**SBIR Phase I**

# Computer-design and Biomechanical Testing of Impact-energy Absorbing Protective Mandibular Appliance

**Akervall Technologies, Inc.**

W91CRB-11-C-0030

Final Report for Phase I.

Prepared by

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## Introduction

In the six month long Phase I of this project, theoretical and experimental research was conducted towards the overall goal of reducing impact energies translated to a Soldier's temporomandibular joint (TMJ) and skull under a variety of impact scenarios. The behavior of existing mouth guard appliance materials and new candidate materials was explored via comparative modeling and simulation testing.

Phase I had two technical objectives: The first technical objective was to measure and characterize the transmission and propagation of forces from jaw or dentition to TMJ, skull, and neck without and with a variety of dental appliances in place, comparing the effectiveness in impact energy dissipation of commercially available appliances to that of the appliance under development by Akervall Technologies, Inc.

The second technical objective is to develop a multiphysics model geared toward optimizing the impact energy dissipation of appliance materials and designs, based on the experimental results obtained in the biomechanics laboratory, and to explore how and to what extent appropriately designed mouth guards can dissipate the energies transmitted to the TMJ and skull.

The project addressed the following specific objectives spelled out in the Statement of Work, in accordance with the SBIR Proposal Topic A10-129:

1. Pressurex® testing and comparative evaluation of the impact energy absorption and dissipation ability of mouth guard materials.
2. Multi-physic modeling of mouth guard materials.
3. Fitting of mouth guards to artificial dentitions in head form.
4. Biomechanics measurements.

**Accomplishments during the first phase of the project (November 9, 2010 – May 9, 2010).**

***Task 1: Pressurex® testing and comparative evaluation of the impact energy absorption and dissipation ability of mouth guard materials.***

***Pressurex® testing:***

The impact energy absorption and dissipation ability of mouth guard materials was tested on flat samples of mouth guard materials, including 4 mm thick ethyl vinyl acetate (EVA and 1.6 mm thick Protech Dent material with perforations developed by Akervall Technologies. Compared to EVA-based materials, the Protech Dent material, a polycaprolactone with a molecular weight $M_w$ of 65,000, has much higher impact strength, as determined by standard pendulum impact tests (Figure 1).

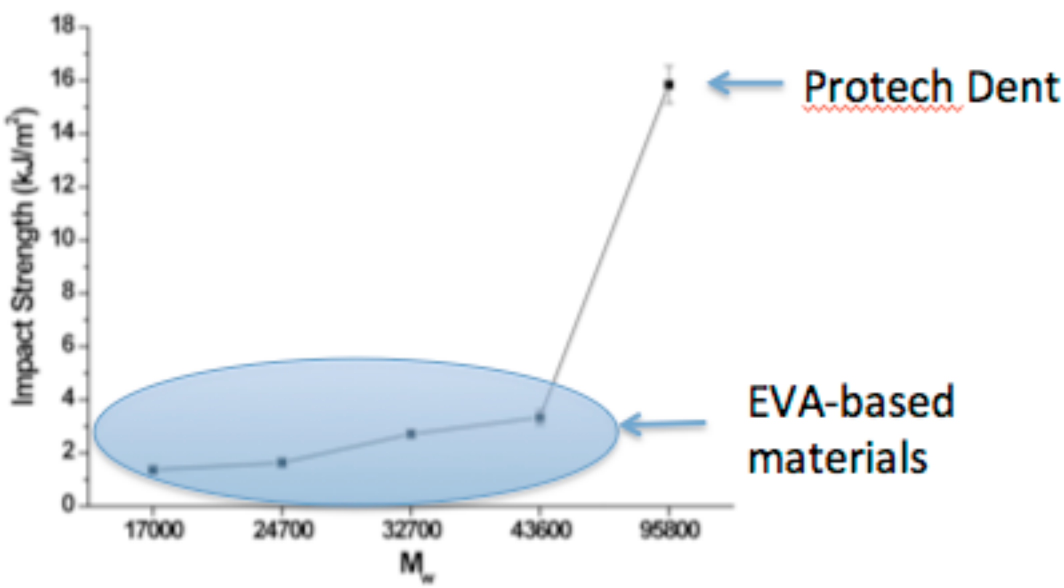


***Figure 1**: Impact strength of EVA and polycaprolactone-based materials as function of molecular weight.*

4 cm x 4 cm squares of 1.6. mm thick perforated Protech Dent mouth guard material and of 4 mm thick ethyl vinyl acetate were cut from sheets. To record pressure transduction during impact tests, Pressurex® pressure indicating films with sensitivity ranges of 5 -500 kg/cm$^2$ were placed underneath the materials. The pressure transduced through the materials to the films was calibrated using a Point Scan system with i1 Pro accessory. A typical impact test result is shown in Figure 2 for a 1.6 mm perforated Protech Dent sheet impacted with an impact energy of 8.232

J and an impact velocity of 4.85 m/s, resulting in a Pressurex® film reading of 373 $kg/cm^2$ (± 12 $kg/cm^2$. The repeatability of the pressure readings was better than ±5%, our criteria of acceptance.

As Figure 2 shows, the perforations in the Protech Dent material decreased in diameter in the center of the impact area, while they expanded towards the edges of the impact area. This confirms our working hypothesis that the deformation of the perforations serve as impact energy absorbing zones. Further support for this hypothesis is provided by the results of multiphysics modeling, described in a later section of the report.

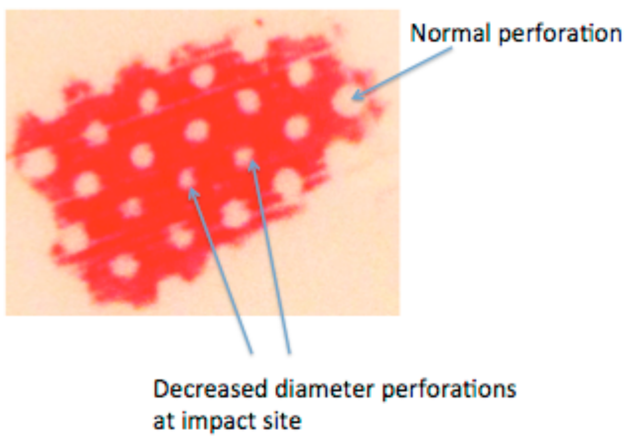


***Figure 2.*** *Pressurex® film imprint obtained on backside of 1.6 mm thick Protech Dent mouth guard material after impact, showing perforations that have changed shape upon impact, with smaller diameter perforations at impact site.*

In pendulum impact tests, a 6 mm thick ceramic tile serving as surrogate for dentitions was placed beneath sheets of mouth guard material. When the tile was protected by 1.6 mm thick perforated Protech Dent material, the pendulum impact energy required to break the tile was 30% higher than for 4mm thick EVA. In other words, the much thinner Protech Dent material provided significantly higher protection for the ceramic tile. Figure 3 summarizes the average impact energy that had to be applied by the pendulum to the mouth guard in order to break the tile underneath the mouth guard material.

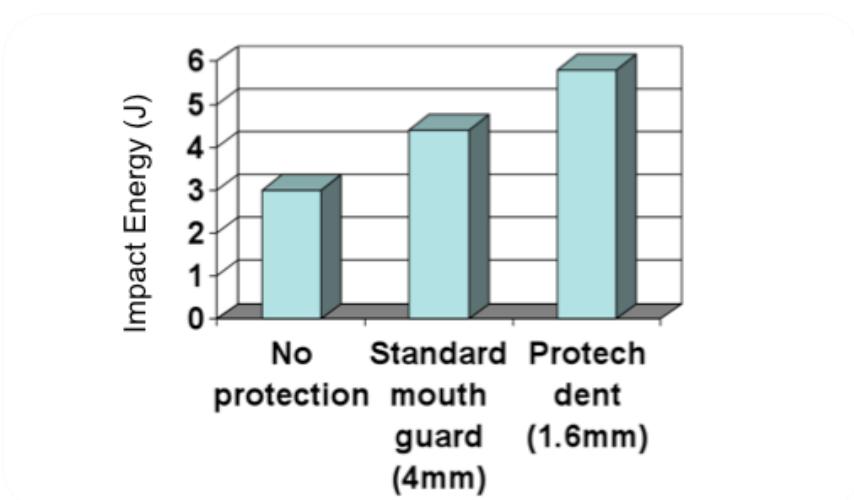


***Figure 3:*** *Comparison of impact energy required to break 6 mm thick ceramic tile without protection, protected with 4 mm thick standard EVA material, and protected with 1.6 mm thick perforated Protech Dent material.*

### ***Comparative evaluation of the impact energy absorption and dissipation ability of mouth guard materials***

Since we have discovered that the perforated Protech Dent mouth guard undergoes energy-absorbing deformation of perforations in the impact zone (Figure 2), there is reason to believe that altering the perforation patterns would have some effect on the energy impact absorption ability of the mouth guard. Therefore, four additional samples of 1.6 mm thick Protech Dent mouth guards were manufactured with different perforation patterns (Figure 4). These Protech Dent samples and 4 mm thick ethylene vinyl acetate (EVA) mouth guard material were tested in a drop stand at three different drop heights of 80 cm, 40 cm, and 20 cm, leading to impact velocities of 13 ft/s, 9.2 ft/s, and 6.5 ft/s, respectively. For comparison purposes, the impact velocities used here are in the range of blunt impact test velocities required for military helmet standards, where impact velocities of 10 and 14.14 ft/s are generally used.

In addition to the tests with 1.6 mm thick Protech Dent mouth guards, drop tests were also conducted on stacked layers of two mouth guards, to bring the thickness to 3.2 mm, closer to that of the 4 mm thick EVA sample, and simulate more closely a situation where both the upper and lower dentitions would be covered with a mouth guard, resulting in a thickness of 3.2 mm at the occlusal surface of the front teeth.

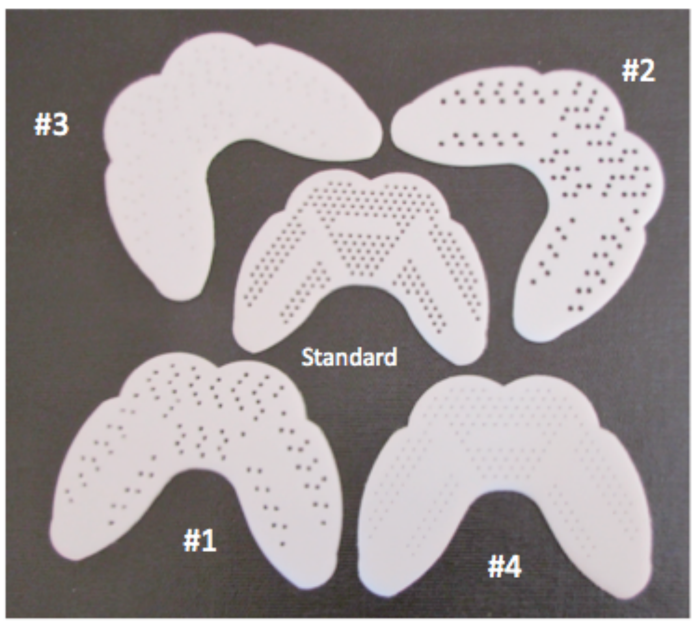


**Figure 4**: *Protech Dent mouth guards with different perforation patterns*

The raw data were collected with 0.5 millisecond time resolution, and the load data for each point in time represent the statistical average of three drop tests. Then, the average load data for a given mouth guard material were normalized with respect to statistically averaged impact data obtained in absence of a mouth guard material. Figure 5 shows the load data obtained for blank runs without mouth guard materials on the transducer, for a drop height of 80 cm and impact velocity of 3 .96 m/s.

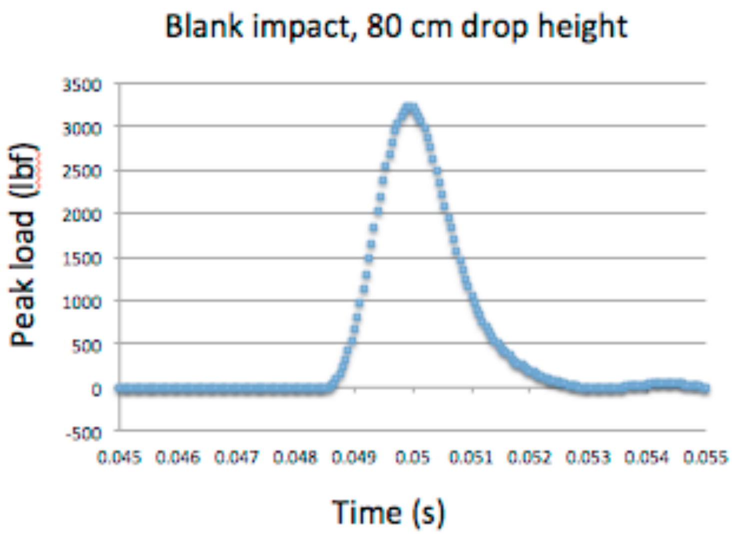


***Figure 5.*** *Load data obtained for blank experiments at 80 cm drop height.*

When a mouth guard material was placed on top of the load cell, the peak loads measured upon impact form 80 cm drop height decreased, and the overall shape of the peak changed. Figure 6 shows an example for the 4 mm EVA, averaged over 3 drop experiments.

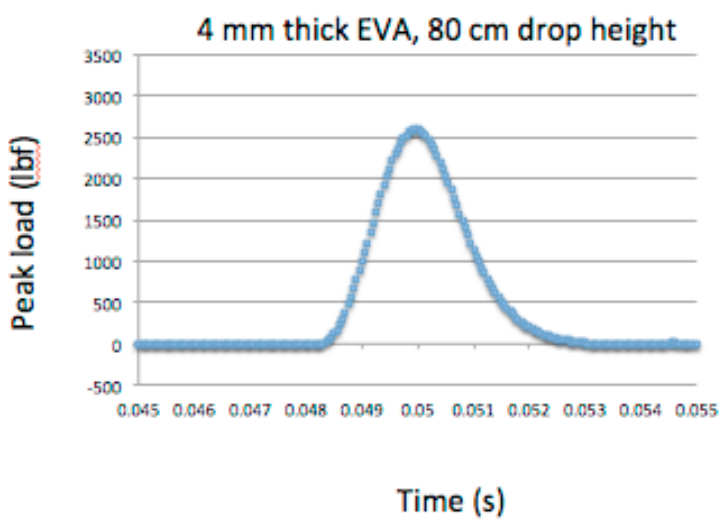


***Figure 6****. Load curve for 4 mm thick EVA at 80 cm drop height.*

To better see the differences in the load curves, the data from Figure 6 were subtracted from the blank data in Figure 5. The results are shown in Figure 7.

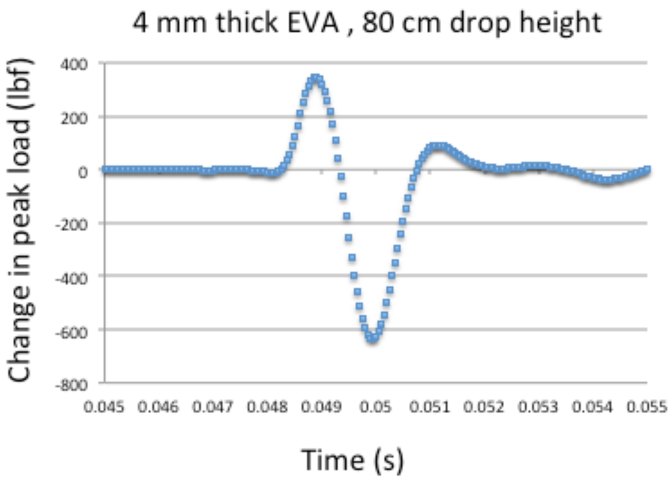


***Figure 7****. Differential load curve, comparing the load curve for 4 mm EVA with that of the blank experiments at 80 cm drop height.*

As shown in Figure 7, the presence of the mouth guard material decreases the peak load, as indicated by the negative peak. The two positive peaks to the left and right of the negative peak indicate that the peak for the 4 mm EVA is broader than in the blank runs. In other words, the overall time interval during which load is transmitted is increased. The initial peak load is transmitted faster by about 1 millisecond (thus the initial positive peak), but overall, the maximum peak load decreased by 636.5 lbf compared to the blank experiment. The negative peak was followed by a second positive peak reaching 91 lbf indicating that the duration of the load transmission was increased by another millisecond or so. In other words, the presence of a mouth guard does not only decrease the peak load, but also spreads the time out during which the load is being transmitted. The 4 mm thick EVA material behaved very similar at 80 cm, 40 cm, and 20 cm drop heights, except for overall smaller peak load values at smaller drop heights.

The Protech Dent mouth guard with the standard perforation pattern gave in contrast to the EVA results two negative peaks in the differential load curve, indicating that the material absorbs energy in two stages, with maximum peak loads decreased by 287 lbf and 108 lbf, respectively (Figure 8). This demonstrates that the perforated Protech Dent material is very effective in damping and dissipating the impact energy over a longer time frame.

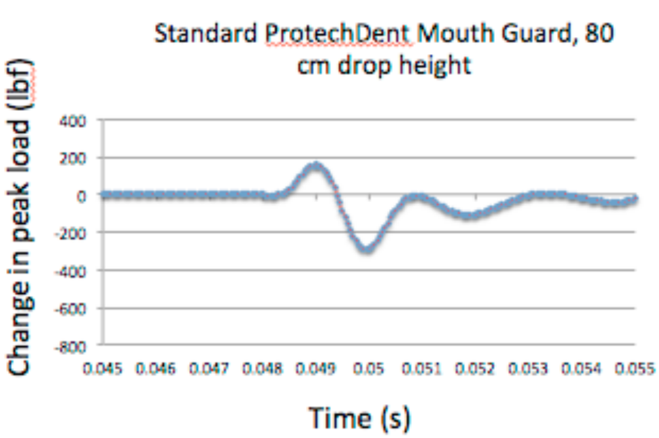


***Figure 8****: Differential peak load measured on 1.6 mm thick Protech Dent material at a drop height of 80 cm.*

To make the comparison with the 4 mm thick EVA more realistic, additional drop tests were carried out where two layers of 1.6 mm Protech Dent material were stacked on top of each other, to give a 3.2 mm thick material. The differential peak load curve for a sample with #4 perforation pattern is shown in Figure 9.

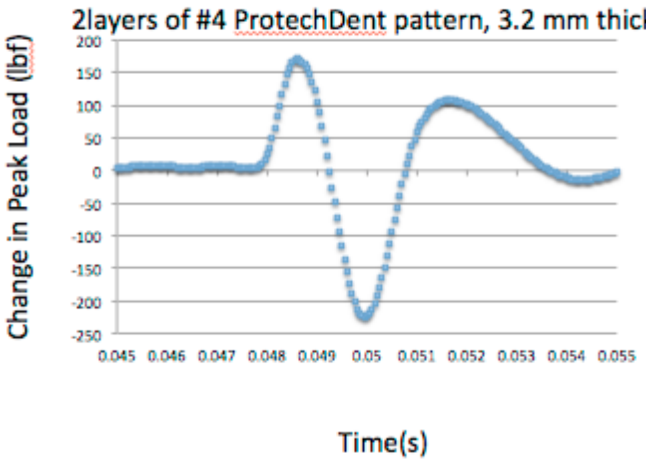



***Figure 9.*** *Differential peak load (compared to blank experiment) on a double layer of 1.6 mm thick Protech Dent material with perforation patterns #4 at a drop height of 20 cm.*

Figure 10 shows the difference in load data, comparing the 4 mm thick EVA directly to the 3.2 mm thick #4 pattern Protech Dent, at 20 cm drop height. The data for the 4 mm thick EVA are subtracted from the data for the 3.2 mm thick Protech Dent. This means that a negative peak indicates better dissipation of impact load. The results demonstrate that 3.2 mm thick Protech Dent outperforms the 4 mm thick EVA under these conditions. The two positive peaks left and right of the main negative peak indicate that the Protech Dent material spreads the impact energy out over a longer time than the EVA.

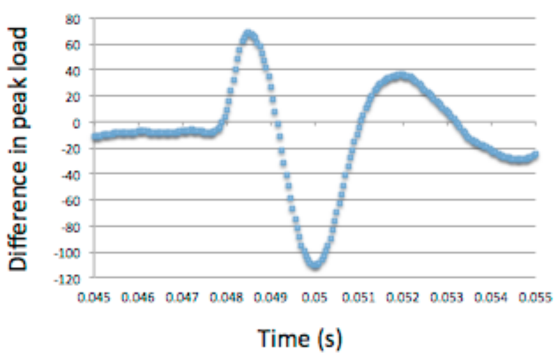


***Figure 10**. Difference in peak load curves of 3.2 mm thick Protech Dent and 4 mm thick EVA at 20 cm drop height.*

To evaluate the effect of different perforation patterns in the Protech Dent mouth guard material, the load data for the different patterns were subtracted from the load data of the standard perforation pattern (Figure 11).

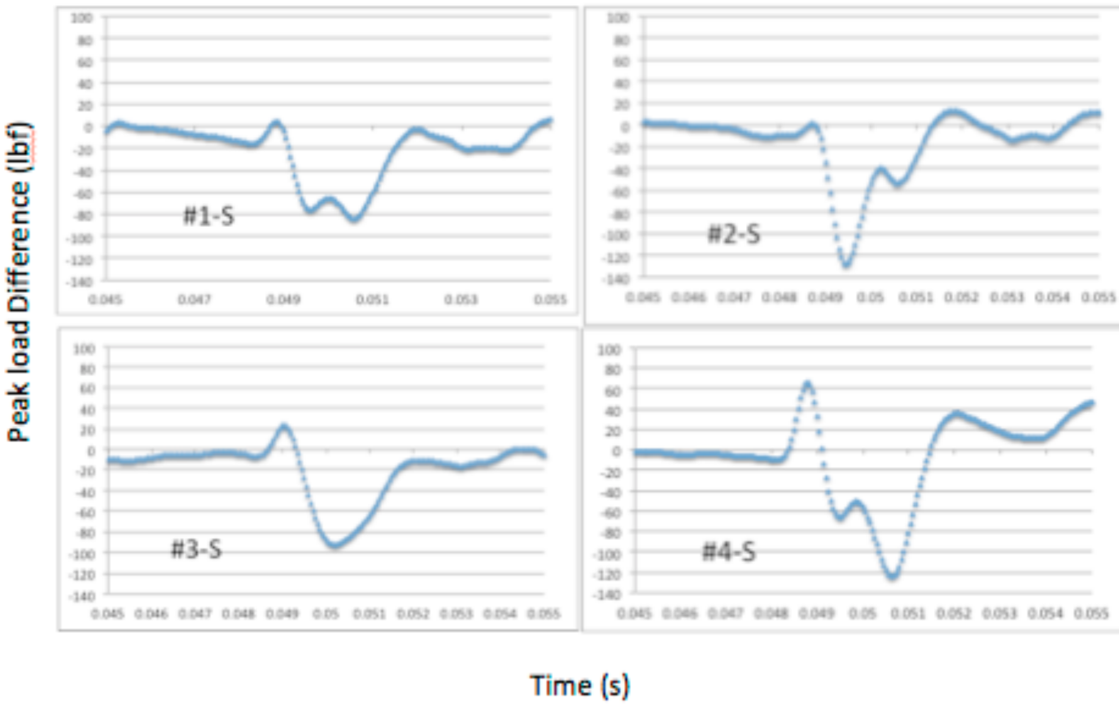


***Figure 11.*** *Differential load curves for patterns # 1,2,3, 4, compared to the standard Protech Dent pattern (S) at 20 cm drop height.*

In all four cases of modified perforation patterns, better impact energy dissipation was achieved, as can be seen from the negative peaks in Figure 11. Patterns #2 and #4 showed the largest decrease in peak load compared to the standard pattern.

The drop tests on the flat samples met the acceptance criteria of repeatability of ±5%. For example, 3 drop tests performed on the standard perforated Protech Dent sample had an experimental variability of the load data of less than ±1%.

In conclusion, the drop test on flat mouth guard samples show that the nearly incompressible 1.6 mm Protech Dent material outperforms the standard soft 4mm EVA material. Furthermore, optimal perforation patterns and double layers for upper lower dentitions further improve the dissipation of impact forces.

### *Task 2: Multi-physic modeling of mouth guard materials.*

A COMSOL™ multi-physics model was created for simulating impact force transmission trough various dental appliance materials. The COMSOL routine was programmed to carry out simulations for flat material samples under static load. The physical properties of ethylene vinyl acetate material as well as of the caprolactone-based Protech Dent material were entered as input into the COMSOL model. The COMSOL model for the Protech Dent mouth guard was based on a technical drawing of the mouth guard, shown in Figure 12:

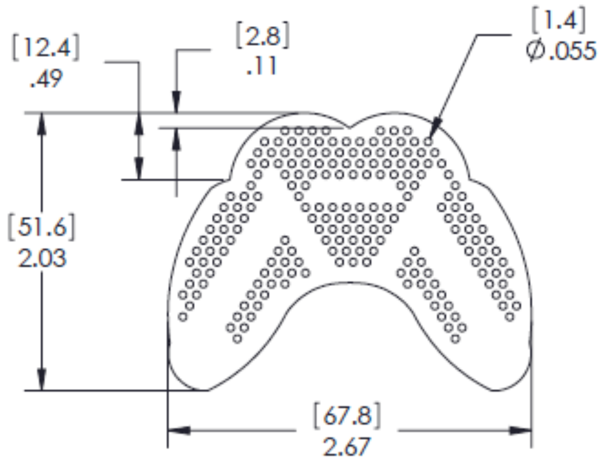


***Figure 12.*** *Technical drawing of perforated mouth guard.*

A static loading of 2 MPa was applied either to the entire top surface of the material, or to selected smaller locations that are indicated by the numbered circles in figure 13. The radius of the first three localized loading areas was 4 mm while that of the fourth loading area was 3 mm.

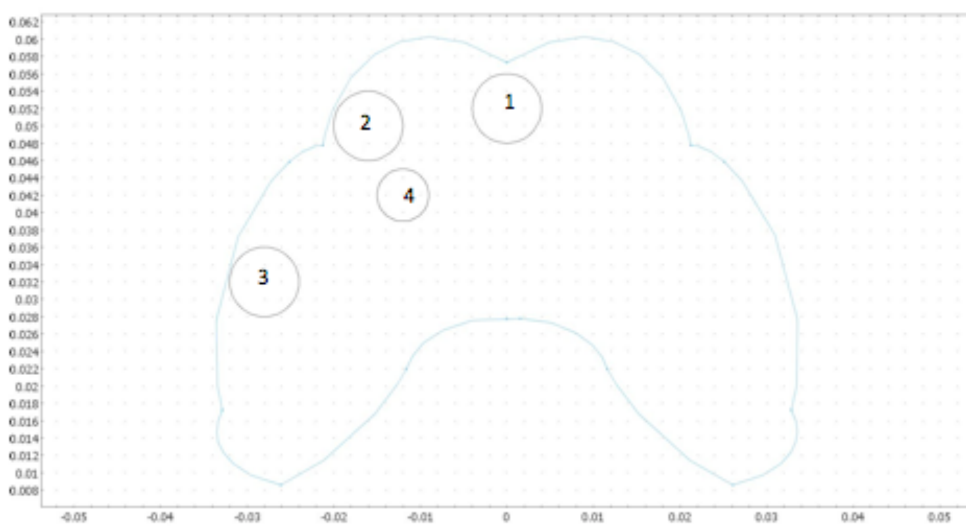


***Figure 13.*** *Regions for static load application on flat mouth guard materials in COMSOL modeling.*

With the exception of the bottom surface, which was fixed, all boundaries and surfaces, including the perforations, were free to move in the model.

The models' behavior and characteristics can be compared by taking a volume integral on the parameter of interest, for example z-axis and total displacements, normal stresses and strains, and dividing the value by the volume of the model, yielding an "average" value. Due to the varying volumes of the three models, this was determined to be the most effective means of comparison. All models were originally auto-meshed by the COMSOL software. For the EVA and unperforated Protech Dent mouth guard materials, the number of elements was under 12,000 while the number was 270,000 for the perforated PCL. To avoid the introduction of potential errors due to vastly different mesh sizes, the mesh of the unperforated PCL model was increased to also contain around 270,000 elements. The COMSOL model provided data on z-axis and total displacements, normal stresses and strains, von Mises stresses, and principal stresses and strains.

Under uniform load applied to the entire surface of the flat mouth guard sample, the most striking observation was the vast difference in parameter values between EVA and the unperforated Protech Dent material. The average z-axis and total displacements differed by two orders of magnitude, and EVA exhibited much larger displacements. From a qualitative observation of the model image, the deformation of the EVA is clearly more pronounced than that of the Protech Dent material (see figures 14 and 15, noting the different scales of the y-axis). The EVA model shows significant deformation from its original geometry, in contrast to the Protech Dent material that showed little deformation.

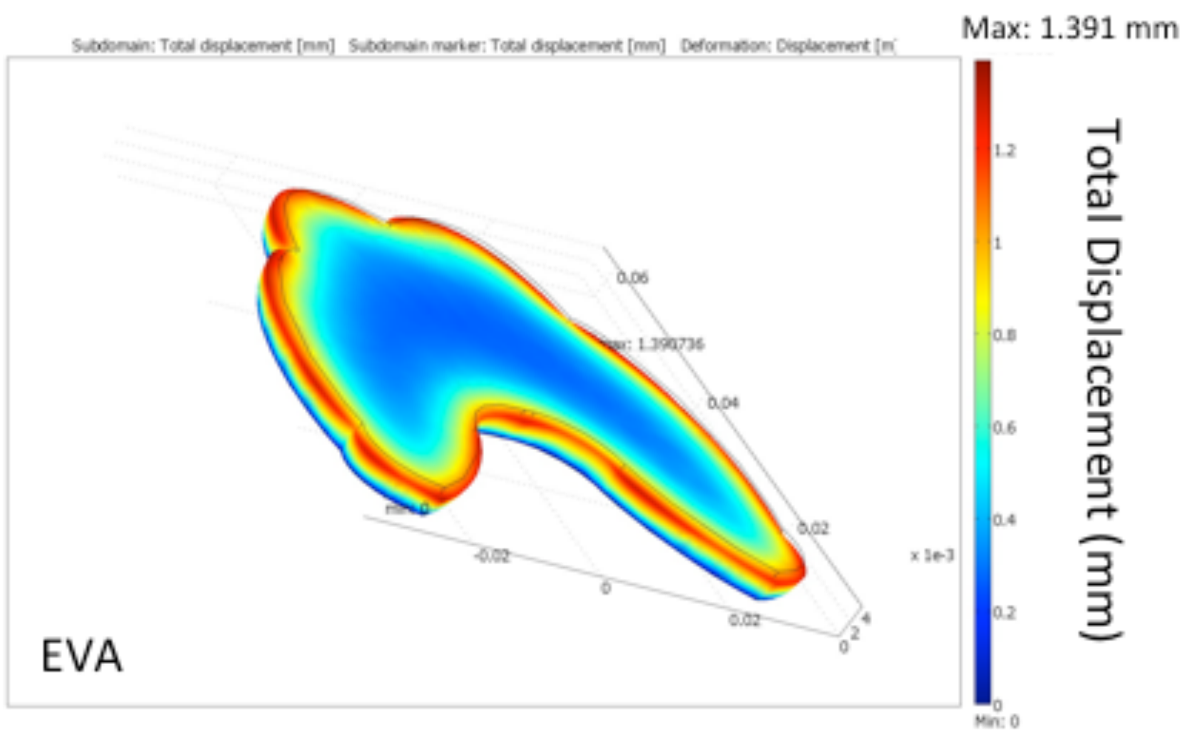


***Figure 14:*** *Total displacement for 4 mm thick EVA under 2 MPa static load*

Interestingly, while the normal stresses of the EVA differed from the Protech Dent material by less than 20%, the normal strains of the EVA model were 66 times that of the Protech Dent material. This indicates that EVA has a stress-strain curve with much lower slope than the Protech Dent material.

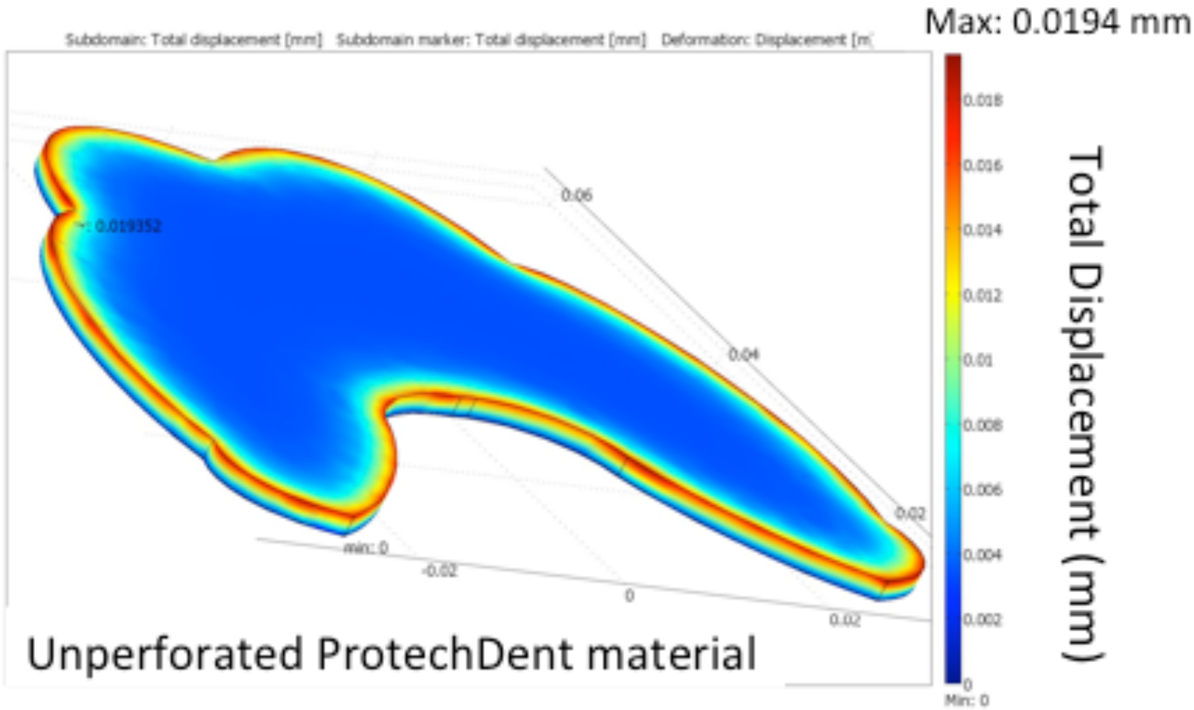


***Figure 15:*** *Total displacement of 1.6 mm thick Protech Dent under 2 MPa static load.*

Comparing the strains of the perforated and unperforated Protech Dent models, the z-normal and third principal strains differed by only 33%, while the x-normal, y-normal, first, and second strains differed by more than 125%. Remarkably, the perforated Protech Dent model yielded a negative second principal strain value, confirming that there is compression within the mouth guard in the planar axis, in agreement with the hypothesis that the perforations deform and thereby absorb energy. Based on the COMSOL modeling results, it can be concluded that the deformation of the mouth guard materials in the z-direction (i.e. the direction of applied load) is much smaller for Protech Dent than for EVA (Figure 16).

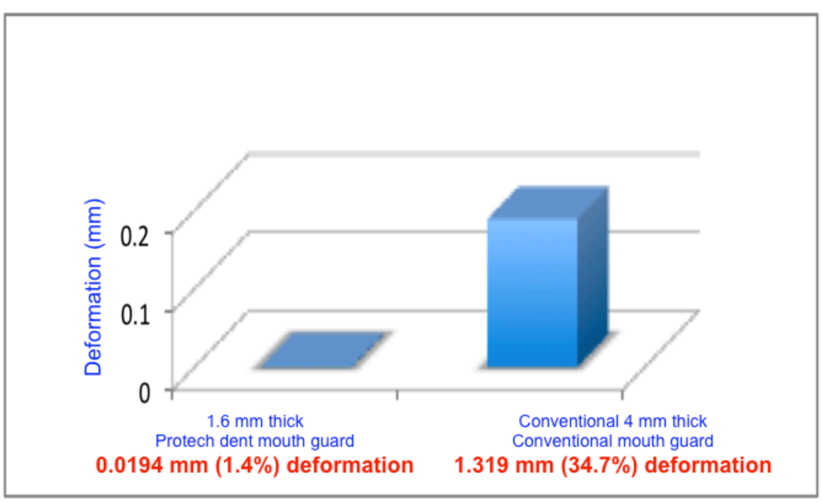


***Figure 16***. *Comparison of z-deformation of Protech Dent and conventional 4 mm thick EVA mouth guard material under 2 MPa static load.*

The COMSOL model was also used to analyze the materials based on the Von Mises-Hencky criterion for ductile failure (often called "Von Mises stress"). The Von Mises criterion is a formula for combining the three principal stresses into an equivalent stress and it represents a critical value of the distortional energy stored in a material. This equivalent stress is then compared to the known yield stress of the material, and if the Von Mises stress exceeds the yield stress, the material is considered to have failed. The von Mises stresses were modeled for a 2MPa load applied to area 4 with 3 mm diameter. Under this 2 MPa load, none of the materials came close to the range where failure would be expected. While the principal stresses were similar in value between EVA, unperforated, and perforated Protech Dent material, EVA and the perforated PCL had similar von Mises stress values while the unperforated PCL had a lower von Mises stress. It is important to remember that one of our objectives was to develop a mouth guard that distributes a significant portion of the impact energy laterally, rather than vertically towards the dentition. The z-displacements exhibited by both the perforated and unperforated Protech Dent materials were substantially smaller than the z-displacement of EVA, proving that EVA transmits more energy vertically. The material should also be tough and dissipate some of the energy within the mouth guard. The fact that the von Mises stress value of perforated Protech Dent is similar to that of EVA, while the vertical deformations in the z-direction are dramatically different, clearly shows that the perforated Protech Dent mouth guard dissipates energy through lateral deformations of perforations while EVA dissipates this energy by vertical deformation, thus increasing the impact force transfer to the teeth. Figures 17 and 18 show the von Mises stress distribution for the top and bottom surfaces of 1.6 mm thick Protech Dent upon application of a 2 MPa load in the region #4 (see Figure 13 for numbering of regions).

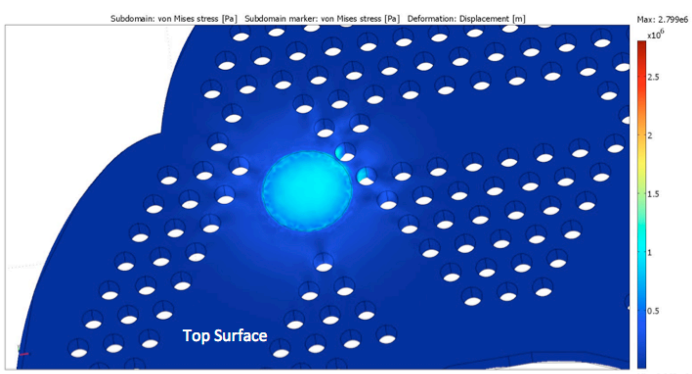


***Figure 17.*** *Von Mises stress distribution on top surface of perforated Protech Dent, with 2 MPa static load locally applied to the region 4 (Scale: 8.068e-8 to 2.799e6 Pa).*

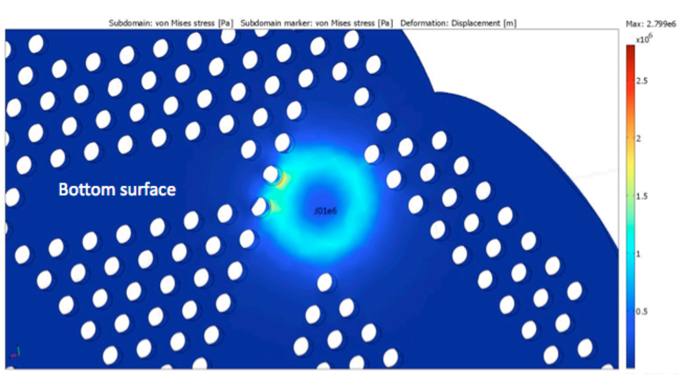


***Figure 18.*** *Von Mises stress distribution on bottom surface of perforated Protech Dent, with 2 MPa static load locally applied to region 4 (Scale: 8.068e-8 to 2.799e6 Pa).*

The top surface shows nearly uniform von Mises stress distribution in a circular area that has a diameter of 3 mm. On the bottom surface the stress is spread out in form of a ring with larger diameter, proving that the material spreads some of the force laterally, rather than transferring it vertically.

The initial version of COMSOL modeling software used was version 3.5, but in May 2011, we have upgraded to version 4.1, which has many additional features. In addition to modeling impact on flat mouth guard samples, we are now able to introduce 3-D modeling to more realistically model the performance of a fitted mouth guard. In these models, in addition to the mouth guard material, a material representing teeth can be introduced as well.

**Task 3. Fitting of mouth guards to artificial dentitions in head form**.

Various types of mouth guard materials have been fitted to the dentitions of a head form shown in Figure 19, by an orthodontist, Dr. Cynthia Fee.

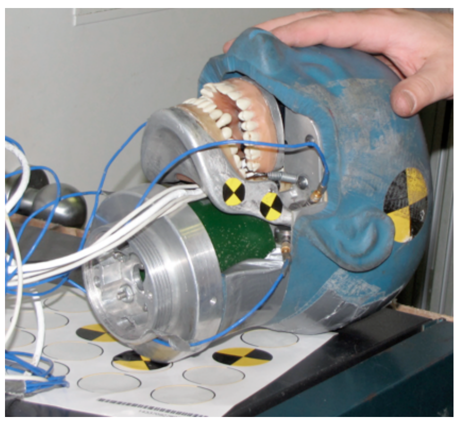

***Fig. 19.*** *Head form with artificial dentitions mounted and accelerometer sensor wiring attached.*

After taking impressions of the dentitions of the head form, nine sets of mouth guards were custom fabricated for the upper and lower dentitions, with three sets each made from colored EVA, clear 2 mm thick EVA, and 2 mm thick acrylic, respectively (Fig. 20).

***Figure 20.*** *Custom fitted mouth guards, showing EVA samples on the left and in the middle, and acrylic samples on the right. Each set contains a mouth guard for the upper and lower dentition.*

In addition, mouth guards were fitted using the 1.6 mm Protech Dent material with standard perforation patterns, and with 4 different perforation patterns (Figure 21).


***Figure 21**. Protech Dent mouth guards with different perforation patters fitted to the upper and lower dentitions of the head form.*

The mouth guards were fitted to the dentition of a head form, as shown in Figure 22.

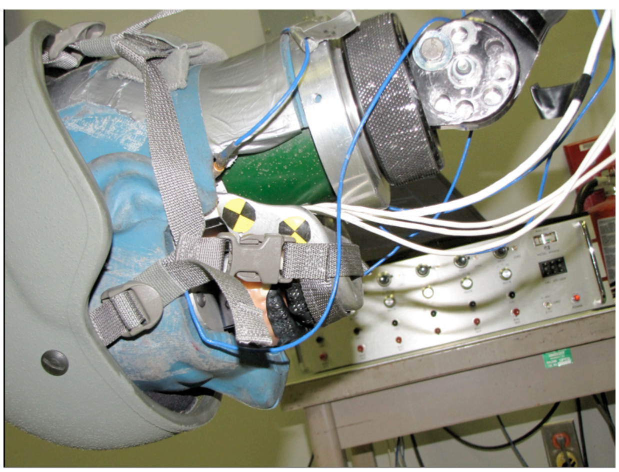

***Figure 22.** Head form with Protech Dent Mouth Guards fitted to the dentitions.*

Dr. Fee verified that the goodness of fit was equivalent to standard custom-made appliances, thereby meeting our criteria for acceptance.

### Task 4. Biomechanics measurements

Biomechanics measurements of force transfer from jaw to TMJ to skull upon impact were conducted at the Bioengineering Center at Wayne State University under the direction of Professor Cynthia Bir. The experiments were carried out by Mr. Nathan Dau, the Manager of the Sports Injury Lab, in presence of Johannes Schwank and Jan Akervall who supervised the experiments.

The drop tests were conducted with a head form corresponding to the National Operating Committee on the Standards for Athletic Equipment (NOCSAE) surrogate (Figure 23).

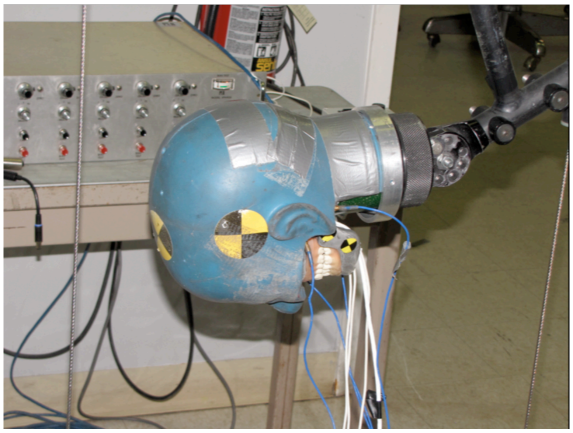

***Figure 23***. *NOCSAE head form.*

However, even this head form does not fully capture the loads experienced in vivo. There is to this date a lack of validated human anthropometric head forms with articulating jaws that would give realistic load transfer through the base of the skull and upper dentition with biomechanical fidelity. According to the conclusions reached in a recent PhD dissertation, "a surrogate with an articulating mandible needs to be developed with known anthropometric and biomechanical fidelity requirements that will allow realistic load transfer through the base of the skull and upper dentition".[1] (***We propose to develop such a head form in Phase II of the project***.)

For the drop tests, the head form was protected by a combat helmet (Figure 24).


***Figure 24.*** *Advanced Combat Helmet used to protect the head form in drop test experiments*

One of the major issues is that the chin strap (Figure 25) is likely to play a significant role in the energy transfer. The type and attachment of chin strap may influence the retention of the helmet upon impact, and this in turn may affect the loads transmitted to the TMJ and skull.

[1] Matthew J. Craig, "Biomechanics of jaw loading in football helmet impacts", Dissertation, Wayne State University 2007.

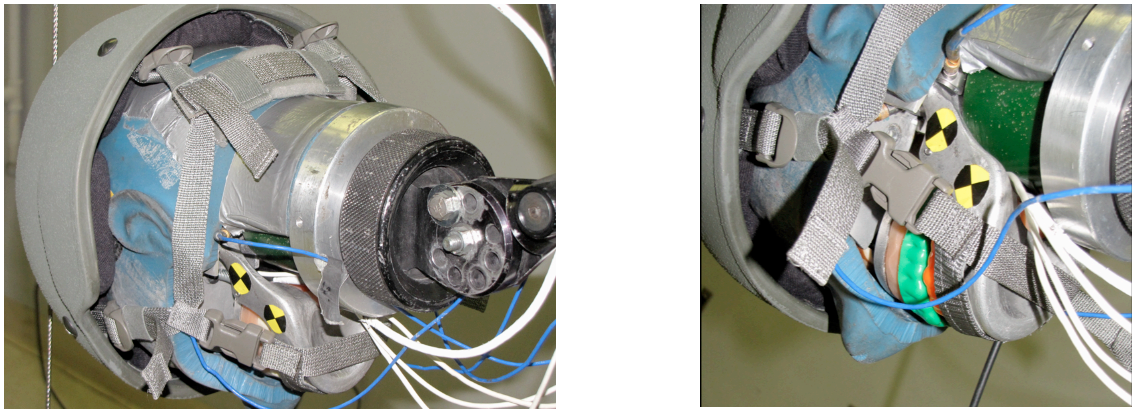

***Figure 25**. Head form with helmet, showing the chin strap position.*

Figure 26 shows the drop stand used for the experiments. A drop height of 47 cm was selected, to match typical conditions used in testing of combat helmets.

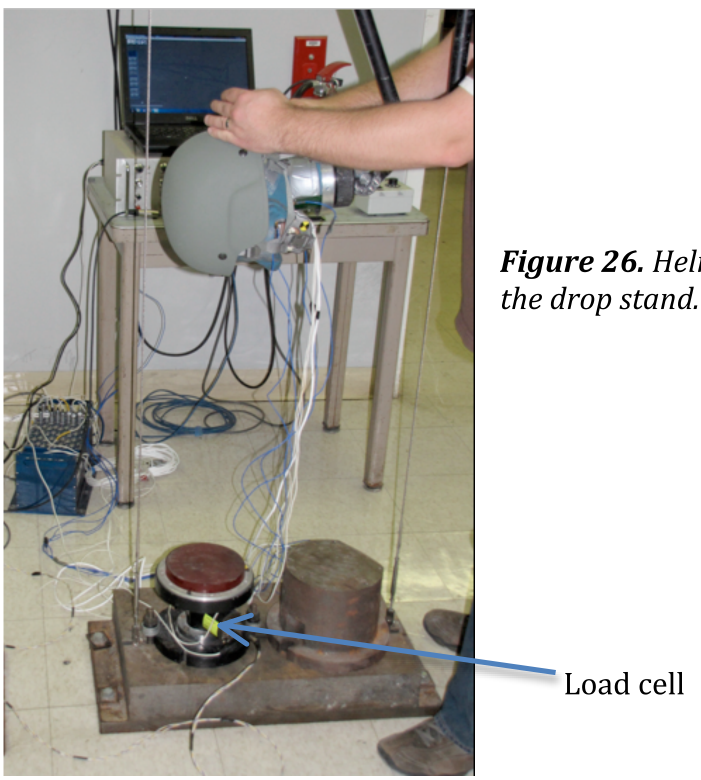


***Figure 26.** Helmet-protected head form mounted on the drop stand.*

The head form was oriented on the drop stand to be in compliance with the standard front impact test configuration used for combat helmet testing, where impact velocities of 10 and 14.14 ft/s are used.[2] (Figure 27)

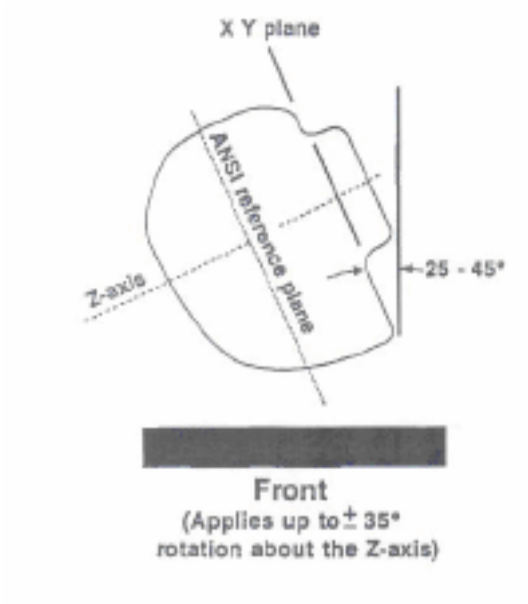


***Figure 27.*** *Test head form orientation for impact testing (adapted from McEntire and Whitley[2]).*

To assess the experimental variability between repeat tests, 6 drop tests were done with the blank head form that had no mouth guards. A drop height to 47 cm was chosen to match the test conditions for standard helmet tests at an impact velocity of 10 ft/s. The first three blank tests were done at the beginning of the experimental set (tests # 4, 5, and 6), and the last three blank tests were performed at the end of the tests (tests # 31, 32, 33), after completing the drop tests with mouth guards mounted on the head form dentitions. Table 1 provides a summary of the results obtained in the 6 blank runs.

***Table 1:*** *Summary of blank run drop test data*

| Test | 4 | 5 | 6 | 31 | 32 | 33 | | |
|---|---|---|---|---|---|---|---|---|
| Mouth Guard | None | None | None | none | none | none | | |
| Drop Height(cm) | 47 | 47 | 47 | 47 | 47 | 47 | Average | Stdev |
| HIC | 69.89 | 70.44 | 79.16 | 99.27 | 123.3 | 121.5 | 88.412 | 22.84035 |
| Max Accel (g's) | 56.7 | 59.42 | 62.77 | 110.12 | 116.62 | 117.66 | 81.126 | 29.60236 |
| SI | 94.36 | 95.21 | 97.76 | 149.6 | 187.69 | 191.59 | 124.924 | 42.14095 |
| TMJ Load (N) | 160.49 | 184.18 | 156.53 | 151.33 | 101.65 | 160.98 | 150.836 | 30.23636 |
| Surface Load (lbf) | 770.75 | 789.65 | 881 | 895 | 992.02 | 956.19 | 865.684 | 89.23064 |

The data show considerable test-to-test variability. To better appreciate the nature and extent of the variability, and to identify any systematic drift in the sensor readings the data sets for Surface Load, Maximum Acceleration, and TMJ Load were plotted as a function of test number.

Figure 28 shows a plot of the surface load readings. One would expect that the load cell at the bottom of the drop stand would give the same load reading for each experiment, as the

[2] USAARL Report No. 2005-12, "Blunt Impact Performance Characteristics of the Advanced Combat Helmet and the Paratrooper and Infantry Personnel Armor System for Ground Troops", B. Joseph McEntire, USAARL, and Philip Whitley, Criterion Analysis Incorporated, August 2005.

drop height was kept exactly the same at 47 cm. However, as one can clearly see form Figure 30, this is not the case, and the signal shows considerable scatter, with a trend toward higher load readings toward the end of the experiments. This suggests a certain degree of signal drift in the load sensor. Since the drop height is carefully controlled, the head form angle is fixed, and the release of the head form in the drop stand is remotely triggered, the most likely explanation for the scatter in the data is that the helmet may slightly and not reproducibly shift with respect to the head form upon impact, thus resulting in different contact positions and areas between helmet and sensor pad.

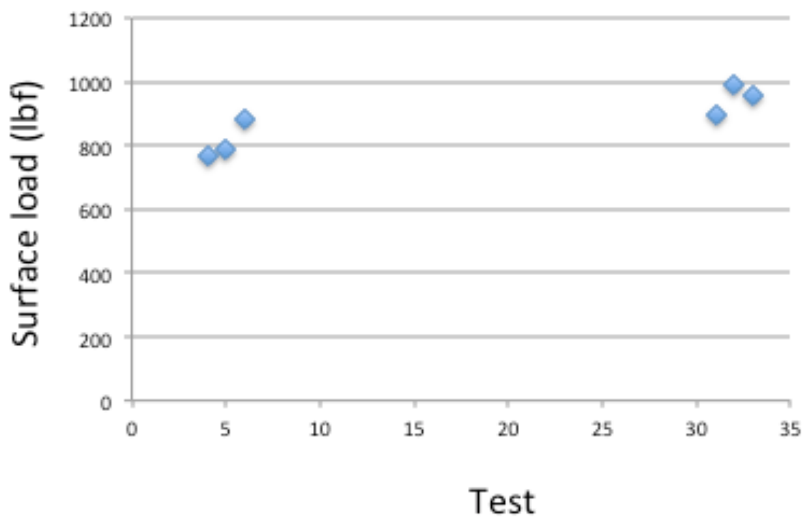


***Figure 28.*** *Surface load readings during six blank experiments without mouth guards.*

Figure 29 shows a plot of the accelerometer readings inside the head form for these same six blank tests. The accelerometer data show a nearly linear signal drift, with the initial readings in the range of 60 g, and final readings towards the end of the test series reaching much higher values of 110-120 g.

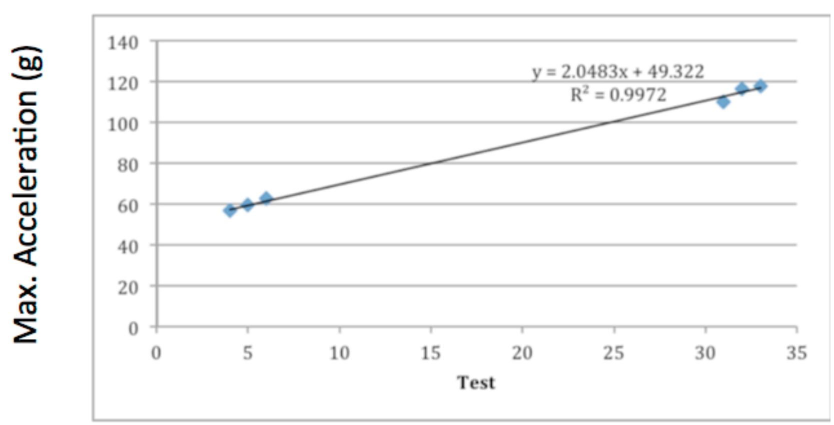


***Figure 29.*** *Maximum acceleration (g) as measured by accelerometer inside the head form during drop test in blank runs without mouth guard.*

Figure 30 shows the load readings of the TMJ load cells. The head form is fitted with four TMJ load cells that independently measure the TMJ load in the right and left jaw. The data plotted in Figure 30 represent the average between the four load cells.

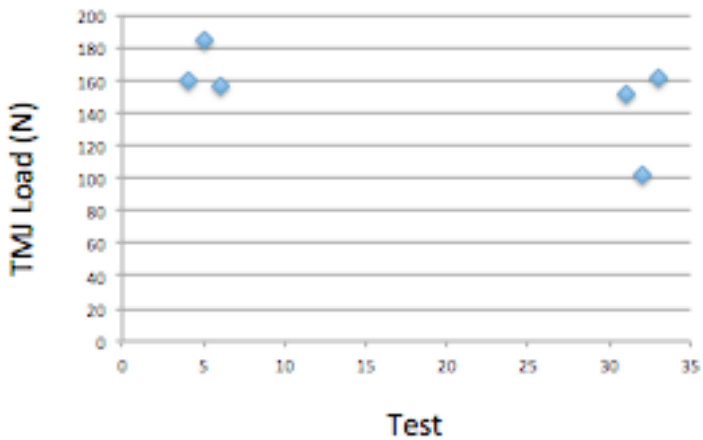


***Figure 30***. *Average TMJ load readings (N) during six blank experiments without mouth guards*

Even though there are these concerns about experimental variability in the drop tests, we still feel that it is of interest to report the drop test data with the mouth guards mounted on both the upper and lower dentitions of the head form. Figure 31 shows the surface load readings for the entire data set, including the Protech Dent mouth guards with standard perforations, the four modified perforation patterns, two sets of EVA mouth guards (clear EVA and orange/green EVA), and a custom-made professional grade acrylic mouth guard.

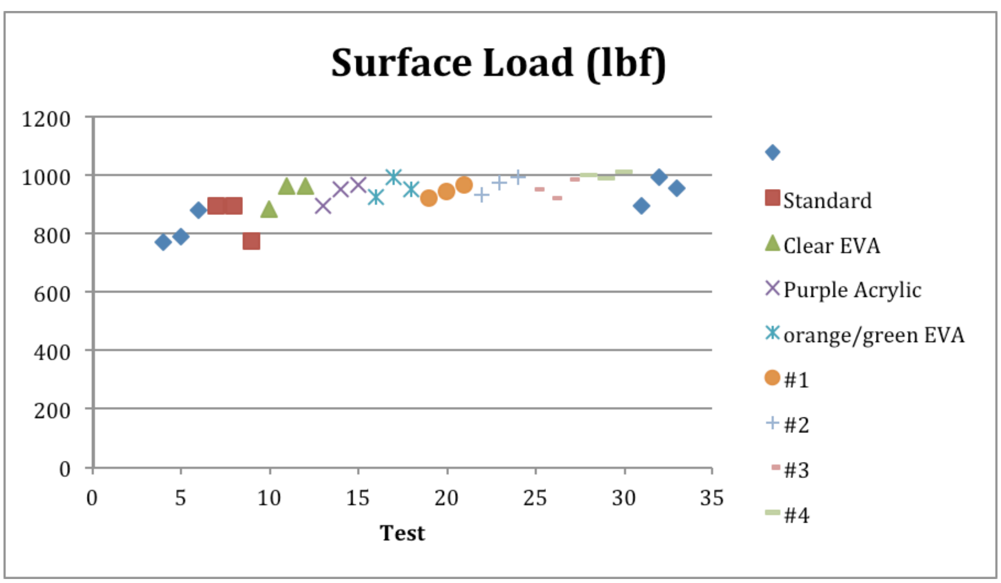


***Figure 31***. *Surface laod readings for the entire set of experiments.*

Inspection of Figure 31 indicates a systematic drift of the load data to higher readings from test to test. Figure 32 provides an overview of the maximum acceleration values recorded by the accelerometers inside the head form.

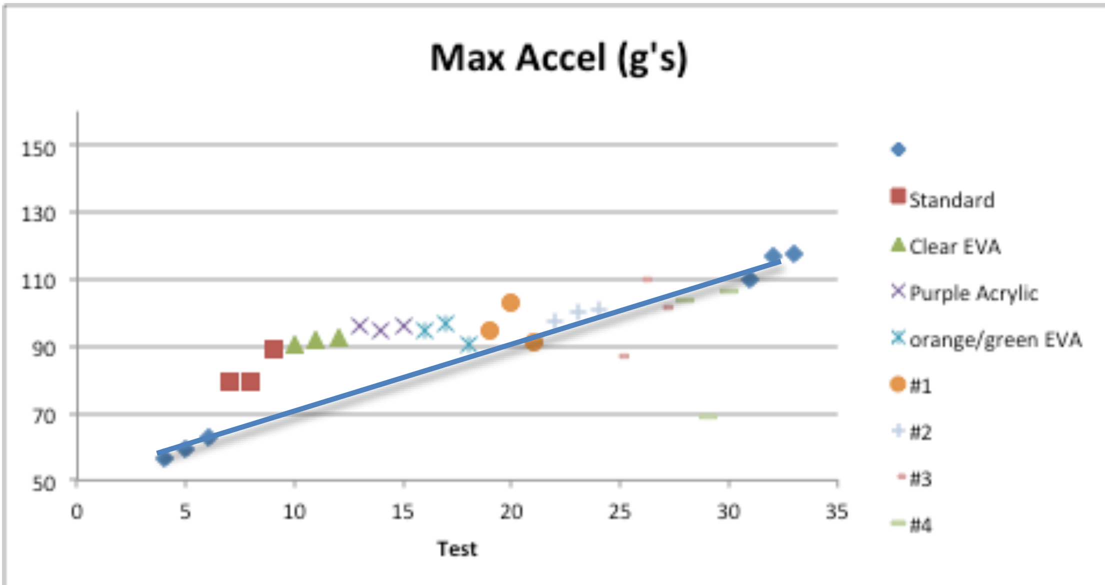


***Figure 32.*** *Acceleration data collected with mouth guards protecting the dentitions. The solid line is an extrapolation of the accelerometer readings obtained in the six blank tests 4,5,6 and 31,32,33, showing accelerometer sensor drift from test to test.*

The straight line represents a linear extrapolation of the acceleration data obtained for the blank experiments, showing the linear upwards drift from test to test. Compared to the blank test accelerometer reading that one would expect for a given test number, the actual data points obtained in the test series with mouth guards in place show higher acceleration up to about test #20. This would indicate that the presence of mouth guards actually increases the acceleration! However, this cannot be generalized, as the tests later in the series fall on the line showing essentially no negative effect of the presence of mouth guards. In one case, namely test #25 with Protech Dent pattern #4, a lower than expected acceleration reading was obtained. However, given the above-mentioned concern about test-to-test variability, it would be premature to draw conclusions about the effect of mouth guards on acceleration inside the head form.

Figure 33 shows the data set obtained for the TMJ loads. Note that each data point represents the average reading of four TMJ sensors, two of them located in the left side and two in the right side of the head form. The outcome of these tests can be called inconclusive at best, and no clear trends are observed. Notably, the professional grade acrylic mouth guard showed the largest TMJ loads!

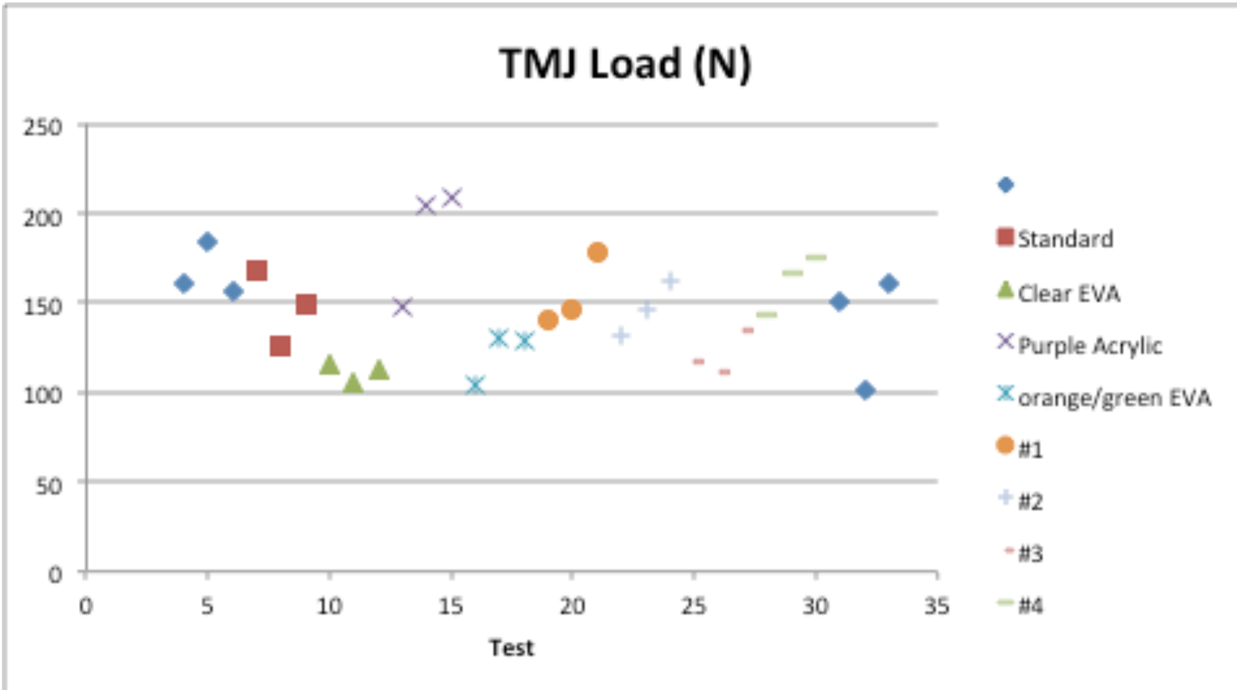


***Figure 33***. *TMJ loads for the entire data set.*

This degree of experimental variability makes it difficult to arrive at accurate comparisons of the effect of mouth guards form these types of drop tests. Upon examination of other data sets unrelated to our work, where similar head forms were used, we realized that this significant degree of experimental variability is quite common. This may explain why there is such inconclusive and contradictory evidence in the literature whether or not mouth guards make any difference with regards to protection from traumatic brain injury (TBI).

To improve this situation, we have come to the conclusion that substantial modifications to the state-of-art surrogate head form need to be made to improve the repeatability. First, we need to change the loading surface of the TMJ load cells. By lowering the stiffness of these surfaces, the resulting data would have less noise and be more repeatable. Also, the mandible retention system will need major improvements. This can be accomplished by increasing the tension in the system and changing the direction of tension. The direction of tension would be changed such that the mandible position is maintained anterior/posteriorly as well as superior/inferiorly. Currently the mandible position is maintained by bilateral, vertical springs. If the inferior attachment of these springs was moved anteriorly, the mandible would be pulled superiorly and posteriorly. This would ensure that the mandible is in contact with all four TMJ load cells prior to test.

We also concluded that further experimentations might need to include shock tube experiments, where the head form is not subjected to any mechanical drop, to get better experimental reproducibility under controlled experimental conditions.

**Proposed Option Effort:**

As indicated in the initial proposal, the Option includes two tasks, namely the multiphysics modeling guided optimization of the perforation patters, and the experimental validation of these improved designs via biomechanics testing. We have acquired the newest version of COMSOL software and are eager to use it for developing 3-D models of fitted mouth guards with high fidelity that will give us insight beyond the behavior of flat material samples. However, before the biomechanics validation of successful perforation pattern optimization can be conducted, the required modifications in the head form need to be made, to assure experimental repeatability that meets our criteria of acceptance. This will require resources that go beyond the funds provided in the option and may need to be included in a Phase II effort.