of sports. However, athletes can often be reluctant to use mouth protection due to impedance with communication and breathing, as well as other factors such as cost.¹⁻⁵ There is also an underlying belief amongst some sport participants that wearing a MG causes discomfort.^{4,6} This could be due to the popularity of ‘over-the-counter’ devices, which can have poor fit and low retention specifically if the participant does not self-adapt the device correctly. The latter was identified as a reason by 24.3% of a cohort of taekwondo players.⁴ Half of the respondents confirmed that wearability would increase if the current issues as well as other factors with MGs were addressed. Thus far, previous work has mainly examined the palatal shape of the MG in relation to comfort issues. Gebauer et. al. (2011) identified that male field hockey and water polo players ($n=27$, aged 23.5 ± 3.8 yrs) rated a device with palatal extension less than a MG without this palatal outline.⁶ Therefore, manufacturers should try new techniques for MG fabrication in order to meet players’ expectations in terms of limiting usage and discomfort. The essential parameters that need to be considered include good fit and high retention, which relate to the ability of the MG to stay in position during dynamic sports. Higher MG retention could potentially increase the athletes’ motivation to wear the device as it could lead to improvements in physical comfort and less interference with performance.⁴ In addition, distraction and interruption of the game due to a loose MG could also be reduced. Currently, there is very little literature examining MG retention, which is of pivotal importance for enhancing wearability.^{7,8,18} Previously, only two studies have conducted a pull test to examine the fit of different custom devices.^{7,8} Del Rossi et al. (2008) investigated the effect of the MG colour on fit and adaptation. They attached a strain gauge to the palatal

aspect of the central incisors and recorded the force required to remove the MGs from the model. It was shown that more force was required to remove the blue, black and green coloured MGs than the clear guard due to pigmentation affecting thermal properties during the fabrication process.⁷ Maeda et al. (2009) examined the accuracy of fit using a chain that was attached to the first upper left molar.⁸ They fabricated three different outlines of custom MGs; all made of 3.8 mm clear ethylene vinyl acetate (EVA) blanks. The first design had a 4 mm palatal extension, whereas the second was finished at the gingival margin, and the third had an extended buccal outline. No statistical difference between the retention of the three MGs was found. However, the pressure-formed MGs over well-dried casts showed better fit and retention than those that were vacuum-formed on dry (133 ± 31 gf $>$ 116 ± 27 gf) and wet casts (133 ± 31 gf $>$ 58 ± 17 gf). Further research is required to assess other factors influencing retention, and propose MG features that may improve the fit of the device. Although the latter study⁸ assessed retention of certain custom devices, the authors outlined some limitations of the retention test used. For instance, it was suggested that the consistency of saliva (wet) should also be considered when examining retention of MGs.

The aim of the present study was to examine the retentive properties of selected customised MGs on a dry model and in the presence of artificial saliva to mimic the oral environment. Additionally, the correlation between MG thickness and retention was investigated to propose further considerations on how to improve potential comfort factors when fabricating custom MGs.

64 **Materials and Methods**

65 Ethical approval was obtained from the School of Healthcare Science, Manchester
66 Metropolitan University (Ethics Number: SE151657C).

67 A fully dentate maxillary anatomical teaching model was fabricated from Nano – Rock liquid
68 die stone (WHW, Hull, UK). The model had arch dimensions of 32 mm length, 36.5 mm
69 inter-canine width and 50.4 mm inter-molar width; similar to the mean arch dimensions of a
70 cohort with normal occlusion.⁹ Six different custom-made MG designs were thermoformed
71 following standard technical procedures as described by Padilla¹⁰ (Table 1). In brief, MG1
72 had a 4 mm palatal extension, whereas MG2, MG3, MG4 and MG6 were trimmed around the
73 gingival margins, and MG5 had no coverage of the palatal aspect of the anterior teeth. To
74 increase the thickness in different regions of the devices, two layers of EVA blanks were used
75 to fabricate MG3, MG4 and MG6. For instance, the double layer in MG3 was present in the
76 anterior region, in MG4 at the posterior region and in MG6 at both the anterior region and
77 over the occlusal surfaces. MG6 was finished distally to the upper second molars, whereas
78 the other designs were finished distally only to the upper first molars. MG designs MG1,
79 MG2, MG4 and MG5 were fabricated following previously published studies examining the
80 effects of the devices on comfort and performance.^{6, 11, 12} Design MG3 is commonly used in
81 dental practice and MG6 was reproduced from Takeda et al.¹³ for a rugby player with a
82 malalignment.

83 All MGs were pressure-formed on a Drufomat–Te machine (Dreve Dentamid GmbH,
84 Germany) with round, clear 2 mm and 4 mm EVA blanks, 120 mm Ø (diameter) (Bracon
85 Dental Laboratory Products, East Sussex, UK). In order to minimise the thinning of the EVA
86 blanks during thermoforming the blanks were pressure-formed onto a dry model embedded
87 into metal pellets.

On each MG, seven anatomical points, both anterior and posterior, were selected to obtain dimensional thickness (Figure 1a-b). The position of these points (excluding Point 3) was similar to those used by Farrington et al.¹⁴ who investigated thickness in relation to the fabrication technique. Each point was measured ten times using an electronic calliper gauge, resolution range ± 0.01 mm (External Digital Calliper 442-01DC Series, Moore and Wright, UK) for consistency and the mean (\pm SD) was recorded. The gauge was zeroed after each measurement for calibration. The thickness of the anterior region equated to the mean value of points (i) - (iii), whereas the thickness of the posterior region equated to the mean value of points (iv) – (vii). Overall MG thickness was obtained from the mean of all points (i-vii) (Figure 1a-b).

Retention was measured at different regions of the MGs using a Hounsfield H10KS Tensometer fitted with a 1kN load cell (Hounsfield Test Equipment Ltd., Surrey, UK). The H10KS was controlled with QMat Professional Material Testing Software. Firstly, orthodontic brackets (Cat No: DB22-0478, DB Orthodontics, Silsden, UK) were secured with adhesive (Araldite® Rapid, Basel, Switzerland) onto each MG at five specific sites (Figure 1c). Then, hard stainless steel wires, 0.035mm Ø and 120mm length, were attached to them (K. C. Smith Ortho Ltd. Hertfordshire, UK) (Figure 1d). The dental model was secured to a stainless steel plate (150x220 mm) placed over the base of the Tensometer. In order to connect the MGs into the grips of the testing apparatus, a novel rig (80x80 mm) was fabricated (Figure 2). Location holes allowed the wires to be parallel and perpendicular to the occlusal plane when secured to the rig with terminal strips.

The maximum force (N) required to fully displace a MG from the model represented the retention force of the device. All MGs were pulled away from the model by an upward movement at a constant rate of 50 mm/min. Ten force measurements were recorded for each site (Figure 2) and then an overall mean value was obtained. In order to reduce the variability

within the testing procedure, after each measurement the load and extension were zeroed and the MG was fitted back onto the model. An overall retention value was obtained by grouping the maximum forces recorded for all loading scenarios (Table 2).

Retention tests were then repeated in wet conditions. Each MG and the dental model were immersed in 500 ml artificial saliva solution for 30 sec prior to testing. After each loading scenario, the MG was immersed again in saliva solution for 30 sec in order to keep it damp. The saliva was mixed according to a basic formulation consisting of: water (1 L), sodium chloride (0.4 g), potassium chloride (0.4 g), potassium dihydrogen orthophosphate (0.218 g) and disodium hydrogen phosphate (1.192 g). Test-retest reliability was conducted by the primary investigator on three randomly selected MGs. A second researcher also repeated the tests independently with the same three MGs in both dry and wet conditions.

Statistical analyses were performed using IBM SPSS Statistics, Version 22.0. Armonk (IBM Corp., New York, US) and Microsoft Excel (2013). Distribution of the data was checked with histogram plots, Shapiro - Wilk normality test and box plots. The Wilcoxon Signed Ranks test was performed to compare the retention in dry and wet conditions. Differences in displacement force between MGs were identified with non-parametric Kruskal-Wallis test (multiple pairwise Mann-Whitney U post-hoc tests). The level of significance (α) was set at 0.05. Trend analysis using coefficient of determination (R^2) examined the correlation between thickness and retention of MGs. Due to the non-parametric nature of the data Spearman correlation was used. Additionally, Cronbach Alpha test was performed to examine the repeatability of the results.

Results

A total of 60 retention force measurements were obtained for each MG design. Only the retention forces recorded at the anterior region showed significantly higher measurements under wet conditions than when dry ($p < 0.001$) (Table 3).

Figure 3 illustrates differences in the total retention between MG designs. However, no differences were found between the pairs of MG1, MG3 and MG4 under dry conditions ($p > 0.121$). Additionally, the pairs of MG1 - MG4 ($p = 0.856$) and MG3 - MG6 did not differ in retention under wet conditions ($p = 0.106$). Overall, the most retentive MG design was found to be MG6 (11.36 ± 2.96 N (Dry) and 9.91 ± 3.48 N (Wet)) and the least retentive was MG5 (3.50 ± 1.93 N (Dry) and 3.49 ± 1.90 N (Wet)) (Figure 3; Table 4).

MG2 and MG5 had the lowest overall mean total thickness of 2.02 mm and 1.96 mm and total retention of 3.50 N – 4.86 N (Dry) and 3.49 N – 4.53 N (Wet) (Table 4). The remainder of the MG designs had a mean thickness of 2.40 mm or greater and showed higher retention of 6.12 N – 11.36 N (Dry) and 5.71 N – 9.91 N (Wet) (Table 4).

A positive relationship between MG thickness and retention was found under both dry ($R^2 = 0.64$) and wet conditions ($R^2 = 0.55$) (Figure 4). Thus, 64% of MG retention could be explained by thickness when dry and 55% when wet.

A total of 180 force measurements were recorded from MG1, MG2 and MG6 under both conditions to assess repeatability. The primary researcher ($\alpha \geq 0.909$) demonstrated high repeatability, although this was reduced when a second researcher conducted the displacement tests on the same three MG designs ($\alpha \geq 0.848$).

Discussion

Retention of custom MGs relates to the superior fit of the devices, which may minimise some of the issues with comfort, communication and breathing that have previously been reported in the literature. Previous literature found that the colour of the MGs and the use of different equipment for MG fabrication were influencing factors on the accuracy of fit.^{7,8} Therefore, the present study considered whether other factors (differences in MG design, final thickness and use of artificial saliva to mimic an oral environment) influenced retention. Statistical differences between MG designs in terms of their ability to withstand displacement forces were found ($p < 0.015$). In addition, it was discovered that the selected MGs differed in retention depending on the presence of artificial saliva solution ($p < 0.001$) and thickness.

The current investigation examined only custom-made devices as published studies have proposed that such MGs are superior to other commercial ‘boil-and-bite’ or stock MGs.^{15,16} It was unexpected that both overall retention of MGs in the posterior region and total retention were higher under dry compared to wet (i.e. saliva) conditions, as viscosity of saliva is believed to improve retention of dental devices.¹⁷ It is also worth considering that displacement of the MGs may have been facilitated by the highly polished surface of the dental casts and the good tooth alignment. However, casting the master model in Nano–Rock liquid die stone allowed no absorption of the artificial saliva to take place during testing, which would have not been possible if a gypsum cast was used.

To obtain more accurate retention measurements, the current study recorded displacement forces from five different sites. In contrast, previous published work has examined MG retention and accuracy of fit at only one site such as the midline between the upper central incisors or the left upper molar.^{7,8} The highest retention at all points and under all conditions was shown by MG6, which had two layers of EVA blanks at the anterior region and the

occlusal surfaces. In contrast, MG5 was the least retentive MG, made of a single 4 mm EVA blank with no palatal coverage behind the anterior teeth. Additionally, the MG1 with 4 mm palatal extension was more difficult to displace under both wet and dry conditions, compared to MG2, which had no palatal extension (Figure 3; Table 4). Although, the palatal outline of MG1 improved retention compared to MG2 and MG5 when a single layer of EVA blank was used, this was not the case when the MGs were made of dual layers. This is an important finding as previous literature has identified that having a MG with palatal outline increased users' discomfort and speech impedance.^{6, 18} Therefore, when manufacturing such devices one should consider techniques such as using two EVA blanks, finishing the outline at the gingival margins or extensively decrease the thickness of the palatal extension to maintain the retention and improve comfort. Maeda et al.⁸ also conducted a retention test but instead of using wires to connect the MG to the testing machine, they attached a screw and washer jig to only one site of the MG (upper left first molar). They measured the force (gf, n=5) when the MGs started to separate from the tooth cervical margin. Maeda et al.⁸ showed that a pressure-formed customised MG with no palatal outline performed better than a MG with 1 mm palatal extension (3.8 mm EVA blank) (133 ± 31 gf < 139 ± 24 gf, $p > 0.05$), MGs fully engaging the cervical undercut area of the dentition were more retentive. Similar to the present study, Del Rossi et al.⁷ proposed a test which also recorded the maximum force of MG displacement by positioning a metal wire behind the central incisors and attaching it to a strain gauge. However, the devices were tested at two angles, 90° and 45°, to the transverse plane to mimic the angle of MG removal used by athletes, and they demonstrated the influence of colour on MG fit. Although the present study examined only clear MGs, Del Rossi et al.⁷ showed that using dark coloured blanks provided better fit and adaptation due to their ability to absorb infrared energy during thermoforming. Despite the differences in

experimental procedures, previous studies alongside this study have concluded that MG design and fabrication technique have an impact on retention.

Previous work has mainly related thickness of MGs to impact absorption but not retention.¹⁹⁻

²² The present study found a positive correlation between MG thickness and retention when the MGs were tested under dry ($R^2 = 0.64$) and wet ($R^2 = 0.55$) conditions. Having a double layer MG (EVA blanks of 2 mm and 4 mm) increased the final thickness of the devices.

MG3, MG4 and MG6 had a mean thickness above 2.40 ± 0.37 mm, which was more than the single layer MGs. However, MG1 with thickness of 2.66 ± 0.49 mm was an exception due to its palatal outline that increased the overall thickness. MG2 and MG5 were thinner than 2.02 mm and showed relatively low total retention (4.53 ± 1.18 N and 3.49 ± 1.90 N). In contrast, the rest of the MG designs, which were thicker than 2.40 mm, were more retentive (5.71 ± 1.79 N – 9.91 ± 3.48 N).

It is also important to take into account the features leading to lower displacement of MGs during use. If a MG is poorly fitted and not retentive, an athlete will try to keep it in position, which could cause distraction, speech and breathing impedances; consequently having a negative effect on performance. In addition, Del Rossi et al.⁷ suggested that MGs with better fit might limit the chewing forces naturally applied by an individual to keep a loose MG in position, thereby prolonging the life of the device.

Dental arch dimensions differ with age, gender and ethnicity,²³⁻²⁵ so ideally future studies should investigate dental anatomy, alignment of the teeth and the presence of undercuts as possible influencing factors on MG retention. The current study did not consider the effect of anatomical differences within the dental arches as only one master cast with no irregular teeth was examined. Improvements to the retention test methodology are also required to propose a better representation of the oral environment and mimic the angle at which MG users apply

227 forces to remove their device. To reflect the oral conditions more appropriately, a
228 glycoprotein such as mucin, which consists of 3 – 18 sugar units and is secreted in the oral
229 cavity,²⁶ could be added to the saliva formula to increase its viscosity. Future research should
230 use a larger sample size including different manufacturing techniques and materials to
231 identify which MG parameter has a predominant impact on retention and where the cut off
232 point is for sufficient retention force.

233 **Conclusion**

234 MG retention could be altered by changes in design. The use of two EVA blanks lead to
235 increase in both MG thickness and retention, whereas the use of a single blank produced
236 thinner MGs with low retention. Higher retention was recorded in the anterior region in the
237 presence of artificial saliva solution.

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325 **Legends to Tables**

326

327 *Table 1.* Types of mouthguards and material dimensions.

328 *Palatal extension – when the mouthguard extends below the gingival margin.

329 *Table 2.* Retention force region in relation to retention force sites.

330 *Table 3.* Median retention forces for all mouthguards when tested at dry and wet condition.





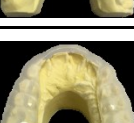

331 *Significant difference between conditions.

332 *Table 4.* Total retention and final thickness (mean± SD) for each MG design

333 in both dry and wet condition.

334 *Table 1.*

335

MG Design	Weight (g)	Number of layers	Thickness of EVA (mm)	Palatal Extension*
MG1 Control	8.7 g	Single	4 mm	4 mm 
MG2 No palatal extension	6.3 g	Single	4 mm	0 mm 
MG3 Thicker Anterior Region	9 g	Double Anterior Region Single Posterior Region	2 mm 1 st layer 4 mm 2 nd layer	0 mm 
MG4 Thicker Posterior Region	8 g	Single Anterior Region Double Occlusal Surface	2 mm 1 st layer 4 mm 2 nd layer	0 mm 
MG5 No palatal coverage anteriorly	6.3 g	Single	4 mm	0 mm 
MG6 Thicker Anterior & Posterior Regions	8.7 g	Double Anterior Region Occlusal Surface	2 mm 1 st layer 4 mm 2 nd layer	0 mm 

336

337 *Table 2.*

338

Retention Force Region	Measurement site
Anterior	Mean of Site 1 & Site (1 - 3)
Posterior	Mean of Site 4, Site 5 & Site (4 - 5)
Total	Mean of All Sites

339

340 *Table 3.*
341

Retention Force Region	Retention at Dry Condition		Retention at Wet Condition		% Difference	Z-score	<i>p</i>	<i>N</i>
	Median (N)	Range (N)	Median (N)	Range (N)				
Anterior	6.28	14.97	6.72	11.57	6.55 %	-4.363	< 0.001*	120
Posterior	5.75	15.71	3.99	13.67	44.11 %	-11.511	< 0.001*	180
Total	6.40	15.77	5.62	13.83	13.88 %	-4.618	< 0.001*	360

342

343 *Table 4.*

344

MG Design	Dry Condition Retention (N)	Wet Condition Retention (N)	Total MG Thickness (mm)
1	6.12 ± 2.84	5.71 ± 1.79	2.66 ± 0.49
2	4.86 ± 1.92	4.53 ± 1.18	2.02 ± 0.46
3	7.36 ± 4.71	9.03 ± 3.36	2.40 ± 0.37
4	7.19 ± 1.76	5.87 ± 1.89	2.42 ± 0.61
5	3.50 ± 1.93	3.49 ± 1.90	1.96 ± 0.47
6	11.36 ± 2.96	9.91 ± 3.48	2.59 ± 0.51

345

346 **Legends to Figures**

347 *Fig. 1.* Thickness measurements at seven anatomical points in the a) anterior (i-iii) and b) posterior
348 region (iv-vii); c) sites 1 – 5 show the location of the orthodontic brackets on a maxillary mouthguard:
349 (1) palatally at the interdental space between the two central incisors (2-3) palatally at the central axis
350 of the right and the left canine (4-5) occlusally at the centre of the first right and left molar; d) attached
351 orthodontic stainless steel wire to a bracket at the region of the left molar.

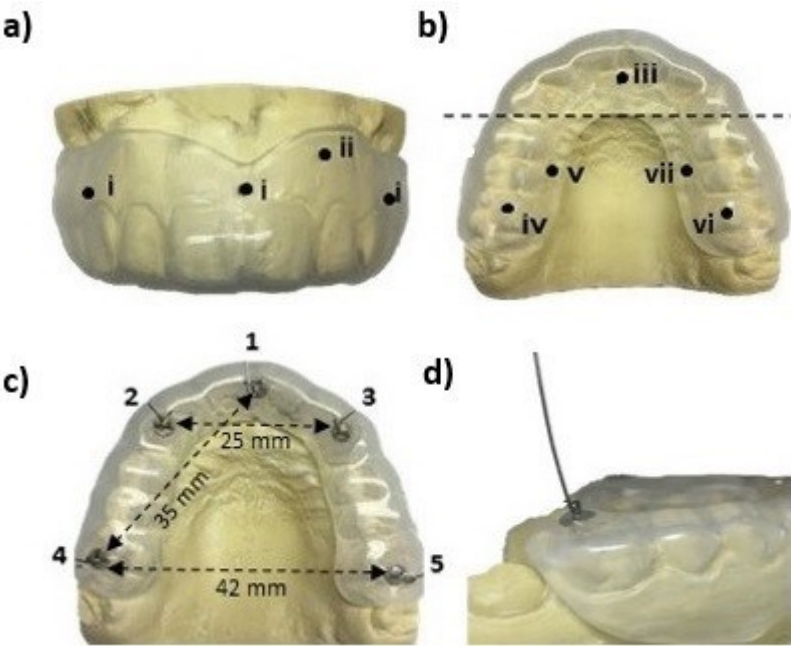
352 *Fig. 2.* Illustration of the testing rig and all loading scenarios to test retention at different sites of the
353 mouthguards.

354 *Fig. 3.* Mean retention forces for each MG design at the Anterior Region, Posterior Region and the
355 Total Retention in both dry and wet conditions; with error bars representing standard error.

356

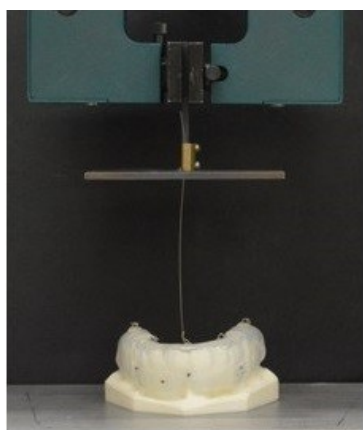
357 *Fig. 4.* Relationship between thickness and retention of the various MG designs.

358 *Figure 1.*

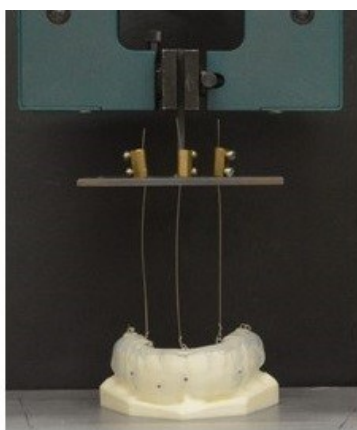


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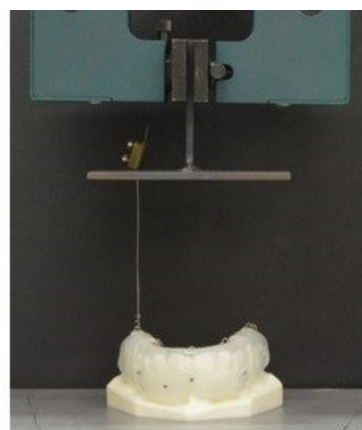
360 *Figure 2.*



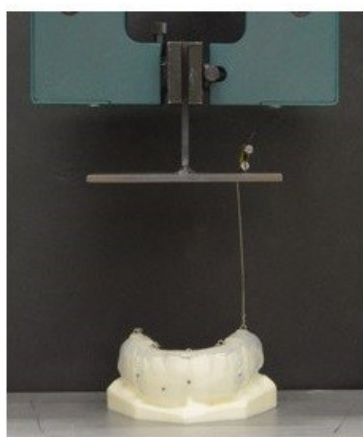
Site 1



Site 1 - 3



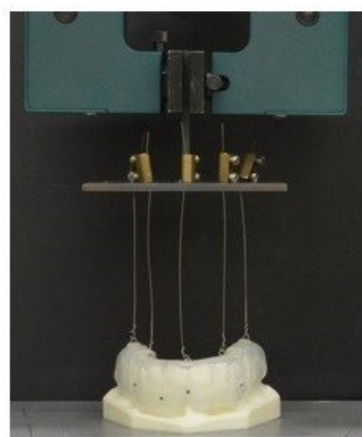
Site 4



Site 5

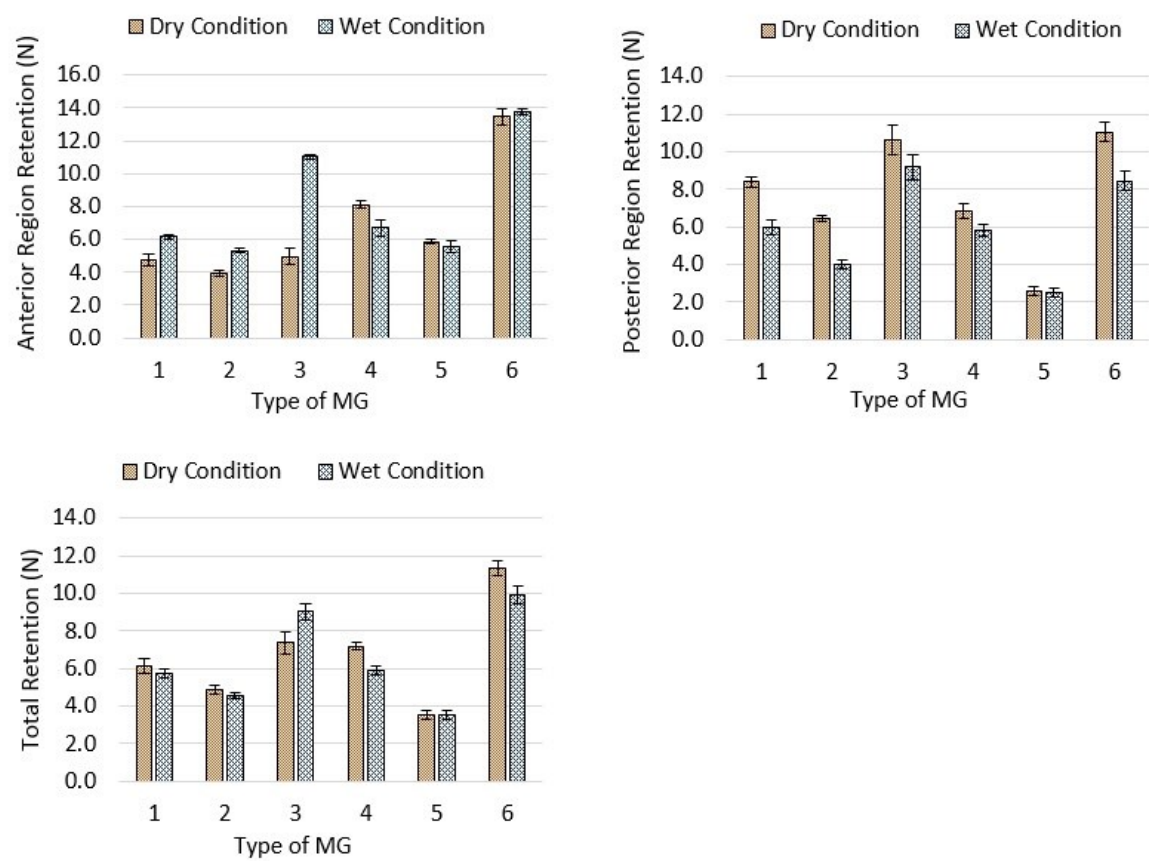


Site 4 - 5

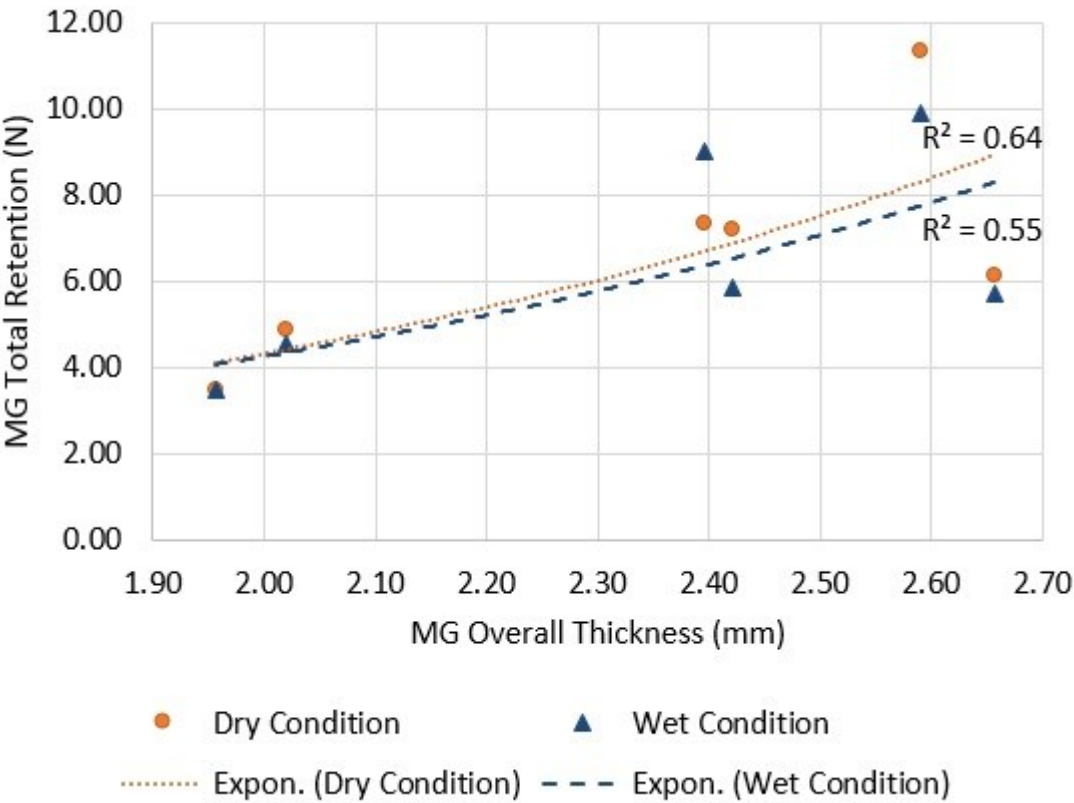


All Sites

361



364 *Figure 4.*



365