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Abstract

Statement of problem. Hard acrylic bite splints for use with sleep bruxism management are expensive, and many insurance providers only cover one splint per lifetime. Hence, there is a need for an alternative splint, which can be inexpensively replaced, for use in managing sleep bruxism. Purpose. The study's purpose was to compare an inexpensive, over-the-counter (OTC) bite splint with the gold standard Michigan (MI) acrylic splint in terms of patient compliance, patient satisfaction, and oral health. Material and Methods. Subjects were randomly assigned to receive either the OTC or MI appliance. Subject fabrication of the OTC splint was assessed. Compliance for both splints was assessed in terms of nights worn over a 4-month time period. Plaque and marginal gingiva were monitored in both splints over this time period as well. At the end of the study, subject satisfaction with both splints was assessed. Results. There were no significant differences in compliance. Both groups showed equal levels of satisfaction with their splints, although the reasons differed somewhat between groups. Plaque and marginal gingiva indices were similar between splints. Fabrication of the OTC splint was somewhat problematic, with significant errors occurring in 90% of the OTC splints. Errors were easily corrected with feedback, however. Conclusions. The OTC splint may be an inexpensive alternative to the traditional gold standard MI splint, as long as its use is carefully monitored by a dentist.

Keywords	sleep bruxism; orthotics; night guard; insurance
Taxonomy	Dental Materials, Mastication, Oral Function, Periodontics, Sleep Disorder, Orofacial Pain

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The authors do not have permission to share data

Dear Editorial Staff:

Enclosed, please find a copy of the manuscript entitled “A comparison of compliance and oral health between two bite splints, a randomized clinical trial”. The results are not being considered for publication elsewhere, and the work is original and free of conflict of interests. All authors have viewed and approved of the manuscript in its submitted form. The IRB-approved randomized clinical trial focuses on comparing the gold standard Michigan orthotic and an over-the-counter, boil-and-bite night guard. Issues investigated are subject compliance, satisfaction, and oral health between the splints and through time. As it does involve more than four authors, an author agreement will be uploaded as well. Briefly, Dr. Gerstner was the PI and was involved with the design, execution and analysis of the study, Dr. Yao was involved with clinical assessments during appointment 1, with the analysis of clinical data, and with editing of the manuscript. Drs. Ludkin, Decker, Sinacola and Frimenko were involved with developing the periodontal investigations, and with sampling the periodontal data during the appointments when these data were collected. All have made contributions to developing and editing the manuscript.

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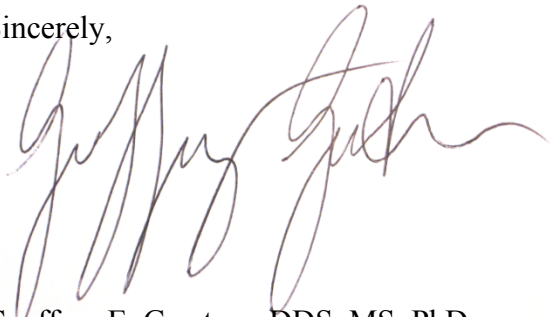

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A comparison of compliance and oral health between two bite splints, a randomized clinical trial

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A comparison of compliance and oral health between two bite splints, a randomized clinical trial

ABSTRACT

Statement of problem. Hard acrylic bite splints for use with sleep bruxism management are expensive, and many insurance providers only cover one splint per lifetime. Hence, there is a need for an alternative splint, which can be inexpensively replaced, for use in managing sleep bruxism.

Purpose. The study's purpose was to compare an inexpensive, over-the-counter (OTC) bite splint with the gold standard Michigan (MI) acrylic splint in terms of patient compliance, patient satisfaction, and oral health.

Material and Methods. Subjects were randomly assigned to receive either the OTC or MI appliance. Subject fabrication of the OTC splint was assessed. Compliance for both splints was assessed in terms of nights worn over a 4-month time period. Plaque and marginal gingiva were monitored in both splints over this time period as well. At the end of the study, subject satisfaction with both splints was assessed.

Results. There were no significant differences in compliance. Both groups showed equal levels of satisfaction with their splints, although the reasons differed somewhat between groups. Plaque and marginal gingiva indices were similar between splints. Fabrication of the OTC splint was somewhat problematic, with significant errors occurring in 90% of the OTC splints. Errors were easily corrected with feedback, however.

Conclusions. The OTC splint may be an inexpensive alternative to the traditional gold standard MI splint, as long as its use is carefully monitored by a dentist.

CLINICAL IMPLICATIONS

Hard acrylic bite splints are expensive and often only covered once by insurers. An inexpensive, OTC splint may be a workable option, which insurers are willing to cover multiple times; however, careful monitoring of splint fabrication and use by a dentist remains highly recommended if not essential.

INTRODUCTION

Tooth wear is a prevalent condition; at least four teeth per dentition show significant wear in over 50% of the human population, and prevalence increases to 60% by the 7th decade of life.[1] Oral appliances or occlusal splints are often used for reducing wear caused by bruxism, clenching and grinding.[1] Patients who have a history of bite splint wear have higher rates of tooth wear,[1] and there is evidence that terminating splint use can cause symptoms to return in patients with both temporomandibular disorders (TMD) and sleep bruxism (SB).[2] This suggests that both early intervention and long-term splint use are required to reduce initial tooth wear and prevent symptom recurrence, respectively.

There are three commonly recognized oral devices,[3] (1) an over-the-counter (OTC) stock type, which does not adjust to an individual's dentition, (2) an OTC, mouth-formed or boil and bite type, and (3) the custom-made appliance. The two OTC devices are typically used without professional dental supervision, whereas the latter requires professional dental intervention. Bite splints for use with bruxism are most often the custom-made variety.

Evidence varies as to whether any one device is superior. Most dental experts presently recommend the custom-made mouth guards for sports purposes.[3] On the other hand, for SB, custom-made hard acrylic or boil and bite night guards are apparently equally efficacious.[4] A review of randomized clinical trials (RCTs) indicates that hard acrylic orthotics are superior to soft appliances or repositioning appliances in managing TMD pain.[5]

However, the issue with custom-made hard acrylic appliances is that they are expensive and typically not repetitively covered by insurance. Hence, there is a need for an inexpensive, alternative that has the functional efficacy of the custom hard acrylic appliances, and which Tooth wear is a prevalent condition; at least four teeth per dentition show significant wear in

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However, the issue with custom-made hard acrylic appliances is that they are expensive and typically not repetitively covered by insurance. Hence, there is a need for an inexpensive, alternative that has the functional efficacy of the custom hard acrylic appliances, and which insurers will cover when appliances require replacement. It is also clear that, for such a device to be a legitimate alternative, it must undergo the appropriate clinical trials.[5-7]

The present study focused on a specific OTC splint, the SOVA night guard (Akervall Technologies, Saline, MI). This splint consists of a novel polymer, and it features a perforated surface. These design features led to a specific concern with regard to impacts on dental plaque and gingival health. Evidence linking sleep bruxism with periodontal disease exists;[8] however, little has been published on the impacts of bite splints on the periodontium. Bite splints have been shown to reduce snoring in children,[9] and patients who mouth breath while sleeping have an increased odds ratio of bruxing (OR = 1.56).[10] This suggests that mouth breathing may be reduced with splint wear, which could have favorable benefits regarding plaque and gingival health.

Thus, the purpose of this study was to compare the OTC SOVA night guard to the Michigan hard acrylic bite splint, the latter serving as a gold standard. Specifically, we focused on patient compliance and satisfaction, while monitoring any changes to dental plaque and gingival health over the course of the study.

METHODS AND STUDY DESIGNS

Figure 1A overviews the study's sequence. The main objectives of this randomized clinical trial were (1) to evaluate the use of two splints over a 4-mo period, (2) to document reasons why subjects did not wear them, (3) to evaluate plaque and gingival health, and (4) to assess self-report of oral health during this time period. Also, because one of the splints was an OTC model, we evaluated the ability of users to follow fabrication instructions by inspecting the final fabrication for clinical acceptability. The study was approved by the University of Michigan Medical Review Board (IRB-MED, ID# HUM00085489), and all participating subjects read and signed informed consents.

Subjects

Figure 1B shows the subject recruitment and retention numbers. Initially 103 candidates were screened, of which 22 either did not meet inclusion/exclusion criteria (see below) or decided not to participate. After being randomly allocated to one of the two groups, an additional 14 subjects decided not to participate. Thus, 67 subjects began interventions, with one subject from the MI and five from the SOVA group not completing the study due to protocol violation or being lost to follow-up. A total of 61 subjects completed the study. This number was considered sufficient, based upon a power analysis using published data on SB treatments,[11] along with an $\alpha = 0.05$ and $\beta = 0.8$. This analysis determined that a study would be sufficiently powered with sample sizes of 29 per group. A total of 31 subjects in the SOVA group and 30 subjects in the MI group completed the study.

Candidates underwent a screening to assess co-morbidities and to identify inclusion and exclusion criteria (Figure 1). Standard survey instruments included the Jaw Function Limitation Scale (JFLS),[12] the TMD Pain Screener (TMDPS),[13] Measure of Symptoms Sleep Scale (MOS),[14] Perceived Stress Scale (PSS),[15] and Oral Behaviors Checklist (OBC).[16] For analysis, the JFLS, OBC, and MOS were subdivided and scored according to published methods and recommendations.[12,14,16] Additionally, a baseline intra- and extra-oral clinical exam was performed to evaluate dental and medical health and to evaluate temporomandibular disorder (TMD) signs and symptoms using the Diagnostic Criteria for TMD (TMD-RDC).[17]

Subject inclusion criteria were: (1) at least 18 years of age, (2) clinical signs of dental wear, (3) self-report of nocturnal grinding and clenching noises, (4) absence of outstanding dental and medical conditions, including cardiovascular disease, sleep apnea, and diagnosed sleep disorders, (5) full dentition sans 3rd molars, (6) no movement nor neurological disorders,

(7) no active orthodontics, (8) no outstanding or previous periodontal problems, (9) no removable prostheses, (10) no use of medications known to have movement disorders or sleep disturbances as side effects, (11) ability to follow instructions, and (12) ability to report to the clinical laboratory at appointed times over the course of the study. The presence of TMD joint noises or masticatory myalgia was permitted; however, joint arthritides were not. A physician with sleep medicine expertise was consulted on medications suspected of having adverse effects that would impact the study; any candidates taking these medications were excluded from the study.

Subjects meeting the acceptance criteria were randomly assigned to one of the two interventions, an OTC, 'boil-and-bite' night guard (SOVA, Ackerval Technologies, Saline, MI, Fig. 2A), or a hard acrylic occlusal night guard referred to hereafter as the Michigan appliance (MI, Fig. 2B). The random assignment relied upon stratified randomization procedures reported in,[18] using a custom algorithm in Excel (Version 2010, Microsoft) to assign groups. Care was taken to match the randomized groups for gender and TMD signs and symptoms. Subjects selected for participation had alginate impressions taken, which were then poured in dental stone. The models were used either to fabricate the MI appliance or to assess SOVA appliances for fabrication efficacy (see below).

Possible and probable bruxing assessments

Question 1 of the OBC was used to screen and to compare severity of self-reported bruxism between groups. Dental wear was clinically evaluated; scores of wear into enamel (1), and wear into dentin (2) were assigned to each subject (candidates with scores of no wear (0) were excluded from the study during the screening process). Use of these scores provided an operational diagnosis of probable sleep bruxism.[19]

Splint delivery; SOVA fabrication assessment

For the SOVA group, subjects were asked to fabricate SOVA devices in the clinic as part of appointment 2 (Figure 1A). Fabrication involved having subjects read the manufacturer's instructions. The instructions also provided a help-line number, which users could call if they had questions about splint fabrication. For the study, subjects were told that such questions should be directed towards a clinical investigator, who was trained to respond in a manner similar to the company's help line.

Once the splint was fabricated according to what the subject considered acceptable and complete standards, an assessment of the splint was performed by a clinical investigator. Critical errors were categorized as: (1) misalignment, defined as having at least 50% of the non-perforated region of the splint occurring on non-occlusal surfaces; this was further defined by rotation (Figure 3A), or translation (Figure 3B) of the splint body, (2) inadequate lingual or facial tissue adaptation, defined as having > 2mm space between the splint and adjacent tissue, which extended mesiodistally at least two tooth lengths, (3) improper posterior coverage, defined by flared flanges, e.g., Figure 3D, or by lack of coverage of occlusal contact areas on posterior molar surfaces (Fig. 3A, circles), (4) excessive mandibular occlusal indentations, defined as surface indentations that reduced the splint material thickness by 50% in the posterior regions bilaterally (Figure 3C). Errors measurements with performed with a perio probe or Boley gauge.

If critical errors were discovered, these were pointed out to the subject, at which time the subjects were required to remold or refabricate the splint. The total number of refabrications, total time spent fabricating and reasons for refabrication were tallied.

The MI appliance was fabricated by technicians in a dental laboratory used by the University of Michigan School of Dentistry. The MI splint was fabricated between appointments

1 and 2 (Figure 1A). Upon delivery, MI splints were checked for internal fit and stability, and the occlusion was evaluated and adjusted by the clinical investigator.

Survey assessments

A custom survey was provided to SOVA subjects that covered ease of fabrication and ease of instructions. At the end of the study, another custom survey was provided to all subjects that covered user satisfaction. Likert scales were used in both custom surveys. Additional standard surveys were provided during appointments 1 and 4 to assess self-reported oral health over the 4-month use period; these surveys included the Oral Health Impact Profile (OHIP),[20] the Tampa Scale for Kinesiophobia for Temporomandibular Disorders (TSK),[21] and the TMD Pain Screener (TMDPS).[13]

Compliance assessment

Compliance assessment was defined by the total number of nights the splint was worn divided by the total number of days between appointments 2 and 4. Compliance assessments were collected via daily diaries filled out at home over the 4-month study period. Subjects were instructed that it was very important to account accurately for the nights the splints were not worn and that there was no judgement associated with missed nights.

Oral health

Oral health was assessed using the Rustogi modification of the Navy plaque index (RMNPI)[22] and the modified gingival index (MGI).[23, 24] Assessments were done by calibrated periodontal residents in the University of Michigan School of Dentistry residency program. The residents were blinded throughout the course of the study to the group assignment of the subjects. Care was also taken to match even numbers of SOVA and MI subjects to each rater. Periodontal data were taken at baseline and after 1 week and 4 months of splint possession. For analyses, the

RMNPI and MGI scores were calculated separately for the upper and lower arches, and based on totals of 28 MGI and 252 RMNPI sites per arch (3rd molars were not assessed in the subjects who possessed them).

Statistical tests

Statistical analyses were done in SPSS 25. Continuous data were evaluated for normality using Q-Q plots and the Shapiro-Wilk test. If normality assumptions were violated, data were transformed. If normality could not be achieved through transformation, data were analyzed with non-parametric tests. General linear models (GLM) were used for tests of within- and between-group differences. A repeated measures design was used for data collected multiple times from subjects during the study. Pearson's product moment was used for correlation analyses involving normally-distributed data.

For non-normally-distributed data and non-continuous data, the Mann-Whitney U test was used for comparisons between treatment groups. For tests involving more than two categories, Kruskall-Wallis or Friedman tests were used. For correlation analyses of non-continuous data, Spearman's rank correlation test was used.

Because the study's aim was to determine whether the SOVA splint was similar to the MI splint, we felt it was critical to identify and report even potentially significant differences between splints and study groups. Therefore, we employed a liberal, non-corrected $P < 0.05$, except in the case where GLM *post-hoc* tests were performed; in the latter case, a Bonferroni correction was used.

RESULTS

Demographics

Table 1 shows subject demographics. Both initial and final enrollment figures are shown. There were no significant differences between the two groups in any demographic categories; statistical results are shown at the bottom of Table 1.

Baseline Between-Group Comparisons

Bruxing habit self-report was based on question 1 of the OBC (see Section 2.1.1). No between-group differences existed in this self-report score (Mann-Whitney $U = 417$, $P = 0.462$). Twenty-five subjects (11 SOVA, 14 MI) reported bruxing 4 – 7 nights / wk, 26 subjects (12 SOVA, 14 MI) reported bruxing 1 – 3 nights / wk, and nine subjects (6 SOVA, 3 MI) reported 1 – 3 nights per month. (The OBC was not available for analysis from one SOVA subject).

Clinical wear assessment was assessed by a clinical investigator (Section 2.1.1). There were no significant differences in clinical wear between groups ($U = 415$, $P = 0.537$). All but one subject had multiple wear facets on all posterior teeth; in the remaining case (1 SOVA subject), multiple wear facets were present in molars only. Wear into enamel only was seen in 22 subjects (12 MI and 10 SOVA), whereas wear into dentin was documented in 39 subjects (19 MI and 20 SOVA). Clinical wear assessment was blinded to the self-report results, above; nevertheless, there was a trend between clinical wear assessment and bruxing habit self-report scores (Spearman's $\rho = 0.248$, $P = 0.059$, $df = 59$).

No significant between-group differences existed for TMD sign/symptom categories. Twelve MI and 16 SOVA subjects had no TMD signs or symptoms ($U = 397$, $P = 0.256$). Of the remainder, 19 SOVA and 13 MI subjects had myalgia ($U = 416$, $P = 0.319$) or headache due to myalgia diagnoses ($U = 453$, $P = 0.824$). Further evaluation of cases reporting myalgia or headache revealed no significant between-group differences in number of painful sites per muscle, nor differences in maximum pain scores in muscles, nor in mean, nor median pain scores

(P > 0.161 for all comparisons). No significant between-group differences existed in TMJ noises (P > 0.363); all cases of TMJ noises were with reduction (15 MI and 11 SOVA).

No significant between-group differences existed for baseline measures of upper arch MGI (U= 447, P=0.799), RMNPI (U=433.5, P=0.654), nor lower arch MGI (U = 449, P = 0.821), and RMNPI (U = 387, P = 0.264).

Intra-oral examinations revealed no significant between-group differences in overbite, overjet, maximum pain-free opening, maximum voluntary opening, maximum opening with passive stretch, maximum protrusion or maximum left or right laterotrusions (P > 0.223 in all tests).

Results from baseline standardized surveys, viz., JFLS, PSS, OBC, and MOS revealed no significant between-group differences (P > 0.05). Only the OBC raw score approached statistical significance (mean(SD) for MI = 30.77(8.44); SOVA = 26.70 (7.01), U = 328.4, P = 0.05).

Self-report oral health through time

Three surveys, the OHIP, TSK, and TMDPS, (see Section 2.3) were filled out by subjects both on appointment 1 and after 4-mo of splint wear. The OHIP was broken down into eight subgroups as per published practice.[20] There were no significant differences between groups (P > 0.31), nor differences through time (P > 0.35), nor were there interactive effects (P > 0.08) involving any of these surveys.

SOVA Fabrication and Errors

Of the 30 SOVA splint subjects, 20 (66.7%) fabricated the splint without asking for help, eight (26.7%) asked for help once, and two (6.7%) asked for help twice. Twenty-eight (93.3%) SOVA subjects had to place all or portions of the SOVA splint back in the water bath in order to refabricate the splint or remold portions of it.

Evaluation of the 'finalized' splints revealed that 27 (90%) splints had errors. Poor splint alignment, e.g., rotation (Fig. 3A) or translation (Fig. 3B) of the splint footprint occurred in 26 (86.7%) of them. Presence of excessive mandibular occlusal indentations occurred in six (20%, Fig. 3C) splints. Lack of tissue adaptation around the facial or lingual surfaces occurred in only one splint (3.3%). Inadequate or excessive coverage of posterior molars occurred in 19 splints (63.3%, e.g., circled in Fig. 3A; arrow in Fig. 3D). Another error, which we did not originally account for, was the material being clearly over-stretched (N = 8 splints, 26.7%), as evidence by having the perforations distorted and the material thinned. Each of the above errors had to be corrected before subjects were dismissed.

Mean (SD) fabrication time for SOVA splints was 14.0 (11.6) min, where time = 0 was defined when subjects first put splints into the water, which they deemed to be sufficiently hot to begin fabrication. Because the splint turned translucent when sufficiently warmed, errors due to early removal from the water bath did not occur. Note that the above-reported fabrication time included the time required to fix errors.

User satisfaction

Table 2 shows mean (SD) results for four surveyed items, to which all subjects responded at the end of the study. The results are based upon a five-point Likert scale, where 1 = Strongly Disagree and 5 = Strongly Agree. There were no significant differences between groups as shown in the table. All results are based on 31 MI and 30 SOVA subjects.

Subjects were also allowed to write open-ended responses to the question, "What do you like best about your splint?" The main responses among MI splint subjects had to do with: (1) fit and comfort (N = 19), (2) protection of the dentition from bruxism (N = 9), or (3) help with relaxing the jaw or jaw muscles (N = 3). The main responses among SOVA subjects had to do

with: (1) fit and comfort (N = 20), (2) the small profile, i.e., lack of bulk (N = 7), (3) protection of the dentition from bruxism (N = 3), (4) help with relaxing the jaw or jaw muscles (N = 2), or (5) affordability (N = 1).

Use Compliance

Figure 4 shows mean (1SD) for splint wear, both as percent of total days the splints were possessed (A), and as total number of nights splints were worn (B). There were no significant differences in the percent nights worn (range, 7.5 – 100% for MI subjects, 5 – 100% for SOVA subjects; $t = 0.602$, $df = 62$, $P = 0.549$), nor in the total number of nights worn (range, 5 – 195 nights for MI subjects; 5 – 144 nights for SOVA subjects; $t = 1.201$, $df = 62$, $P = 0.233$). Note that these analyses included the data for subjects that dropped out after the 1-wk follow up, but prior to the 4-mo follow-up appointment, i.e., results are based on 64 total subjects (cf. Figure 1A). Removal of the 3 subjects that dropped out did not significantly change statistical results.

Table 3 lists the reasons for lack of compliance for those subjects who wore the splint < 90% of the time and who provided reasons for this non-compliance (written in spaces provided in the daily diaries). The most common reason for lack of compliance among SOVA subjects was forgetting to insert the splint at home, misplacing splint, and/or forgetting to take the splint with them on vacations (7 of 9 subjects). This was also a common reason among MI subjects (7 of 14). Issues with splint comfort, e.g., occlusal changes or tightness caused by splint wear, represented the remainder of reasons, with only 2 of 9 SOVA subjects reporting this and 8 of 14 MI subjects reporting such issues.

Periodontal Tissue Health

Figure 5 shows means and 1 SE for RMNPI (A) and MGI (B), at baseline, after one week, and after 4 months of splint wear. No significant differences existed between subject groups for

either of the two periodontal indices, (RMNPI, $F[1,58] = 0.01$, $P = 0.919$; MGI, $F[1,58] = 0.237$, $P = 0.628$). There were also no significant differences across appointments (RMNPI, $F[1.596, 92.555] = 1.504$, $P = 0.229$; MGI, $F[1.698, 98.509] = 1.472$, $P = 0.235$), nor was there an interaction between appointment and splint for either index (RMNPI, $F[1.596, 92.555] = 0.211$, $P = 0.76$); MGI, $F[1.698, 98.509] = 0.189$, $P = 0.793$). For within-subject comparisons, the RMNPI did not differ between upper and lower arches ($F[1, 58] = 1.614$, $P = 0.209$); however, the MGI was significantly lower in the maxillary arch compared with the mandibular arch ($F[1, 58] = 4.874$, $P = 0.031$, partial $\eta^2 = 0.078$). Also, although a significant interaction between splint and arch existed in the full model ($F[1, 58] = 6.362$, $P = 0.014$), pairwise comparisons revealed no significant differences. No other significant two-way nor three-way interactions occurred ($P > 0.3$ in all cases).

DISCUSSION

The study was a randomized clinical trial, in which we were careful to match for gender and TMD status. Attempting to match more than these using the stratified randomization procedure [18] would have been difficult. Fortuitously, the resultant groups were closely matched in terms of age and ethnicity, as well as with respect to all other oral health, psychosocial, sleep, and jaw function factors measured. Specifically, there were no significant differences in baseline periodontal health factors, JFLS, OBC, MOS, OHIP, TSK nor PS scores. Even more detailed assessment of TMD signs and symptoms turned up no significant differences in terms of pain readings among muscles. This lack of significance is all the more impressive, given that the reported results for these baseline measures all used an uncorrected P value.

The main goal of the project was to compare the SOVA splint with the MI bite splint, the latter serving as a gold standard. The splints were similar on a variety of factors, viz., compliance, patient satisfaction, and impact on periodontal health. However, some important caveats emerged, with respect to user fabrication of the SOVA. The number of critical errors observed in the fabrication process, suggested that a dental professional must be involved with inspecting splint fabrication. Moreover, since the splint is easily reheated and reformatted, follow-up care is equally important. Additionally, amendments to splint instructions to emphasize specific, critical fabrication endpoints might alleviate many errors. Indeed, given the fact that subjects were capable of significantly reducing the errors in splint fabrication, once they were told what those errors were, suggests that improved fabrication by users is possible. Again, because the splint is easily reheated, removal of critical errors is easily achieved. Hence, feedback from dental care providers can eliminate most fabrication errors without increased expense to the patient. Given that expense is the primary benefit of these splints, this is an important point to recognize.

Many of the issues with splint compliance were due to feelings of bite changes, tightness or soreness (Table 3). These issues can be easily alleviated via strategically applied rewarming of problematic splint areas in the OTC appliance. Such issues can also be addressed by modifying hard acrylic splints by a dental professional. This would necessitate returning to the dental office. However, given that modifications in the OTC splint should be evaluated by the dentist, the need for a dental office visit would occur in both cases when splint adjustments are necessary.

The main, objective clinical measures we evaluated were plaque and gingival indices. These were found not to differ between the splints, nor did they differ through time. This suggests that splints neither negatively nor positively impact periodontal health, at least in the short term. The lack of studies looking at bite splints and periodontal health is likely due to this

being an implicit non-issue among clinicians. However, given the SOVA night guard's structural novelties, e.g., perforations and unique polymers, it was important to confirm that changes in plaque or gingival health were, indeed, non-issues.

However, it is important to note that our subjects had no history of periodontal problems, which is a possible reason for lack of any significant changes with time or significant group differences in periodontal health. Further study involving patients with histories of periodontitis will be in order to determine how periodontal health issues may be exacerbated or reduced by the use of either splint in such patients.

This study was not designed to generate definitive diagnoses of sleep bruxism according to current criteria.[19] Rather it was designed to compare orthotics in a population that would very likely receive orthotics after consulting a 'typical' dentist. Indeed, since a definite diagnosis of bruxism requires a polysomnographic sleep study, which is expensive,[19] it was beyond the scope of this study to employ sleep studies for the sake of screening. Hence, we included subjects with a probable sleep bruxism diagnosis as per recognized operational definitions of sleep bruxism.[19]

A potential weakness of the study was reliance on self-report with respect to splint wear. We stressed the need for full honesty to our subjects, emphasizing that no judgement was involved with missed nights of wear. Results suggested that subjects were reasonably accurate at reporting splint wear, in that virtually all the diaries had missed nights of splint wear. Excuses included simply forgetting to wear the splints, forgetting to take splints on vacation, misplacing splints for a few days, not wearing the splints because of bulk, tightness, sensitivity, etc. (Table 3). These responses suggest that most subjects cooperated reasonably well in this regard.

Future studies can address many of the current study's limitations, including addition of a cross-over design, increased length of the study, and inclusion of sleep studies. A cross-over

design would help determine splint preferences on a case-by-case basis. In the case of a long-term study, it would be useful to evaluate splint longevity, as the main rationale for the study, from an insurance perspective, was to determine whether the OTC splint would reduce costs. We evaluated splint material wear as part of another study, and neither splint showed remarkable wear within 4 months. Hence, a long-term study will be important for a more accurate assessment of the cost savings of such appliances. Inclusion of sleep studies will help provide a measure of actual night time bruxism, which would be a useful metric for identifying severe bruxers in order to assess differences in splint wear in such groups.

CONCLUSION

The SOVA splint and MI splint were comparable in terms of subject compliance and satisfaction. We would recommend that use of the SOVA splint (and other OTC splints) be used in conjunction with dental professional oversight.

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Table 1. Demographics

Initial enrollment	**SOVA**	**MI**	**Tot**
N	35	32	67
Age	25.5 (3.30)	25.5 (3.82)	25.5 (3.53)
Gender (F:M)	19:16	15:17	34:33
Ethnicity			
Amerind	0	1	1
Asian	7	5	12
Native Hawaiian; Pacific Islander	0	0	0
Black / African American	2	2	4
White / Caucasian	26	23	49
> 1 race	0	1	1
Unknown/unreported	0	0	0
Hispanic / Latin	3	1	4
Not Hispanic / Latin	0	0	0
Unknown/ not reported	0	0	0
Final enrollment			
N	30	31	61
Age	25.0 (2.91)	25.1 (3.24)	25.0 (3.06)
Gender (F:M)	16:14	15:16	31:30
Ethnicity			
Asian	0	1	1
Native Hawaiian; Pacific Islander	6	4	10
Black / African American	0	0	0
White / Caucasian	2	2	4
> 1 race	22	23	45
Unknown/unreported	0	1	1
Hispanic / Latin	0	0	0
Not Hispanic / Latin	2	1	3
Asian	0	0	0
Unknown/ not reported	0	0	0
Reason for attrition			
Lost to follow-up	1	0	1
Protocol violation	0	1	1
Withdrawal by subject	3	1	4

Age: Initial enrollment, P=0.932; final enrollment, P=0.903.
Gender: Initial enrollment, P = 0.547; final enrollment P = 0.702.
Ethnicity: Initial enrollment, P = 0.545; final enrollment, P=0.302.

Table 2. User satisfaction scores by group.

Survey Item	Group	Mean (SD)	U	P
The splint fits well.	MI	4.3 (0.8)	444.5	0.75
	SOVA	4.1 (1.2)		
I am unable to use the splint nightly	MI	1.8 (1.2)	389.0	0.25
	SOVA	2.2 (1.4)		
I used an additional splint.	MI	1.5 (1.1)	442.5	0.63
	SOVA	1.6 (1.3)		
The splint helps my bruxism	MI	4.0 (0.9)	388.5	0.26
	SOVA	3.7 (1.0)		

Key: U, Mann-Whitney U; SD, standard deviation.

Table 3. Rationale for lack of compliance.

Splint	Rational	% nights worn
SOVA	Fell out or removed at night for unreported reasons	51.1
SOVA	Forgot to wear; forgot it on vacations	65.1
SOVA	Temporarily misplaced splint several times	56.8
SOVA	Forgot it on vacation; removed during night due to bite changes	62.3
SOVA	Removed during night due to tightness and gagging	80.6
SOVA	Forgot to wear it; forgot it on vacation	73.0
SOVA	Forgot to wear it	73.2
SOVA	Fell out or removed during night for unreported reasons	78.1
SOVA	Forgot to wear it; did not wear on vacation	86.5
MI	Not worn due to discomfort with bulk	65.2
MI	Removed during night due to bite changes	73.8
MI	Removed during night for unreported reasons; forgot it on vacation	76.5
MI	Forgot to wear it; forgot it on vacation	81.6
MI	Forgot it on vacation; removed during night due to tooth soreness	52.8
MI	Forgot to wear it	87.5
MI	Forgot it on vacations; removed during night due to tightness	7.5
MI	Removed during night due to bulk and bite changes	80.0
MI	Fell out during night; forgot it on vacations	76.2
MI	Removed during night due to increased clenching and interference with sleep	52.8
MI	Removed during night due to tooth/jaw pain	77.3
MI	Removed during night due to bulk, tooth/jaw pain	37.3
MI	Forgot to wear	85.0
MI	Removed at night due to tooth soreness	10.6

FIGURES

Fig. 1. A. Sequencing of study components. Subjects meeting selection criteria were involved in four appointments (app). Key: IC, informed consent; Perio, evaluation of gingiva and plaque indices (see text). B. Summary of participant numbers at selective time points during study.

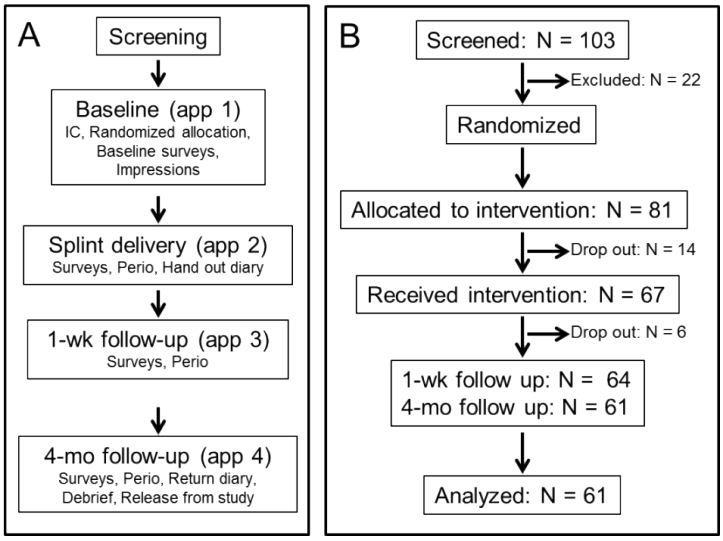


Fig. 2. Occlusal views of appliances. A. SOVA. B. MI.

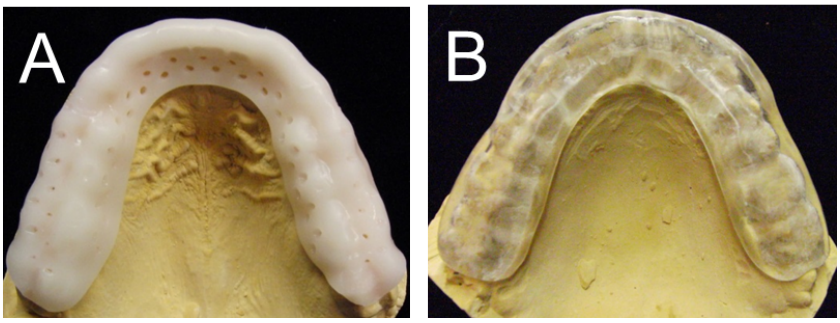


Fig. 3. Examples of common splint fabrication errors (see text). A. Rotation of splint; note red lines indicating the non-perforated splint component that should be on the occlusal table. B. Translation of splint, here in a posterior direction (arrow); this would also be inadequate tissue adaptation if the region spanned 2 or more teeth. C. Excessive occlusal indentations. D. Excessive material posterior to 2nd molar, here seen as a flared flange.

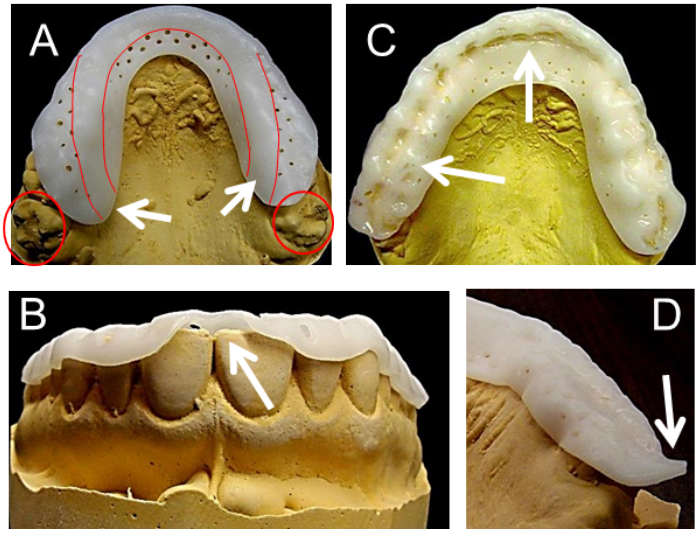


Fig. 4. Compliance. A. Percent days splint worn by both groups, MI and SOVA. B. Number of days splint worn by groups. Error bars = 1 SE.

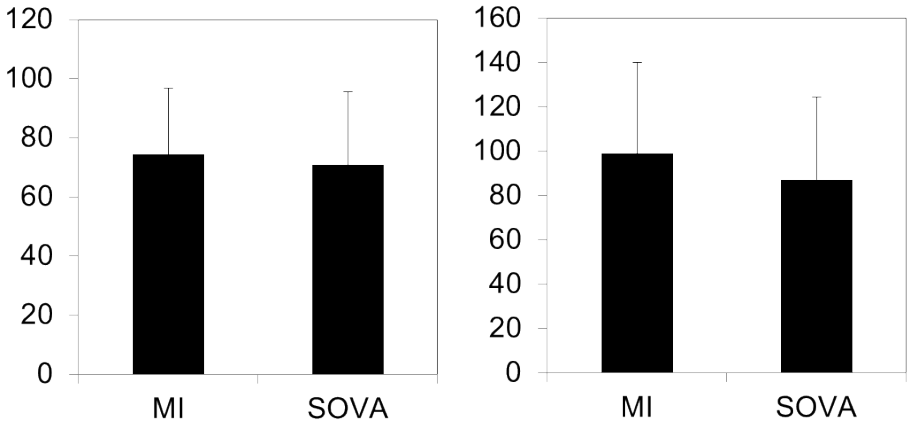
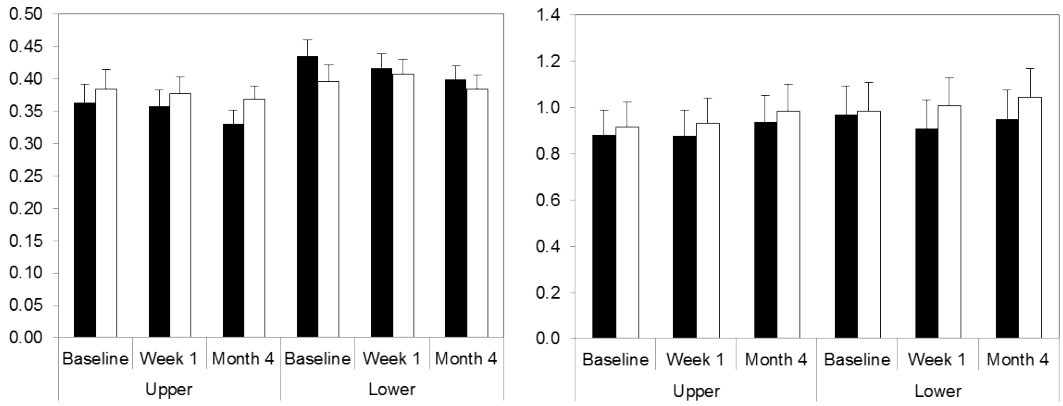
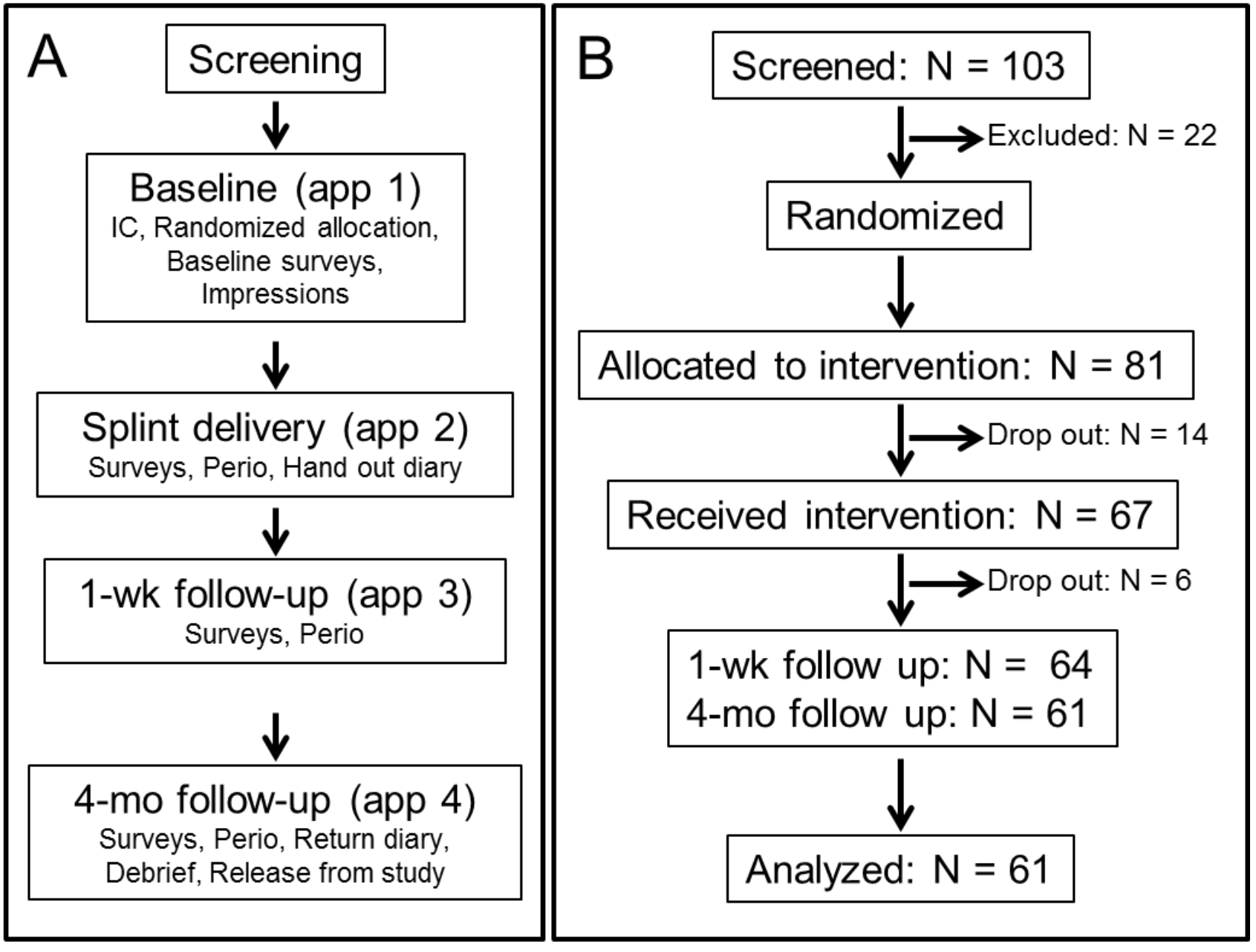
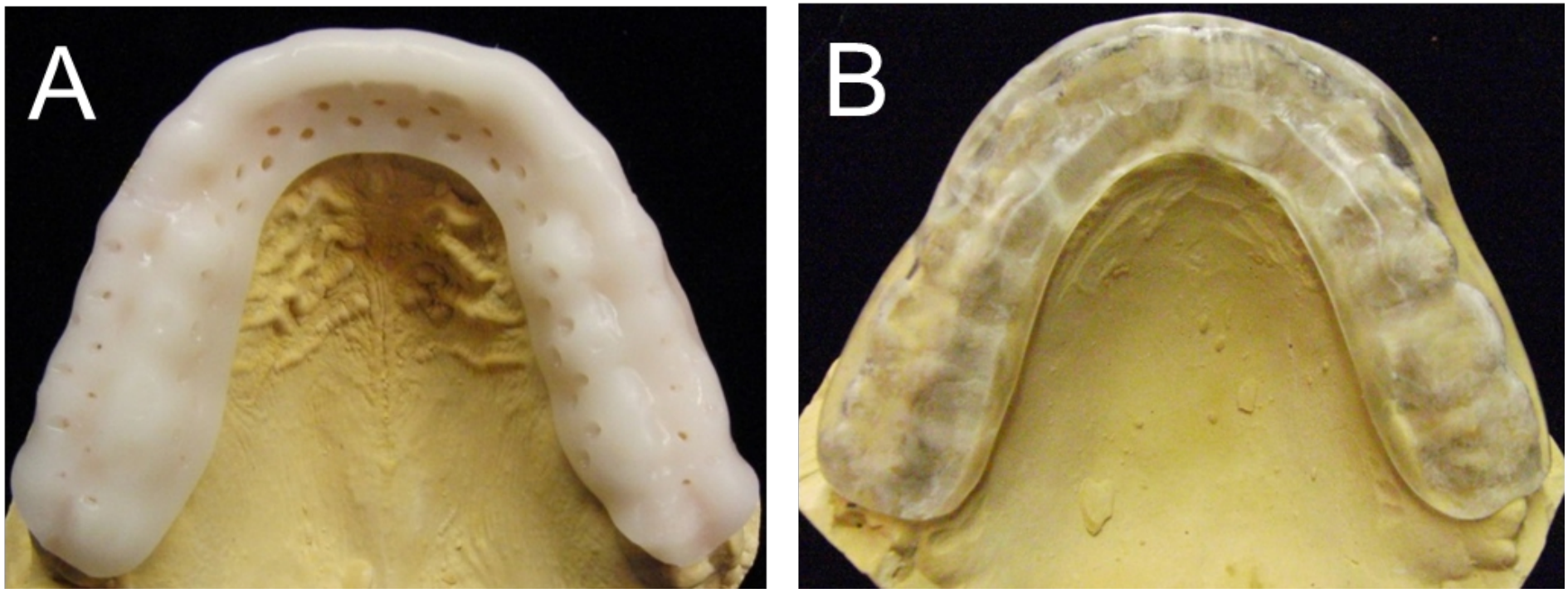


Fig. 5. Periodontal indices. A. RMNPI. B. MGI. In both plots, the Michigan group (filled) and SOVA group (unfilled) data are shown at baseline (appointment 2), after one week (appointment 3) and 4 months (appointment 4), separated according to arch, viz., upper and lower. Error bars = 1 SE.




A
Screening
Baseline (app 1)
IC, Randomized allocation,
Baseline surveys,
Impressions
Splint delivery (app 2)
Surveys, Perio, Hand out diary
1-wk follow-up (app 3)
Surveys, Perio
4-mo follow-up (app 4)
Surveys, Perio, Return diary,
Debrief, Release from study
B
Screened: N = 103
Excluded: N = 22
Randomized
Allocated to intervention: N = 81
Drop out: N = 14
Received intervention: N = 67
Drop out: N = 6
1-wk follow up: N = 64
4-mo follow up: N = 61
Analyzed: N = 61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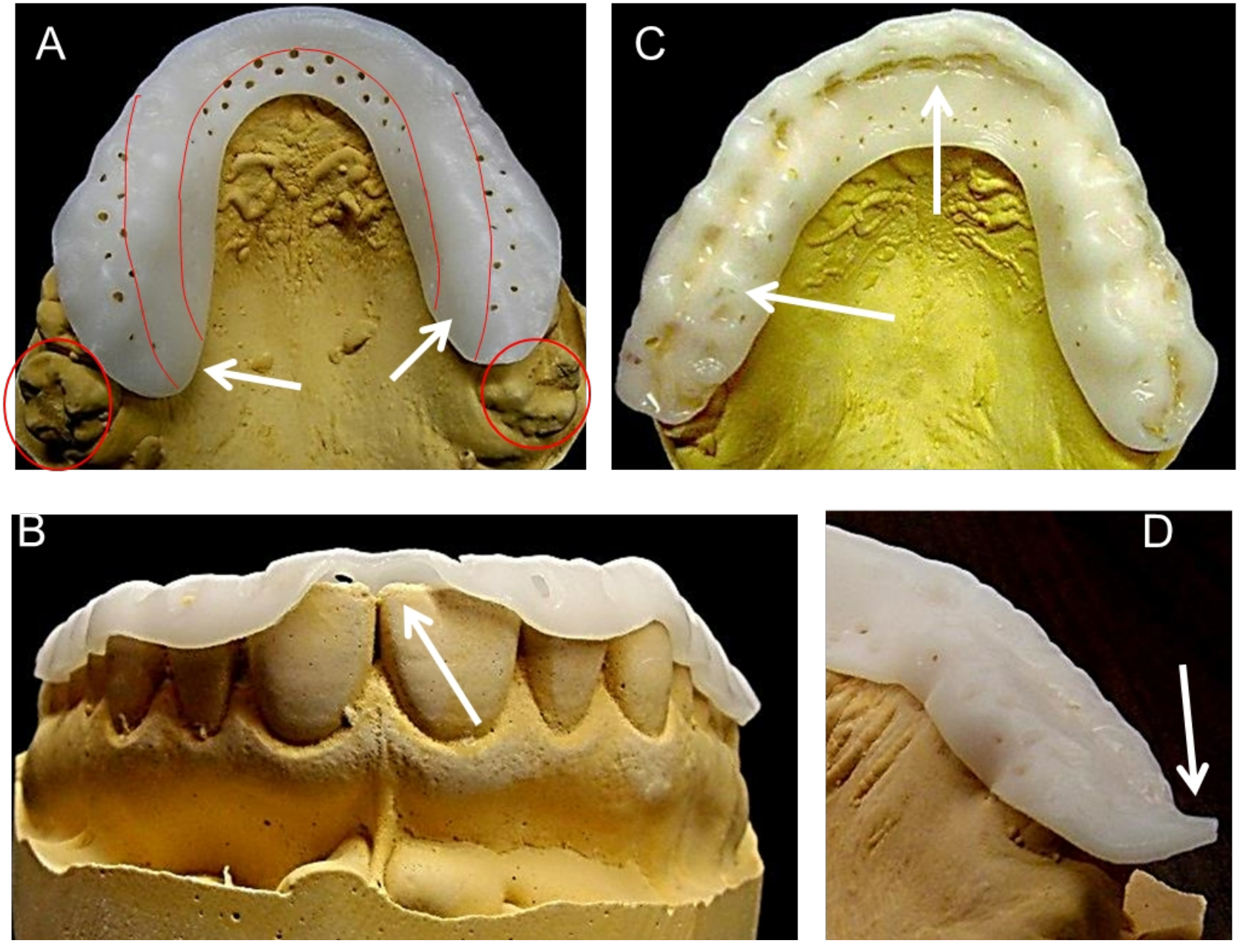
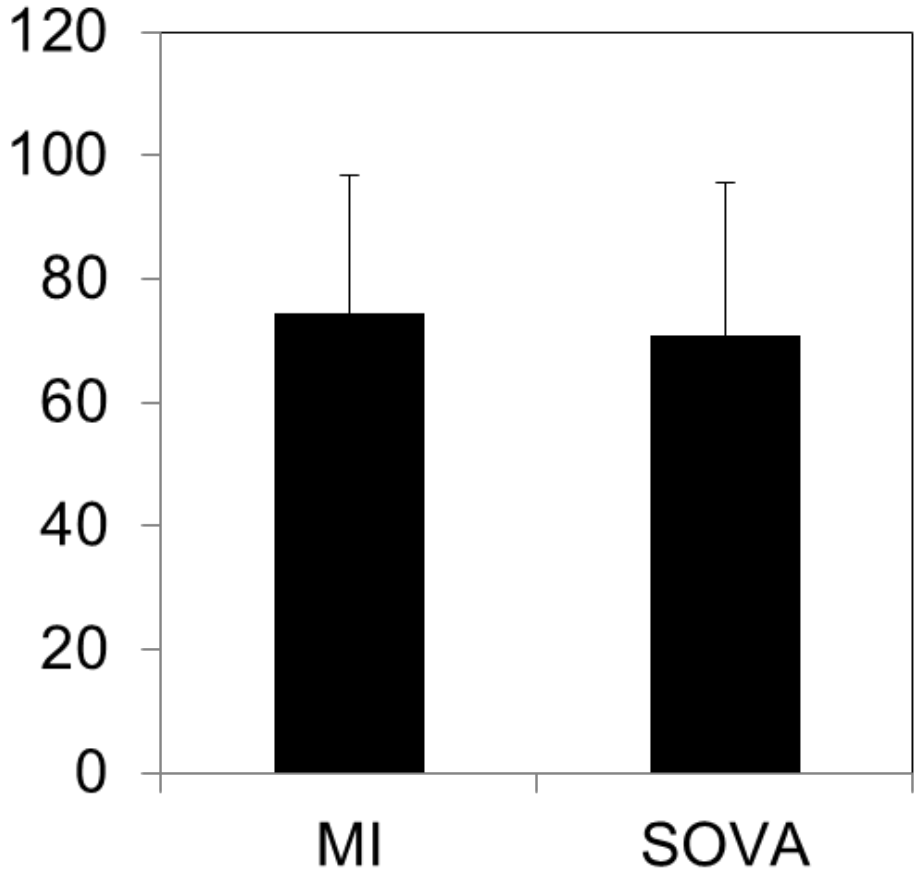
B


A
C
B
D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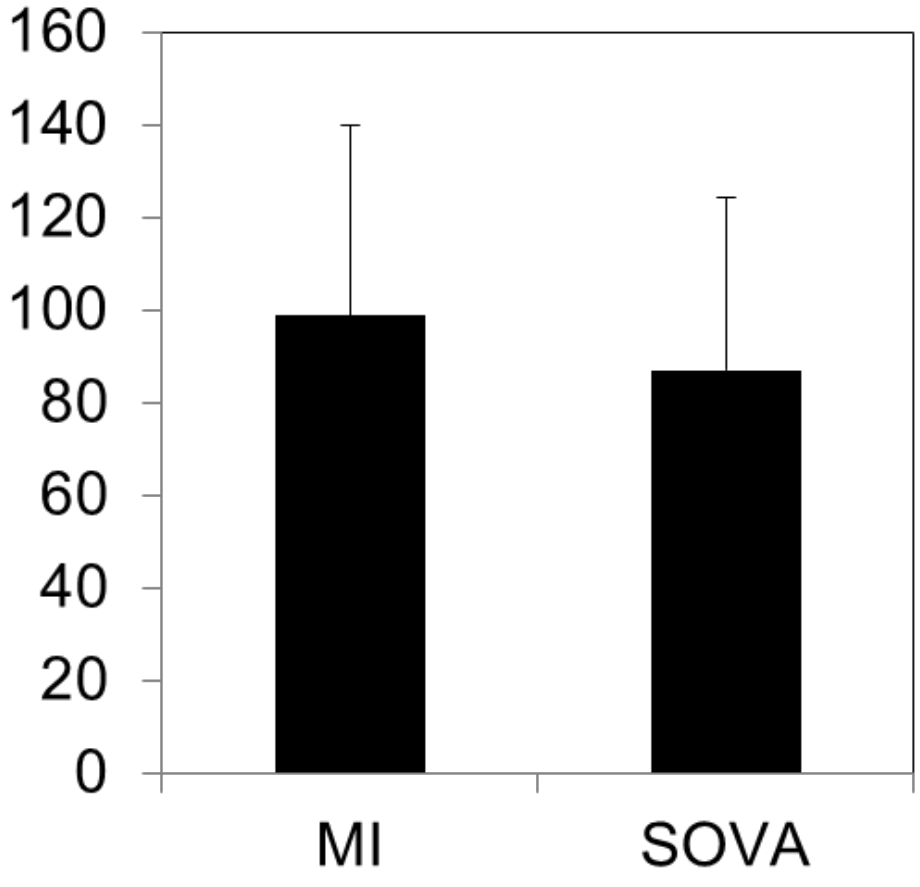
80
60
40
20
0
MI
SOVA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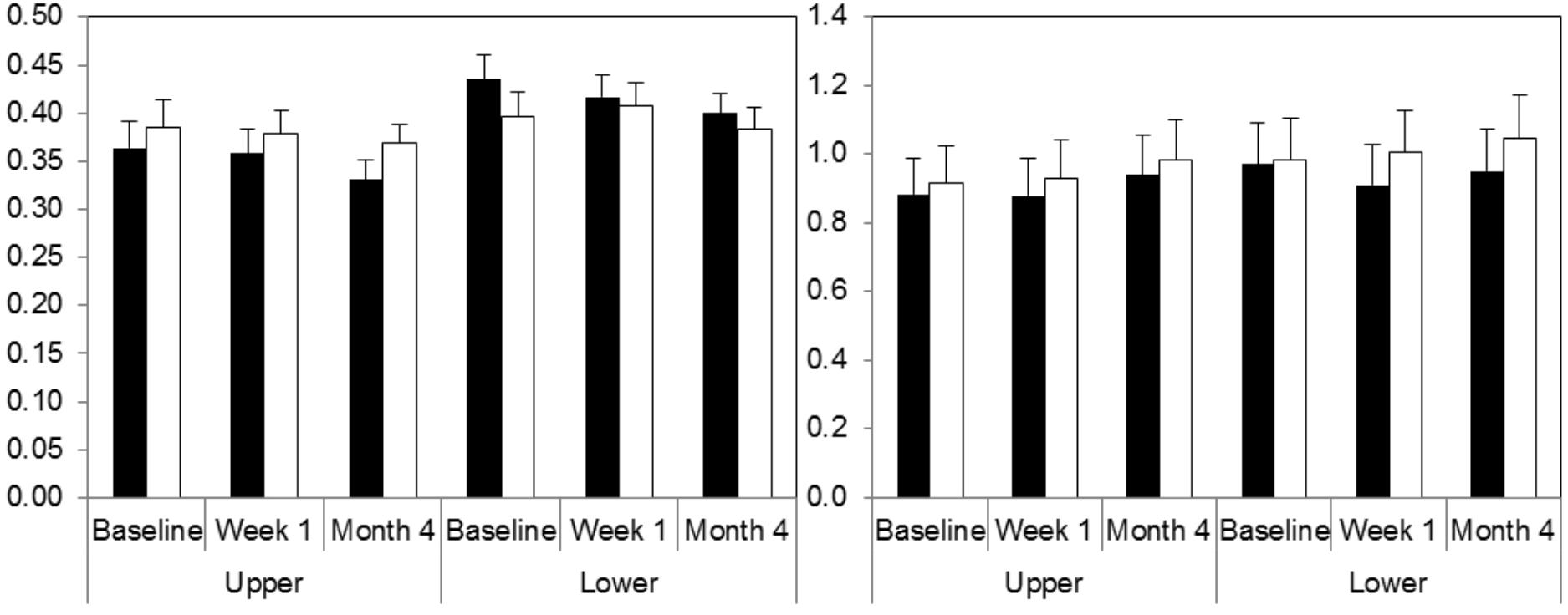
MI
SOVA


0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
Baseline
Week 1
Month 4
Baseline
Week 1
Month 4
Upper
Lower
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0
Baseline
Week 1
Month 4
Baseline
Week 1
Month 4
Upper
Lower

Authors contributed to the study as follows:

(1) Study conception and design

Gerstner generated the conception and design of the overall project.

Drs. Ludkin, Decker, Sinacola, and Frimenko, developed the design for the periodontal data collection.

(2) Acquisition of data

Dr. Gerstner acquired the survey and compliance data.

Dr. Yao acquired the clinical examination data.

Drs. Decker, Ludkin, Sinacola and Frimenko acquired the periodontal health data.

(3) Analysis and interpretation of data

Dr. Gerstner oversaw analysis and interpretation. He performed all final analyses.

Dr. Yao analyzed clinical and survey data.

Drs. Decker, Ludkin, Sinacola and Frimenko interpreted the periodontal data.

(4) **Drafting of manuscript**

Dr. Gerstner wrote the bulk of the initial manuscript.
Drs. Yao, Decker, Ludkin, Sinacola and Frimenko all provided important contributions to the manuscript, tables and figures. All read the final submitted manuscript.

eResearch REGULATORY MANAGEMENT

Date: 8/20/2014 11:04:33 PM

Print Close

01. General Study Information

All questions marked with a red asterisk (*) require a response. Questions without a red asterisk may or may not require a response, depending on those questions' applicability to this study.

1.1* Study Title:

Mouthguards and night-time grinding

1.1.1 Full Study Title:

Studies of mouthguards for bruxism

1.1.2 If there are other U-M studies related to this project, enter the eResearch ID number (HUM#) or IRBMED Legacy study number. Examples of related projects include, but are not limited to:

- Projects funded under the same grant
- IRBMED Legacy study being migrated into eResearch
- Previously approved Umbrella applications (such as Center Grants or approvals for release of funding)
- Previously approved projects for which this is a follow up study

1.2* Principal Investigator:

Geoffrey Gerstner
Note: If the user is not in the system, you may Create A New User Account...

1.3 Study Team Members:

Study Team Member	Study Team Role	Appointment Dept	Appointment Selection Complete?	Student	Friend Account	COI Review Required	Edit Rights	Accepted Role?	PEERRS Human Subjects?
Geoffrey Gerstner	PI	Biologic and Materials Science	Yes	no	No	no	yes	N/A	yes

1.8* Project Summary:

The project investigates the uses of two night guard or bite splints designed for use in cases of nocturnal bruxism (night-time clenching and grinding). The outcome variables for the study fall into four categories: (1) fabrication efficacy, (2) compliance, (3) functional efficacy, and (4) user satisfaction. The immediate goals of this preliminary proposal will: (1) focus on the SOVA night guard and "Michigan" bite splint, (2) conduct in vivo tests of the night guards under controlled clinical laboratory conditions, and (3) evaluate compliance and functional efficacy in the 'natural' environment of the patient's home. The clinical application involves protection of dental structures during nocturnal parafunction (sleep bruxism).

Specific Aim 1. Compare the SOVA night guard to the custom-acrylic "Michigan" bite splint in clinical laboratory conditions. Hypothesis: There will be no significant differences between the

devices in terms of fabrication efficacy, functional efficacy or user satisfaction.

Specific Aim 2. Compare the SOVA night guard to the custom-acrylic "Michigan" bite splint under ecologically relevant conditions, i.e., the home environment. Hypothesis: There will be no significant differences between the devices in terms of compliance or functional efficacy.

1.9* Select the appropriate IRB:

IRBMED

1.10* *Estimated* Study Start Date (Not required for IRBMED): *(mm/dd/yyyy)*

5/1/2014

1.11* *Estimated* Duration of Study:

2 years

01-1. Application Type

1-1.1* Select the appropriate application type.

Standard, non-exempt, research project

01-2. Standard Study Information

1-2.1* Who initiated this study?

Investigator

If other, please specify:

1-2.2* Are you or any students working on this project being paid from a federally funded training grant?

○ Yes ◉ **No**

1-2.3 This study is currently associated with the following department. To associate this research with a different department, click Select. If the department has defaulted to "student", click select to specify the department through which this application is being submitted.

Biologic and Materials Science

1-2.4 Will the study utilize resources from the following centers?

Select all that apply:

There are no items to display

1-2.5* Does this study require review by the UM Health System Comprehensive Cancer Center Protocol Review Committee (PRC)?

○ Yes ◉ **No**

1-2.6* Has the scientific merit of this study already been peer reviewed (i.e., reviewed by one or more recognized authorities on the subject)?

○ Yes ◉ **No**

1-2.7* Is this a clinical trial?

◉ **Yes** ○ No

1-2.7.1* Please select the trial phase

	Trial Phase	Description
○	Phase 0	Exploratory study to determine whether agent behaves in humans as pre-clinical testing indicated
○	Phase I	Evaluate safety, dose range, and identify side effects in healthy volunteers or in patients with the disease of interest
○	Phase I/II	Safety, dosage levels and efficacy of new treatment; device pilot study
○	Phase II	Evaluate safety and efficacy of selected dosage levels and duration of treatment
○	Phase II/III	Larger study to confirm safety and efficacy of selected dose(s) and duration of treatment
○	Phase III	Larger, controlled trial to confirm efficacy compared to a standard treatment regimen or to no treatment; device pivotal study
○	Phase IV	Post-market study to provide additional information on risks, benefits, and optimal use
◉	**Other**	

If other, please specify:
This is a pilot study that resembles a Phase IV clinical trial.

1-2.8* Would the integrity of this research study be compromised if the subject were able to view results of their research tests or medications in the Patient Portal of MyUofMHealth.org? Research results displayed to the subject in MyUofMHealth.org will include: lab results, radiology examinations and outpatient medication lists. Contracts and protocols should be assessed by the Principal Investigator for specific language regarding blinding of subjects and their research results.

(NOTE: Additional actions are required in order to limit the subject's view into their electronic medical record. Contact the IRB for additional information or see additional guidance for blinded studies at http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/blinded-studies)

○ Yes ◉ **No**

Study Team Detail

1.4 Team Member:

Geoffrey Gerstner

Preferred email: geger@umich.edu

Business phone 734-763-7717
Business address: Biologic & Materials Sci K1030 Dent 48109-1078

1.5 Function with respect to project:

PI

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

yes

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
University Biosketch | History	0.04

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

C1 Do you, your spouse, domestic partner, or dependents have any outside interests or relationships to companies or entities related to this research that the IRB should consider?

Examples of outside interests include, but are not limited to the following:

- receiving compensation whose value could be affected by the study outcome
- IN THE AGGREGATE, expecting to receive compensation from the sponsor of the research of $10,000 or greater in the next year
- having a proprietary interest in the sponsor of the research or a product tested by this research including but not limited to, a patent, trademark, copyright, or licensing agreement, or the right to receive royalties from product commercialization
- individually or collectively, having an ownership interest (equity or stock options) in the sponsor of the research or product being tested whose value cannot be readily determined through reference to public prices
- individually or collectively, having an ownership interest (equity or stock options) in a company or product whose value could be affected by the study outcome
- IN THE AGGREGATE, having an ownership interest (equity or stock options) in the sponsor of the research that exceeds $10,000 or 1% when the sponsor is a publicly traded entity
- receiving significant payments of other sorts with an aggregate value of $10,000 or more (or payment of ANY amount to medical school or hospital employees) made directly by the sponsor of this research for unrestricted research or education, equipment, consultancy, or honorarium
- holding a position of management or leadership in company or entity related to this research including, but not limited to, officer, director, or member of an advisory board.
- providing consulting services or serve on a Speaker's Bureau, either paid or unpaid, to the financial or non-financial sponsor of this study
- when the sponsor is a publicly traded entity, having any ownership interest (equity or stock options) in the sponsor
- expecting to receive any loans, educational support, contributions of in-kind for equipment, or any other non-compensatory payment from the sponsor of the research in the next year

no

C2 Please provide a detailed description of the outside interest in the box below.

C2.1 Where have you submitted a disclosure of this outside interest?

C2.2 Has a management plan been formalized?

C2.2.1 Click the View Management Plan in M-Inform button below to see your management plan for this study.

C2.2.2 If no, describe the financial interest in sufficient detail to permit the COI Ancillary Committee and the IRB to determine if such involvement represents a potential conflict-of-interest and/or should be disclosed to potential research subjects in the informed consent form.

02. Sponsor/Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.

* Note: At least one of the following sections must be answered. Multiple sponsors or sources of support must be added one at a time.

2.1 External Sponsor(s)/Support:

	Type	Name	Other Direct Sponsor/Support	Support Type	Has PAF?
View	Other		Delta Dental Foundation	Financial	no

2.5 Internal UM Sponsor(s)/Support: [Including department or PI discretionary funding]

Type	Department Sponsor	Support Type

There are no items to display

2.8 Check here if the proposed study does not require external or internal sponsorship or support:

☐

External Sponsor Detail

2.2* Direct Sponsor/Support:

If the Direct Sponsor/Support does not appear in the Select list, enter the name of the Direct Sponsor/Support below:

Delta Dental Foundation

2.2.1* Sponsor Type:

Other

If other, please specify:

Foundation is providing a gift donation to the PI

2.2.2* Support Type:

Financial

2.2.3* Is the support confirmed?

(●) **Yes** ( ) No

2.2.4* Is there an existing Proposal Approval Form (PAF) for this IRB Application

( ) Yes (●) **No**

2.2.6 Previously entered PAF ID:

2.3* Is this a subcontract to UM?

( ) Yes (●) **No**

2.4 Upload all of the following documents that apply:

- **Grant (*required for "Government - Federal" sponsor types)**
- **Contract application (*required for "Government - Federal" sponsor types)**
- **Sponsor budget (*required for use of MCRU resources)**
- **Sponsor application**
- **Most recent competing renewal application**

Name	Version

There are no items to display

Note: *Study Teams are encouraged to scan and upload documents. See Help for a list of sites with scanning facilities.*

03. UM Study Functions

3.1* Indicate all functions that will be performed at University of Michigan locations.

Select all that apply:

- Recruitment (including screening)
- Interaction (e.g., information gathering, survey, interview, focus groups, etc.)
- Intervention (e.g., use of drug or device, medical procedures, educational intervention, group intervention, social/psychological intervention etc.)
- Primary or secondary analysis (data/specimen)
- Storage (data/specimen)

If other, please specify.

03-1. Performance Sites

3-1.1* Performance Sites:

Location	Country	"Engaged" in the research?	Site Function
University of Michigan	USA	yes	Intervention,Storage,Interaction,Analysis,Recruitment

Performance Site Detail

3-1.2* Location or Institution:

University of Michigan

3-1.3 Address:

City
State
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

Recruitment (including screening)
Interaction (e.g., information gathering, survey, interview, focus groups, etc.)
Intervention (e.g., use of drug or device, medical procedures, educational intervention, group intervention, social/psychological intervention etc.)
Primary or secondary analysis (data/specimen)
Storage (data/specimen)

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

(●) **Yes** ( ) No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

FWA00004969

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version

There are no items to display

05. Research Design

5.1* Is there a stand-alone scientific protocol document and/or research plan associated with this application?

(●) **Yes** ( ) No

5.1.1* Click ADD to attach the document(s) electronically.

Name	Version
DDF Proposal | History	0.04

5.1.2* Indicate the section where each of the following are covered in the attached protocol:

Objective	Please see 1. Overview and Objectives, Page 1
Specific Aim/Hypothesis	Please see 1. Overview and Objectives, Page 1
Background Information	Please see 2. Background and Significance, Page 1
Methodology	Please see 3. Methods and Study Design, Page 2
Statistical Design	3. Methods and Study Design contains some information about Statistical Design. General linear models will be used to compare results between the two study groups. Repeated measures designs will be used to study changes through time in variables measured several times over the 6-mo time period.

5.1.3* Study team Experience: Briefly outline the experience and competence of the study team to pursue the proposed study.

PI Gerstner has over 20 yr experience with orofacial studies of function and parafunction, including expertise in kinematics, electromyography, occlusion (i.e., the bite and bite forces), clinical studies and dental materials.

5.2* Will the involvement of ANY subjects in this study be limited to analysis of their existing data or specimens?

( ) Yes (●) **No**

5.3* Will the study involve recruitment and/or participation of subjects in order to produce new data *(e.g., surveys, interaction, intervention)*? *[Require sections 8-1 and 11-3]*

(●) **Yes** ( ) No

5.4* List the inclusion and exclusion criteria for this study population and/or data set. *(If covered in attached protocol, indicate section)*

See Section 3.1, Subjects, of attached protocol.

5.5 Identify any racial, ethnic, or gender group(s) that will be specifically excluded from participation in this research study and provide a compelling justification for such exclusion:

No racial, ethinic or gender groups will be specifically excluded.

5.6* Indicate the age range (in years) of the subject population in this study.

Minimum Age: 18

Maximum Age: 70 If no upper limit, enter "999"

06. Benefits and Risks

6.1 * Describe the potential benefits of this research to society.

Reduced cost of bite splints and mouth guards, due to use of OTC devices. Improved retention of mouthguard/bite splint due to use of "smart" materials that conform to tissue outlines. Improved compliance due to ease of use. Improved efficacy (fewer traumas) due to use of "smart" materials for bite splints and mouth guards.

6.2 * Will results of the research be communicated back to the subjects?

○ Yes ◉ **No**

6.3 * Describe any direct risks to the public or community, which could result from this research?

There are no direct risks to the public or community at large.

6.4 * Does this project involve study arms that have differing levels of benefit or risks to subjects?

○ Yes ◉ **No**

6.5 * Benefits and Risks:

Click "Add" to begin entering the benefit and risk level detail information associated with this study.

	Name	Risk Level	Direct Benefit
View	HUM00085489	No more than minimal risk	yes

Benefits and Risk Level Detail

If a study involves multiple arms or phases that pose different levels of risk or direct benefits to subjects, then create an entry for each arm or phase using the "OK and Add Another" option at the bottom of this page. Only one entry is necessary if the risk level and the direct benefit to subjects is the same for the entire project, even if the study involves multiple arms or phases.

6.5.1 * Name of Arm (experimental group, study wave, etc.)

HUM00085489

6.6 * Are there potential direct benefits of this research to the subjects?

◉ **Yes** ○ No

6.6.1 * Describe the potential direct benefits.

The device could help reduce the impacts of night-time grinding and clenching (reduced tooth wear).

6.7 * Provide a description of the foreseeable risks to subjects. For studies involving multiple arms or phases, enter the risks for this arm or phase only.

Provide a description of the foreseeable risks to the subjects.

For EACH identified risk, include:

- **Likelihood of the risk,**
- **Seriousness to the subject; and**
- **What measures will be taken to minimize the risk (for example, study design includes the substitution of procedures already being performed on the subject for diagnostic or treatment purposes, or in a study of Post-Traumatic Stress Disorder, the investigator takes steps to identify, manage, or refer as appropriate, subjects for whom the study may evoke very difficult emotions)**

If possible, please use the following categories to assess the likelihood:

- **"Common" (i.e., approximate incidence > 25%)**
- **"Likely" (i.e., approximate incidence of 10-25%)**
- **"Infrequent" (i.e., approximate incidence of 1-10%)**
- **"Rare" (i.e., approximate incidence < 1%):**

The known or expected risk are:
(1) Unpleasant tastes from the alcohol tooth cleansing and subsequent impressions of teeth. This is a common experience. It is not serious. Investigators will minimize this risk by isolating the areas of the mouth being cleansed with dental suction and by using small cotton swabs.
(2) Mild discomfort from the warm water required to fabricate the splint. This is a common experience and not a serious risk. Investigators will monitor and control the temperature of the water bath so that it is warm enough to fabricate the splint, but not hot enough to cause burning or scalding. The water temperature will be tested, by hand, by investigators as well.
(3) Temporary changes in the bite as a result of night-time splint wear. This is a common experience, although it should be transient and disappear shortly after removing the splint in the morning; hence, it is not serious. Temporary changes in the bite can be minimized by making sure that subjects do not wear the splint during the day. This is stressed in several places in the IC and will be stressed several times during appointments to help minimize this risk. If a subject's bite-changes do not go away within an hour after removing the splint, the should notify study personnel to set up an appointment to have the splint evaluated. Investigators will minimize this risk by making certain that the splint fits well before subjects leave and by being available to make adjustments as necessary.
(4) Increased drooling or increased salivation, changes in speech or difficulty talking, or pressure on the teeth while the splint is worn. This is a common set of experiences, but are not serious risks. The investigators minimize this risk by making sure the splint fits well during the try-in appointment. For this risk to be effectively minimized, it is stressed to subjects that they must provide feedback during the try-in as well. The experiences are also minimized by wearing the splint only while subjects sleep instead of during the day.
(5) Trouble sleeping, staying asleep or falling asleep, and changes in sleep postures or sleep patterns as a result of wearing the sleep monitoring device. This is a common experience, but not directly serious. The investigators minimize these risks by using a wireless, small, in-home sleep monitoring device, rather than using the services of a sleep laboratory.
(6) Skin irritation from wearing the electrodes and sleep monitoring device sensors. This is a likely risk but not serious. Investigators minimize this risk by using hypoallergenic creams and adhesives.
(7) Discomfort with tooth-bite and lip positions due to wearing the jaw tracking device. This is a likely risk but not serious. Investigators minimize this risk by using a device that has a small footprint size in the mouth.
(8) Personal embarrassment or psychological discomfort from being videotaped. This is a rare risk and not serious. To minimize the risk, investigators keep videos under lock and key and access them as infrequently as possible. Also, subjects are free to observe the videos and determine whether they should be destroyed and redone.
(9) Personal embarrassment or psychological discomfort resulting from answering the questionnaires. This is an infrequent risk and not serious. Investigators minimize this risk by coding responses—the questionnaires contain no personal-identifying information.
(10) Personal embarrassment or psychological discomfort associated with learning how to fabricate a bite splint and doing so in the presence of laboratory personnel. To minimize this risk, study personnel are trained to behave professionally and to recognize that splint fabrication requires learning and teaching; they will attend to and be sensitive to any personal

embarrassment or psychological discomfort associated with learning how to fabricate a night guard.

6.8 * What is the level of risk of harm to the subjects, resulting from this arm of the research? For studies involving multiple arms or phases, enter the level of risk for this arm or phase only.

No more than minimal risk

6.9 * Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits.

The benefit of having a greatly improved method of counteracting the effects of night-time bruxism on the dentition far outweighs the riks from discomfort (use of warm water on the stove) accompanying fabrication of the night guard. Also, given that the mouthguard is a reversible treatment, cessation of use has not subsequent risks or consequences.

07. Special Considerations

7.1* Does this study involve human tissue or biological specimens (use, collection, or secondary analysis) ***(e.g. blood, urine, bone marrow, skin, etc.)? [Require Section 18]***

○ Yes ◉ **No**

7.2* Does this study involve the secondary analysis of a pre-existing data set, including data associated with any specimens identified in response to question 7.1? ***[Require Section 24]***

○ Yes ◉ **No**

7.3* Will the research involve the access, collection, use, maintenance, or disclosure of University of Michigan protected health information (PHI)? PHI is:

- **information about a subjects past, present, or future physical or mental health, the provision of healthcare to a subject, or payment for the provision of healthcare to a subject; AND**
- **maintained by a University of Michigan school, department, division, or other unit that is part of the University's HIPAA-covered component (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).**

[Require Section 25]

○ Yes ◉ **No**

07-1. Special Considerations - Continued

7-1.1* Will subjects receive payment or other incentives for their participation in the study? ***[Require Section 13]***

◉ **Yes** ○ No

7-1.2* Will subjects undergo healthcare-related treatments or procedures (standard of care and/or research) as part of the study? ***[Require Section 14]***

○ Yes ◉ **No**

7-1.3* Does this study involve the deception or concealment of subjects? ***[Require Section 27]***

○ Yes ◉ **No**

7-1.4* Excluding routine email correspondence, does this study involve the use of the Internet or email as an integral part of the research design or will sensitive information be transmitted by e-mail? ***[Require Section 28]***

○ Yes ◉ **No**

7-1.5* Will the study collect data using surveys, interviews, or focus groups? ***[Require Section 29]***

◉ **Yes** ○ No

7-1.6* Does this study require subjects to listen to an audio recording or view images? [*Require Section 31]*

○ Yes ◉ **No**

7-1.7* Will any drugs, biologics, nutritional ***(e.g., herbal or alternative medication)*** **supplements or other material be administered, implanted, or applied to the subjects as the object of the study?** ***[Require Section 15]***

○ Yes ◉ **No**

7-1.8* Will the study involve a placebo ***(drug, device, procedure, intervention, surgery, etc.)*** **control group?** ***[Require Section 17]***

○ Yes ◉ **No**

7-1.9* Will the study involve human embryonic stem cells (hESCs) or induced pluripotent stem cells? ***[Require Section 19]***

○ Yes ◉ **No**

7-1.10* Will the study have a Data and Safety Monitoring Plan (DSMP)? ***[Require Section 32]***

○ Yes ◉ **No**

7-2. Special Consideration - Continued

7-2.1* Will any devices be used, administered, implanted, or applied to the subjects, or will human specimens be used to test in vitro diagnostic devices?
[Non-IRB HSBS and Non-IRB Dearborn Applications Require Section 16]

◉ **Yes** ○ No

7-2.2* Will the subjects be exposed to any ionizing radiation during the course of this study? ***[Require Section 21]***

○ Yes ◉ **No**

7-2.3* Will any organs, tissues, or cells from other humans ***(including fetal tissue)*** **or animals be administered to the subjects for the purposes of this study?** ***[Require Section 22]***

○ Yes ◉ **No**

7-2.4* Does this study involve a gene transfer intervention or an intervention based on recombinant DNA technology? ***[Require Section 23]***

○ Yes ◉ **No**

08. Subject Participation

8.1* Please indicate the number of subjects to be enrolled from ALL study locations to achieve the goal of the study:

80

8.2* Enter the estimated number of subjects to be enrolled at each University of Michigan site:

Location Or Institution	Total
University of Michigan	
Adults	80
Children	0
Total from all University of Michigan sites:	**80**

08-1. Subject Recruitment

8-1.1* At what point in the study are you planning on beginning the recruitment of subjects?

0-2 years after approval

8-1.2* Indicate which of the following established subject pools, if any, will be used for recruitment.

Select all that apply:

UM Ann Arbor Introductory Psychology Pool

Provide Related UM IRB Project Number or Subject Pool Description:

8-1.3* Describe the manner in which potential study subjects will be recruited. List how, when, who will recruit and where they will be recruited. Include any provisions to protect or maintain subject privacy.

Recruitment bulletins will be placed on the School of Dentistry's electronic bulletin boards and in association with the UM Introductory Psychology Pool. Candidates from dental school classes will also be verbally solicited. Dr. Gerstner (PI) will do the verbal solicitations at the start of didactic classes, with permission from course chairs/instructors. To avoid any hint of coercion, this will be performed in courses in which he does not teach, and he will stress that participation is entirely voluntary and is in no way tied to course grades or requirements. The verbal recruitment will state that the study is looking for subjects to wear bite splints for 6 months, and the verbal solicitation will list the inclusion/exclusion criteria. Candidates will be asked to call or report to Dr. Gerstner's office for screening or to have questions or concerns addressed.

Candidates who report for screening will fill out a prescreening questionnaire (attached) and an Informed Consent (IC). A secure spreadsheet will list candidate names and codes. The pre-screening questionnaires contain no subject-specific information. All study copies of the IC will be kept in a secure filing cabinet in the PI's office. Dr. Gerstner will perform the recruitment and

pre-screening procedures in Dr. Gerstner's office.

No medical records nor appointment logs will be searched for eligible subjects.

The prescreening questions will be asked prior to filling out the IC.

8-1.3.1 If applicable, how will prospective subjects' healthcare providers *(e.g., physician, dentist, etc.)* be involved in the recruitment and/or be notified of their individual patients' participation in the study?

NA

8-1.4* Explain how the recruitment strategy is equitable and represents the population required for the study. ***If the information is covered in the attached protocol, please indicate section.***

This is a preliminary study designed to compare compliance, efficacy and satifisaction of use of two mouth guards over a 4 month time-course. A convenience sample (dental and undergraduate psychology students) combined with subjects that likely characterize the general population (dental school patients) is considered the 'best' pool for several reasons. First, the study requires subjects to report 5 times to the dental school over a 5- to 6-mo time period and these samples are likely to be able to do that conveniently and with no additional incurred costs (travel, parking). Second, students and dental patients are most likely to understand and need the use of bite splints, characteristics that enhance successful study outcomes. Finally, although the use of dental patients is ideal for obtaining ecological validation, the use of dental students as an alternative source of subjects all but guarantees that the study's necessary sample sizes can be obtained within the alotted time scale.

8-1.5* Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their initial enrollment into the study?

○ Yes ◉ **No**

8-1.6* Indicate which methods will be used for recruitment?

Check all that apply:

- Face-to-face contact (e.g. during a health care visit or an interview at a home address, etc.)
- Public advertisement (e.g., bulletin boards, newspapers, radio, TV, websites, or on-hold telephone scripts, etc.)

If other please specify:

8-1.7 How will any email, address, and/or telephone lists be obtained?

Email and/or telephone information will be obtained from only those candidates who meet the inclusion/exclusion criteria, sign an IC and fill out the three pre-screening forms (Pre-screening, demographics, TMD pre-screening, see below). This will be done during the recruitment appointment in Dr. Gerstner's office (see 8-1.3).

8-1.8* What materials will be used for recruitment? ***The IRB must approve all recruitment materials.***

See Help for important information regarding the requirements for recruitment materials

Check all that apply:

- Pre-screening questions
- Flyers
- Oral scripts

If other please specify:

If Web pages will be used, provide the Web address (URL) for the location where the pages will be posted (also upload the content of the pages below):

Upload recruitment materials here:

See Help for more information about working with documents (e.g. uploading, downloading, and editing).

Name	Version
Electronic flyer | History	0.06
Oral Script | History	0.06
Pre-screening questions | History	0.05
Standardized demographic form | History	0.01
TMD Pre-screening Form | History	0.01

☐ **Check here if any of the materials are not available electronically.**

Note: *Study Teams are encouraged to scan and upload documents. See Help for a list of sites with scanning facilities*

09. Survey Populations

9.1* Is the study limited to a survey of either:

- The general adult population (aged 18 or older); or
- A subgroup of the general population which does not specifically target:
  - Pregnant women and/or fetuses
  - Lactating women
  - Women of child-bearing potential
  - Prisoners
  - Cognitively impaired adults
  - College students
  - Economically or educationally disadvantaged persons
  - Patients of the study team
  - Employees, students or trainees of the study team
  - Family members of the study team

where the survey is the sole interaction with the subject and does not pose more than minimal risk?

○ Yes ◉ **No**

09-1. Subject Populations

9-1.1* Is the research designed to include or allow the following populations?

Select all that apply

☑ **Normal, healthy subjects**

☑ **Adults** *age 18 and older*

Minors able to consent *to treatments or procedures involved in the research, under*

- [ ] *the applicable law of the jurisdiction in which the research will be conducted (e.g. emancipated minors or minors seeking treatment for certain conditions.)*
- [ ] **Children and/or Viable Neonates** *(i.e. persons who have not yet reached the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted) [Require Sections 33 and 41]*
- [ ] **Neonates of uncertain viability and/or nonviable neonates** *(do not check this box if the research is solely retrospective. For retrospective research regarding neonates of uncertain viability, check the box for 'Children'. See Help for additional information.) [Require Section 34]*
- [ ] **Individuals and/or products involving human in vitro fertilization**
- [ ] **Pregnant women and/or fetuses** *[Require Sections 35 and 41]*
- [ ] **Lactating women** *[Require Section 36]*
- [x] **Women of child-bearing potential** *[Require Section 37]*
- [ ] **Prisoners** *(If the research includes a study population that is likely to become incarcerated during the conduct of the research, also select this category) [Require Section 38 and 41]*
- [ ] **Cognitively impaired adults** *[Require Sections 39 and 41]*
- [x] **College students** *[Require Sections 40 and 41]*
- [ ] **Economically or educationally disadvantaged persons** *[Require Section 41]*
- [ ] **Patients of the study team** *[Require Section 41]*
- [x] **Employees, students or trainees of the study team** *[Require Section 41]*
- [x] **Family members of the study team** *[Require Section 41]*
- [ ] **Unknown, unspecified population**

10. Informed Consent - Adults

10.1* What type of informed consent will be obtained from adults or minors legally able to consent to treatments or procedures involved in the research?

Select all that apply:

Comprehensive written

Request for waiver of informed consent/parental permission/legally authorized representative consent

10.1.2* Describe the process to seek and obtain informed consent and/or assent from adults. If requesting a waiver of documentation of assent, provide justification here.

Candidates who report for a screening appointment and will fill out the three pre-screening questionnaires. Those who meet the inclusion criteria will be given an informed consent to fill out. Questions and concerns will be addressed by Dr. Gerstner while the candidates read the informed consent. At the end, Dr. Gerstner will reiterate the details of the informed consent. Candidates will be given an opportunity to ask any questions and will then sign the consent form.

10.1.3* Is the cognitive capacity of the subjects expected to change significantly during the study?

○ Yes ◉ **No**

10-1. Informed Consent

10-1.1* All documents related to consent, assent, permission, and or debriefing documents, including oral scripts must be uploaded here. If you are requesting a waiver of documentation of informed consent, upload a copy of any written materials to be provided to participants, and provide a written description of any information to be provided orally.

Name	Version
IC-clean | History	0.03
IC--showing changes | History	0.03
X - DO NOT USE - Informed Consent | History	0.05

10-1.1.1* Does the Informed Consent use the sentences required for Applicable Clinical Trials: "A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."?

○ Yes ◉ **No**

10-1.2* Will the subjects be audiotaped, videotaped, or photographed (identifiable images of subject) during the research?

◉ **Yes** ○ No

10-1.3* Is there a substantial likelihood that the research will be conducted among a non-English-speaking population?

○ Yes ◉ **No**

10-1.4* Indicate which anticipated costs could be the full or partial responsibility of the subject.

Check all that apply:

Parking
Travel

If other, please specify:

10-1.5* Is the study designed to collect identifiable information from primary research subjects about other individuals, including family members?

○ Yes ◉ **No**

10-3. Informed Consent Waiver

10-3.1* This request is for:

Select all that apply:

Waiver of informed consent for PART of the project (Note: Applicable only to the recruitment aspects of the study if the study is subject to FDA oversight)

10-3.1.1 If this request is for PART of the project, identify the specific research procedures *(e.g., screening interview)* and/or the specific subject populations *(e.g., parents of child-subjects)* involved.

Answering pre-screening questions. No medical or dental records will be searched.

10-3.1.2 Explain any requested alterations to the informed consent process.

10-3.2* Check below to affirm that this study meets each of the following four criteria for waiver or alteration of informed consent and explain how:

☑ The research involves no more than minimal risk to the subjects.

Explain:
The pre-screening questions pose no risks.

☑ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Explain:
The pre-screening questions do not adversely affect the rights or welfare of subjects.

☑ Research could not practicably (i.e., feasibly) be carried out without the waiver or alteration.

Explain:
The pre-screening questions are necessary to identify eligible subjects.

☑ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Explain:
Enrolled subjects will receive complete information.

11. Confidentiality/Security/Privacy

11.1* Will the study team access any data that is linked to a subject's identity by name or other identifier or code? *[Require Section 11-1]*

◉ **Yes** ○ No

11.2* Explain how the subjects' privacy will be protected.

The study will use codes which will be linked to subject names by a secure spreadsheet. All digitized data used by the principal investigator will be coded and de-identified.

11.3* How will the research records, data and/or specimens be protected against inappropriate use or disclosure, or malicious or accidental loss or destruction in order to protect the confidentiality of subject data?

Select all that apply:

Locked office
Locked cabinet or storage unit
Restricted access
Restrictions on copying study-related materials
Access rights terminated when authorized users leave the project or unit

Individual ID plus password protection

Routine electronic back up

Network restrictions

No non-UM devices are used to access project data, or any that are used to access project data use secure connections to communicate with U-M services (e.g. VPN – "virtual private network")

Security software (firewall, anti-virus, anti-intrusion) is installed and regularly updated on all servers, workstations, laptops, and other devices used in the project

If other please specify:

11.4* Will the research generate information that, if revealed, might place the subjects at risk of personal safety, criminal or civil liability, or damage to their financial standing, employability, or reputation [Require Section 11-2]

○ Yes ◉ **No**

11.5* Will data be provided to a repository as part of a data sharing agreement?

○ Yes ◉ **No**

11.6* What will happen to the data and/or any specimens at the conclusion of this study?

Select all that apply:

Retain for study recordkeeping purposes

Retain for future research use - requires Section 11-4

11.6.2* If the data and/or specimens will be retained for study recordkeeping purposes, provide the following information (if covered in the attached protocol, please indicate section):

- expected duration of the retention period,
- any changes in the conditions or arrangements for storage of research data/specimens during the retention period, if different from those listed above in question 11.3.

Expected duration of retention: 10 years from date of study completion.
During retention (after initial 2-year study period), the single spreadsheet linking subject identities to codes will be destroyed. All de-identified information will be encrypted and stored in another password-protected dental school server space accessible by the PI and authorized personnel. The password for this space will be regularly changed on a semester-by-semester basis or as personnel in the laboratory change, whichever is sooner.

11-1. Identifiable Data

Completion of this section is required based on the response provided to question 11.1.

11-1.1* Indicate how subjects are identified in the research records.

Select all that apply:

Indirectly -- linked to data record but stored separately (e.g., name, initials, phone number, SSN, or medical record number linked to data record but stored separately)

11-1.2* Explain the necessity for collecting or maintaining data linked to subjects' identities. If the information is covered in the attached protocol, please indicate section.

During the study, subjects will be given bite splints and electronic recording equipment to take home with them. It is critical to be able to contact them at home so that neither the equipment is lost nor that a person with a dental device that they are wearing is without advice on care and use of the device. We must be able to retrieve both devices throughout the study and to retrieve the bite splint at the study's end.

11-1.3* How long will the identifiers be retained?

Until subjects are dismissed from the study, after which time they will be destroyed.

11-1.4* Will individually identifiable sensitive data be accessed, collected, used, maintained, or disclosed in the study?

○ Yes ◉ **No**

11-3. End of Subject Participation

11-3.1* What specific criteria will be used to prematurely end a particular subject's participation in the study (If covered in attached protocol or informed consent, indicate specific location).

Non-compliance with bite splint wear. This will be identified either through subject self-report or through evidence obtained during the study, viz., microwear on the teeth indicating no splint wear. Additional critieria would include becoming ineligible through development of signs, symptoms or conditions that are exclusion criteria for participation.

11-3.2* If a participant withdraws from the research, what is the plan to use, disclose, store, or destroy the participant's data and/or specimen?

If data are useful to the study, the plan will be to use them. Otherwise, data will be stored (if it provides information that will be useful for development of future study plans) or destroyed.

11-4. Retention of Data and/or Specimens Detail

Retention may be for future research by the investigator and/or the creation of a bank or repository.

Completion of this section is required based on the response provided to question 11.6.

11-4.1* What is the intent or purpose of retaining the data and/or specimens?

Use in future studies including refining study design, identification of such information as potential adverse events to inconveniences that could impact subject compliance, study completion, subject satifisaction and study rigor.

11-4.2* Where will you store the data and/or specimens?

Only at the University of Michigan

If Other Institutions, please specify:

11-4.3* Describe the arrangements for the storage conditions, management, and security of the data and/or specimens. ***Include the following as applicable:***

- ***Personnel access to data and/or specimens***
- ***Whether identifiers will be removed and the key to any code destroyed***
- ***For coded data and/or specimens, indicate who holds key to the code and where it is stored in relation to the data and/or specimens***
- ***Storage plan***
- ***Plan to protect privacy in transfer to other collaborators.***

The PI alone will have access to the subject-identifiable spreadsheet. This spreadsheet will be maintained on a dental school server space that is dedicated to and accessible by the PI alone. Videotapes are kept in locked cabinets in the PI's office. They are used only to digitize kinematic data for analysis purposes. Once this digitization is done, they are not used again unless: (1) a kinematic data set is corrupted and requires redigitization, (2) a question regarding kinematics arises that can be addressed by viewing the videos. In either case, the evaluation of the videos is done under the guidance of the PI and by as yet-to-be-named study personnel who have BIomed Human Subject PEERRS training.
Data that are de-identified will be stored on separate dental school server space, separate from the space above, with distinct password protection, known only to authorized study personnel and changed every semester if not more often, depending upon changes in personnel. All data will be encrypted on the servers.
There are no plans to transfer data to other collaborators.

11-4.4* Does the informed consent document explicitly notify subjects that their data and/or specimens will be stored for future research?

(●) **Yes** ( ) No

11-4.5* Are subjects required to agree to retention of their data and/or specimens as a condition of participating in the research?

( ) Yes (●) **No**

13. Subject Payments Or Other Incentives

Completion of this section is required based on the response provided to question 7-1.1 or 7-3.3.

13.1* Indicate all payments or other incentives provided to subjects for their participation in this study:

Select all that apply:

Cash
Visa Gift Card (HSIP Office issued)

If other, please specify:

13.2* If the subject is a child (under the age of 18 in Michigan), are any of the payments or incentives intended for the parent/guardian of the child?

N/A

13.3* Estimate the maximum total payment (including cash, checks, gift cards, and other cash-equivalent incentives) that an individual subject could receive for participating in this research in a single calendar year.

$26-$100

13.3.1* Please indicate what information you will be collecting from subjects that will be paid for their participation.

Select all that apply:

Email
Name

13.4* Describe the frequency of the payments or incentives. If applicable, list any healthcare procedure(s) that will be provided to subjects at no charge.

$20 at each visit
Appointment 1 = initial week ($20)
Appointments 2 and 3 = about two weeks into study participation ($20 x 2 = $40)
Appointments 4 and 5 = about 4.5 months into study participation ($20 x 2 = $40)
Total for all 5 appointments = $100

13.5* What is the justification for offering these payments or incentives?

Appreciation for participation.

13.6* What is the plan to compensate subjects withdrawing from the research prior to completing the entire study.

They will receive a pro-rated sum based upon the number of visits they successfully completed (see 13.4).

16. Devices

Completion of this section is required based on the response provided to question 7-2.1 or 7-3.8.

16.1* For all devices to be used at the Hospital and Health Centers, has the Biomedical Engineering Unit (BEU) assessed all devices for safety and tagged or registered all devices?

- ○ Yes
- ◉ **No**
- ○ Not Applicable

16.2* In the questions that follow, list all devices that will be used (including in vitro), administered, implanted, or applied as the object of the study, or are relevant to the study.

16.2.1 Devices Not Approved or Not Cleared for Marketing by the FDA:

	Name	IDE Number	Risk Designation
View	"Michigan" bite splint		Non-significant Risk (NSR)
View	BioRadio 150, a wireless physiology monitor.		
View	Jaw tracking device		

16.2.12 Devices being used "Off-Label" or for a Non-Approved Indication or in a Non-Approved Population that have already been Approved (PMA) or Cleared (510(K)) or exempted from the (510(K)) requirements by the FDA:

Name	IDE Number	Risk Designation
There are no items to display		

16.2.28 Devices being used "On-Label" that have already been Approved (PMA) or Cleared (510(k)) or exempted from the (510(k)) requirements by the FDA:

	Name
View	Night guard or bite splint
View	T-Scan Computerized Occlusal Analysis

Device Not Approved by the FDA:

16.2.2* What is the generic name or descriptor of the device? Include trade names if available.

"Michigan" bite splint

16.2.3* What is the source of the device? Include both supplier and manufacturer if different.

Fabricated by trained dentists--all dental students learn how to make these from heat-cured acrylic resin.

16.2.4* What is the purpose of the device and how will it be used in the study? ***Include any post-manufacturing modifications to the device.***

It is used to control night-time grinding and clenching (Bruxism).

16.2.5* What is the frequency and total duration of use of the device for an individual subject?

Used nightly, 7 days per week, for 6 months. This is typical weekly wear time frames, with 6 months being well within the usual standard practice (3 months to indefinite continuous use are the usual ranges, with estimated usual use being 2-5 years).

16.2.6* Is this an in vitro diagnostic device? [WHERE ALL THE FOLLOWING STATEMENTS ARE TRUE]

- **The diagnostic device complies with the labeling requirements of 21 CFR 809.10(c)**
- **The testing is non-invasive**
- **The testing does not require sampling procedures that present significant risks to the subject(s)**
- **The testing does not introduce energy into a subject**
- **The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure**

○ Yes ◉ **No**

16.2.7* Is this a medical device being tested for safety and/or efficacy?

◉ **Yes** ○ No

16.2.8* What is sponsor's risk designation for the device? ***[NOTE: if this is a sponsor-investigator study, the PI provides this designation. Complete the MIAP IDE Checklist to provide validation of the risk designation.]***

Non-significant Risk (NSR)

16.2.9.1* Upload a completed MIAP IDE Checklist, as well as any documentation from the sponsor that supports the determination that the device does not pose a significant risk to subjects. ***Include documentation of any prior investigations or other supporting materials.***

Name	Version
IDE Document | History	0.01

Note: *Click here for a list of sites with document scanning facilities.*

16.2.9.2* Describe why this device and its use, as proposed in this study, constitute a non-significant risk to the subjects involved. ***Include an evaluation of the safety risks to the subject in the event of a device failure.***

This device is the gold standard of care for curbing tooth wear due to clenching and grinding. It is routinely provided by dentists to patients for this purpose. Because of its inherent low risk, it is the first clinically operational device made by second-year dental students, i.e., students learn to make them by fabricating one to be worn by themselves. Many dentists provide splints to patients and never follow up. We consider this to be an unacceptable practice, as there are risks, albeit minimal, that can occur as a result of lack of monitoring by a trained clinician. Our evaluation of safety risks include the planned follow-up visits to evaluate the integrity of the device. Also, at the study's end or when the subjects leave the study, they will be required to return the splint. These devices rarely fail, but when they do failure typically involves fracture of the acrylic. When this occurs, the device will be returned to the laboratory by the subjects where it will be inspected and either repaired or replaced.

16.2.10* Describe the device control and accountability plan. In other words, describe the procedures for receiving, storing, dispensing, and otherwise controlling the use of the device(s), and who will be responsible for the device(s). Include in your answer at least the following information:

- **How will the device(s) be shipped to UM?**
- **Who will be responsible for receiving, labeling, storing, and dispensing the device(s)?**
- **What are the arrangements for chain-of-custody documentation, if needed?**
- **How will the principal investigator assure that the device will be secured so that it will only be used in a manner consistent with the IRB-approved protocol?**
- **What happens to the device(s) at the end of the study?**

The devices are either made at UM or delivered to UM from a local dental lab that routinely delivers the splints for use within the School of Dentistry, viz., in dental student training laboratories, to dental student patients, to dental faculty patients. Dr. Gerstner will be responsible for receiving, labeling, storing and dispensing the device. No chain-of-custody documentation is needed. The device will be delivered to subjects during a try-in appointment. At this time, subjects will be taught how to use and care for the splint. The IC explicitly states that the splint should only be worn at night, that it should be brought back by the subject at every follow-up visit and that it should be returned to the PI at the conclusion of the study. The device will be destroyed by the PI at the study's end.

16.2.11 If you have any additional correspondence with the FDA or the sponsor, upload it here. (e.g. acknowledgement, exemption, or FDA Hold letters)

Name	Version

There are no items to display

Device Not Approved by the FDA:

16.2.2* What is the generic name or descriptor of the device? Include trade names if available.

BioRadio 150, a wireless physiology monitor.

16.2.3* What is the source of the device? Include both supplier and manufacturer if different.

Great Lakes Neurotechnologies
10055 Sweet Valley Drive
Valley View, OH 44125
website: http://glneurotech.com/bioradio/

16.2.4* What is the purpose of the device and how will it be used in the study? *Include any post-manufacturing modifications to the device.*

The device is a battery-operated wireless physiology device and will be used to record some polysomnographic data, e.g., EMG, EEG, respiration, heart rate.

16.2.5* What is the frequency and total duration of use of the device for an individual subject?

The device will be used while subjects sleep in their own home beds (6-9 hours per night) on a total of 4 separate nights.

16.2.6* Is this an in vitro diagnostic device? [WHERE ALL THE FOLLOWING STATEMENTS ARE TRUE]

- **The diagnostic device complies with the labeling requirements of 21 CFR 809.10(c)**
- **The testing is non-invasive**
- **The testing does not require sampling procedures that present significant risks to the subject(s)**
- **The testing does not introduce energy into a subject**
- **The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure**

○ Yes ◉ **No**

16.2.7* Is this a medical device being tested for safety and/or efficacy?

○ Yes ◉ **No**

Device Not Approved by the FDA:

16.2.2* What is the generic name or descriptor of the device? Include trade names if available.

Jaw tracking device

16.2.3* What is the source of the device? Include both supplier and manufacturer if different.

The device consists of gen-locked cameras that track the movement of the jaw and head through use of retro-reflective markers attached to a moving target. The only part of the device in contact with the subject consists of two orthodontic facebows (http://sophia20110218.en.ec21.com/Orthodontic_Face_Bow--5199894_5273980.html has a picture of a facebow). These facebows are commonly known as "headgear" appliances and are worn at night by orthodontic patients to induce or inhibit bone growth. They are available through the dental school as 'reuseable' appliances. Hence, for our purposes, the dental school will be the supplier. They are attached to the teeth with a temporary dental cement.

16.2.4* What is the purpose of the device and how will it be used in the study? *Include any post-manufacturing modifications to the device.*

The jaw movements are captured to digital video by tracking the movements of orthodontic facebows outfitted with extra-oral, non-toxic retro-reflective markers and attached to the patient's teeth. The facebow is the only component of the jaw tracking system that is directly in contact with the subjects. Facebows are stainless steel, and for our purposes they will be temporarily cemented to the facial or cheek-side surfaces of upper and lower teeth with a temporary dental cement. Whereas facebows are designed to be attached via circumferential clasps fitted to molars, we wish only temporary attachment. Their usual clinical use requires them to remain in place for months and to be stable against high forces. For our purposes, no forces will be applied as we wish to interfer with jaw movements associated with chewing as little as possible. The small profile and footprint makes facebows ideal for our purposes. We have discovered through previous studies that judiciuos use of dental acrylic on the facial

surfaces of the posterior teeth provides sufficient mechanical stability to hold such devices in place through normal function. After a study, a gentle lateral force applied by a clinician to the facebow arms will release the temporary bond between the facebow and teeth without damage to teeth. The facial surfaces of the teeth are then inspected and any residual cement is removed. Subjects can inspect their teeth with their tongue and cheeks to determine whether all the cement is removed and small dental instruments can be used to remove any remaining cement.

16.2.5* What is the frequency and total duration of use of the device for an individual subject?

It will be used on three separate occasions in the laboratory for about 15 minutes per occasion.

16.2.6* Is this an in vitro diagnostic device? [WHERE ALL THE FOLLOWING STATEMENTS ARE TRUE]

- **The diagnostic device complies with the labeling requirements of 21 CFR 809.10(c)**
- **The testing is non-invasive**
- **The testing does not require sampling procedures that present significant risks to the subject(s)**
- **The testing does not introduce energy into a subject**
- **The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure**

(●) **Yes** ( ) No

FDA Approved Device:

16.2.29* What is the generic name or descriptor of the device? Include trade names if available.

Night guard or bite splint

16.2.30* Please enter the FDA 510(K) or Premarket Approval (PMA) number.

K121272

16.2.31* What is the source of the device? Include both supplier and manufacturer if different.

Akervall Technologies Inc., 5643 Plymouth Road, Ann Arbor, MI 48105, 800-444-0540

16.2.32* What is the purpose of the device and how will it be used in the study? *Include any post-manufacturing modifications to the device.*

Used for controlling the tooth-wear impacts from nocturnal bruxism (clenching and grinding).

16.2.33* What is the frequency and total duration of use of the device for an individual subject?

Every night during sleep, 7 days per week for 6 months. This is typical weekly wear time frames, with 6 months being well within the usual standard practice (3 months to indefinite continuous use are the usual ranges, with estimated usual use being 2-5 years).

16.2.34* Is this device the OBJECT of the study?

(●) **Yes** ( ) No

16.2.35* Upload the product label and any additional supporting documentation here:

Name	Version
Product Label | History	0.01
SOVA Website information | History	0.01

Note: *Click here for a list of sites with document scanning facilities.*

FDA Approved Device:

16.2.29* What is the generic name or descriptor of the device? Include trade names if available.

T-Scan Computerized Occlusal Analysis

16.2.30* Please enter the FDA 510(K) or Premarket Approval (PMA) number.

K870032

16.2.31* What is the source of the device? Include both supplier and manufacturer if different.

TekScan
307 West First Street.
South Boston, MA. 02127-1309, USA
tel: 800.248.3669 / 617.464.4500 fax: 617.464.4266
This facility is registered with the FDA as a manufacturer of Class I devices.

16.2.32* What is the purpose of the device and how will it be used in the study? ***Include any post-manufacturing modifications to the device.***

The device is used to obtain bite forces in real time while a person bites on a plastic sensor array. The device is in wide use in private practices and is also used in clinical research studies. It will be used to obtain bite force data on subjects biting on their teeth and on bite splints.

16.2.33* What is the frequency and total duration of use of the device for an individual subject?

The device will be used three times (3 separate visits) for about 10 minutes per visit.

16.2.34* Is this device the OBJECT of the study?

○ Yes ◉ **No**

29. Survey Research

Completion of this section is required based on the response provided to question 7-1.5.

29.1* Provide a list of all surveys and interviews used in the study:

Name	# of Questions	Duration	Sensitive?	Disturbing?
Compliance and Satisfaction	38	10 min	no	no
Explanatory Model Scale	6	1 to 2 min	no	no
Jaw Function Limitation Scale	20	2 min	no	no
Kinesiophobic Index-TMD	21	2 min	no	no
Oral Behavior Checklist	21	2 min	no	no
Oral Health Impact Profile	49	2 - 5 min	no	no
Patient Health Questionnaire	15	1 min	no	no

Perceived Stress Scale	10	1 min	no	no
Sleep-MOS	12	1 min	no	no
Survey of Treatments	30	2 min	no	no
TMD Demographics	5	1 min	no	no
TMD Pain drawing	2	1 min	no	no
TMD Pain Screener	3	< 1 min	no	no
TMD-Symptom questionnaire	7	1-min	no	no

29.13* Will the research involve the use of focus groups?

Yes **No**

29.14* Is any of the material disturbing?

Yes **No**

Survey Detail

29.2* Survey or interview name:

Compliance and Satisfaction

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

Yes **No**

29.4* In what manner will the survey or interview be conducted ***(e.g., in-person, Internet, mail, telephone, etc.)*****? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.***

In-person

29.5* What is the predicted response rate?

95 %

29.6* What is the total number of questions?

38

29.7* What is the anticipated cumulative amount of time required for each subject?

10 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

3

29.9* Does the survey or interview contain questions of a sensitive nature ***(e.g., mental illness, sexual abuse, illicit drug use, etc.)*****?**

Yes **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

Yes **No**

29.11* Has the survey instrument been validated or used in standard practice?

Yes **No**

29.12* Upload the survey instrument here.

Name	Version
Compliance and statisfaction worksheets | History	0.01

Survey Detail

29.2* Survey or interview name:

Explanatory Model Scale

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

Yes **No**

29.4* In what manner will the survey or interview be conducted *(e.g., in-person, Internet, mail, telephone, etc.)*? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

in-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

6

29.7* What is the anticipated cumulative amount of time required for each subject?

1 to 2 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature *(e.g., mental illness, sexual abuse, illicit drug use, etc.)*?

Yes **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

Yes **No**

29.11* Has the survey instrument been validated or used in standard practice?

(•) **Yes** ( ) No

29.11.1* If yes, describe the origin of the instrument.

International RDC/TMD Consortium

29.12* Upload the survey instrument here.

Name	Version
Exlanatory model scale | History	0.01

Survey Detail

29.2* Survey or interview name:

Jaw Function Limitation Scale

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

( ) Yes (•) **No**

29.4* In what manner will the survey or interview be conducted *(e.g., in-person, Internet, mail, telephone, etc.)*? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

20

29.7* What is the anticipated cumulative amount of time required for each subject?

2 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature *(e.g., mental illness, sexual abuse, illicit drug use, etc.)*?

( ) Yes (•) **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

( ) Yes (•) **No**

29.11* Has the survey instrument been validated or used in standard practice?

(•) **Yes** ( ) No

29.11.1* If yes, describe the origin of the instrument.

International RDC/TMD Consortium

29.12* Upload the survey instrument here.

Name	Version
JFLS-20 | History	0.01

Survey Detail

29.2* Survey or interview name:

Kinesiophobic Index-TMD

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

( ) Yes (•) **No**

29.4* In what manner will the survey or interview be conducted *(e.g., in-person, Internet, mail, telephone, etc.)*? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

in-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

21

29.7* What is the anticipated cumulative amount of time required for each subject?

2 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature *(e.g., mental illness, sexual abuse, illicit drug use, etc.)*?

( ) Yes (•) **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

( ) Yes (•) **No**

29.11* Has the survey instrument been validated or used in standard practice?

(●) **Yes** ( ) No

29.11.1* If yes, describe the origin of the instrument.

Visscher CM, Ohrbach R, van Wijk AJ, Wilkosz M, Naeije M (2010). The Tample Scale for Kinesiophobia for Temporomandibular Disorders (TSK-TMD). Pain 150:492-500.

29.12* Upload the survey instrument here.

Name	Version
Kinesiophobia Scale | History	0.01

Survey Detail

29.2* Survey or interview name:

Oral Behavior Checklist

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

( ) Yes (●) **No**

29.4* In what manner will the survey or interview be conducted *(e.g., in-person, Internet, mail, telephone, etc.)*? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

21

29.7* What is the anticipated cumulative amount of time required for each subject?

2 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature *(e.g., mental illness, sexual abuse, illicit drug use, etc.)*?

( ) Yes (●) **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ◉ **No**

29.11* Has the survey instrument been validated or used in standard practice?

◉ **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

International RDC/TMD Consortium (R. Ohrbach)

29.12* Upload the survey instrument here.

Name	Version
OB Checklist | History	0.01

Survey Detail

29.2* Survey or interview name:

Oral Health Impact Profile

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ◉ **No**

29.4* In what manner will the survey or interview be conducted *(e.g., in-person, Internet, mail, telephone, etc.)*? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

49

29.7* What is the anticipated cumulative amount of time required for each subject?

2 - 5 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature *(e.g., mental illness, sexual abuse, illicit drug use, etc.)*?

○ Yes ◉ **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative

feelings in the subjects?

○ Yes ◉ **No**

29.11* Has the survey instrument been validated or used in standard practice?

◉ **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

G Slade and J. Spencer. Development and evaluation of the Oral Health Impact Profile. Community Dental Health 11:3-11, 1994.

29.12* Upload the survey instrument here.

Name	Version
OHIP Instrument | History	0.01

Survey Detail

29.2* Survey or interview name:

Patient Health Questionnaire

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ◉ **No**

29.4* In what manner will the survey or interview be conducted ***(e.g., in-person, Internet, mail, telephone, etc.)? Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.***

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

15

29.7* What is the anticipated cumulative amount of time required for each subject?

1 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature ***(e.g., mental illness, sexual abuse, illicit drug use, etc.)?***

○ Yes ◉ **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ◉ **No**

29.11* Has the survey instrument been validated or used in standard practice?

◉ **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

Pfizer

29.12* Upload the survey instrument here.

Name	Version
PHQ-15 | History	0.01

Survey Detail

29.2* Survey or interview name:

Perceived Stress Scale

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ◉ **No**

29.4* In what manner will the survey or interview be conducted ***(e.g., in-person, Internet, mail, telephone, etc.)*****? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.***

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

10

29.7* What is the anticipated cumulative amount of time required for each subject?

1 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature ***(e.g., mental illness, sexual abuse, illicit drug use, etc.)*****?**

○ Yes ◉ **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

Yes **No**

29.11* Has the survey instrument been validated or used in standard practice?

Yes No

29.11.1* If yes, describe the origin of the instrument.

S. Cohen, T. Kamarck, and R. Mermelstein. A global measure of perceived stress. J.Health Human Behav. 24:385-396, 1983.

29.12* Upload the survey instrument here.

Name	Version
PSS-10 | History	0.01

Survey Detail

29.2* Survey or interview name:

Sleep-MOS

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

Yes **No**

29.4* In what manner will the survey or interview be conducted *(e.g., in-person, Internet, mail, telephone, etc.)*? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

12

29.7* What is the anticipated cumulative amount of time required for each subject?

1 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature *(e.g., mental illness, sexual abuse, illicit drug use, etc.)*?

Yes **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ◉ **No**

29.11* Has the survey instrument been validated or used in standard practice?

◉ **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

Hays, R. D., & Stewart, A. L. (1992). Sleep measures. In A. L. Stewart & J. E. Ware (eds.), Measuring functioning and well-being: The Medical Outcomes Study approach (pp. 235-259), Durham, NC: Duke University Press. (and RAND)

29.12* Upload the survey instrument here.

Name	Version
Sleep-MOS Instrument | History	0.01

Survey Detail

29.2* Survey or interview name:

Survey of Treatments

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ◉ **No**

29.4* In what manner will the survey or interview be conducted *(e.g., in-person, Internet, mail, telephone, etc.)*? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

in-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

30

29.7* What is the anticipated cumulative amount of time required for each subject?

2 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature *(e.g., mental illness, sexual abuse, illicit drug use, etc.)*?

Yes **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

Yes **No**

29.11* Has the survey instrument been validated or used in standard practice?

Yes **No**

29.12* Upload the survey instrument here.

Name	Version
Survey of Tx | History	0.01

Survey Detail

29.2* Survey or interview name:

TMD Demographics

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

Yes **No**

29.4* In what manner will the survey or interview be conducted ***(e.g., in-person, Internet, mail, telephone, etc.)*****? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.***

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

5

29.7* What is the anticipated cumulative amount of time required for each subject?

1 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature ***(e.g., mental illness, sexual abuse, illicit drug use, etc.)*****?**

Yes **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

Yes **No**

29.11* Has the survey instrument been validated or used in standard practice?

Yes No

29.11.1* If yes, describe the origin of the instrument.

International RDC/TMD Consortium

29.12* Upload the survey instrument here.

Name	Version
TMD demographics | History	0.01

Survey Detail

29.2* Survey or interview name:

TMD Pain drawing

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

Yes **No**

29.4* In what manner will the survey or interview be conducted ***(e.g., in-person, Internet, mail, telephone, etc.)*****? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.***

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

2

29.7* What is the anticipated cumulative amount of time required for each subject?

1 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature ***(e.g., mental illness, sexual abuse, illicit drug use, etc.)*****?**

Yes **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ◉ **No**

29.11* Has the survey instrument been validated or used in standard practice?

◉ **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

International RDC/TMD Consortium

29.12* Upload the survey instrument here.

Name	Version
TMD pain drawing | History	0.01

Survey Detail

29.2* Survey or interview name:

TMD Pain Screener

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ◉ **No**

29.4* In what manner will the survey or interview be conducted ***(e.g., in-person, Internet, mail, telephone, etc.)*****? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.***

In person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

3

29.7* What is the anticipated cumulative amount of time required for each subject?

< 1 min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature ***(e.g., mental illness, sexual abuse, illicit drug use, etc.)*****?**

○ Yes ◉ **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ◉ **No**

29.11* Has the survey instrument been validated or used in standard practice?

◉ **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

International RDC/TMD Consortium

29.12* Upload the survey instrument here.

Name	Version
TMD Screener | History	0.01

Survey Detail

29.2* Survey or interview name:

TMD-Symptom questionnaire

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ◉ **No**

29.4* In what manner will the survey or interview be conducted ***(e.g., in-person, Internet, mail, telephone, etc.)*****? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.***

In-person

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

7

29.7* What is the anticipated cumulative amount of time required for each subject?

1-min

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature ***(e.g., mental illness, sexual abuse, illicit drug use, etc.)*****?**

○ Yes ◉ **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ◉ **No**

29.11* Has the survey instrument been validated or used in standard practice?

◉ **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

International RDC/TMD Consortium

29.12* Upload the survey instrument here.

Name	Version
TMD Sx short form | History	0.01

37. Women of Child Bearing Potential

Completion of this section is required based on the response provided to question 9-1.1.

37.1* Is there a potential that any of the study procedures pose significant physical or psychological risks to women who are or may be pregnant, or to a fetus?

○ Yes ◉ **No**

41. Subjects Vulnerable to Coercion

Completion of this section is required based on the response provided to question 9-1.1, 9-2.1, or 9-3.1

The following subject populations, vulnerable to coercion or undue influence, have been identified for inclusion in the study.

College Students
Employees, Students, Trainees of Study Team
Family Members of Study Team

41.1* What is the justification for the inclusion of these subject populations?

There is no reason not to include them. The study involves the use of bite splints for a ~5-month period. Demographics show that young adults in the ages 20-40 are most susceptible to bruxism and therefore in greatest need for the intervention. Also, many of the dental school's patients are economically or educationally deprived. Since the intervention is without significant risks, requires several visits, and can be ideally performed with convenience samples, the study can be mutually beneficial to these subjects.

41.2* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

They will be informed that their participation is completely voluntary, that they can withdraw at any time without impacting either their treatment in the dental school or without impacting their college enrollment, grades, employment. In addition, Dr. Gerstner will make announcements in dental school classrooms to raise awareness of the study; however, no dental students will be specifically targeted and he will emphasize that decisions to participate

will not impact grades or class status in any way.

44. Additional Supporting Documents

44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

Name	Version
BioRadioInformationSheet | History	0.01
Jaw Tracking Device | History	0.01
TMD/RDC protocols | History	0.01

44.2 If the study sponsor requires that the IRBMED approval letter contain a list of supporting documents, list the names of the documents in the box below as they should appear on the IRBMED approval letter:

45. End of Application

The form was successfully submitted. Click 'Exit' or 'Finish' to leave the form.