Oral splints for patients with temporomandibular disorders or bruxism: a systematic review and economic evaluation

Philip Riley,[1] Anne-Marie Glenny,[1]
Helen V Worthington,[1*] Elisabet Jacobsen,[2]
Clare Robertson,[3] Justin Durham,[4] Stephen Davies,[5]
Helen Petersen[6] and Dwayne Boyers[2]

[1]Cochrane Oral Health, Division of Dentistry, School of Medical Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK
[2]Health Economics Research Unit, University of Aberdeen, Aberdeen, UK
[3]Health Services Research Unit, University of Aberdeen, Aberdeen, UK
[4]Centre for Oral Health Research and School of Dental Sciences, Newcastle University, Newcastle upon Tyne, UK
[5]TMD Unit, University Dental Hospital of Manchester, Manchester, UK
[6]University Dental Hospital of Manchester, Manchester, UK

*Corresponding author helen.worthington@manchester.ac.uk

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Scientific summary

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Scientific summary

Background

Splints have long been used as a non-invasive, reversible management option for patients presenting with certain orofacial signs and symptoms including orofacial pain, joint clicking, limited mouth-opening and tooth wear. Typically they have been used with patients presenting with temporomandibular disorders or bruxism. The clinical effectiveness and cost-effectiveness of splints remain uncertain.

Objectives

The objectives were to evaluate the clinical effectiveness and cost-effectiveness of splints for patients with temporomandibular disorders or bruxism. The comprehensive evidence synthesis compared (1) all types of splint versus no/placebo splints and (2) prefabricated splints versus custom-made splints, for the primary outcomes orofacial pain for temporomandibular disorder patients and tooth wear for bruxism patients.

Methods

In the systematic review, we included randomised controlled trials that included children (aged > 11 years) and adults with either temporomandibular disorders or bruxism, for whom the dental or other health-care worker was considering treatment with an oral splint, in either primary or secondary care. We excluded studies in which the majority of patients were undergoing fixed or removable orthodontic treatment. The no splint/control splint group also included watchful waiting or minimal treatment or self-management.

The primary outcome for the review was pain, which was measured in a variety of ways. For bruxism patients, we also considered tooth wear as a primary outcome. Harms were also a primary outcome, which included any problems such as soreness of the oral cavity caused by the splint. Secondary outcomes included clicking of the temporomandibular joint, change in restricted mouth-opening, frequency of headaches (secondary to pain-related temporomandibular disorders) and quality-of-life data (including physical and emotional function). Patient satisfaction and adherence to treatment data were collected whenever possible. For bruxism, the index and frequency of bruxism activity was recorded. Follow-up periods for the outcome data were divided into short-term follow-up (0–3 months), medium-term follow-up (3–6 months) or long-term follow-up (6–12 months). After discussion with the clinicians during the data extraction period, it was decided to present the results for the 0- to 3-month time period for the primary analysis. A systematic literature search was also undertaken to identify any cost-effectiveness evidence.

Four databases were searched on 1 October 2018: (1) Cochrane Central Register of Controlled Trials in The Cochrane Library, (2) MEDLINE via OvidSP (from 1946 onwards), (3) EMBASE via OvidSP (from 1980 onwards) and (4) Cumulative Index to Nursing and Allied Health Literature from EBSCO*host* (from 1937 onwards). When appropriate, the searches of these databases were linked to study design search filters developed by Cochrane for identifying reports of randomised and controlled clinical trials. They were undertaken without restrictions on language or date of publication.

We undertook the systematic review using Cochrane methods. All data extraction was undertaken independently in duplicate. The following domains were assessed for the risk-of-bias assessment for each included trial: sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessors (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias) and other bias.

Pain was frequently measured by a visual analogue scale and we had planned to use the mean and standard deviation of this as the treatment effect, using standardised mean difference if different scales were used (e.g. pain could be measured as pain experienced now or the worst pain experienced over the previous month). We used risk ratios with 95% confidence intervals for the effect estimates of the dichotomous data. We contacted authors, when feasible, for missing outcome data.

Heterogeneity was assessed by the chi-squared test and quantified by I^2. We undertook data syntheses, when appropriate, using random-effects models. We planned to undertake subgroup analyses for different splint types.

Summary of findings tables were used to summarise the results, and the quality of the body of evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation methods.

A Markov cohort state-transition decision-analysis model was developed to assess the cost-effectiveness of splints compared with no splints for temporomandibular disorders from an NHS perspective. A separate model was structured for bruxism but could not be populated owing to a lack of cost, utility, transition probability or clinical effectiveness data.

The temporomandibular disorder model was structured to estimate cost-effectiveness based on three pain tertile health states (low, moderate or high) based on current pain or Characteristic Pain Intensity definitions. In each 3-monthly model cycle, the cohort had a probability of transiting between health states (or remaining in the current health state) based on a reanalysis of the Developing Effective and Efficient care pathways in chronic Pain (DEEP) UK cohort study (Durham J, Breckons M, Araujo-Soares V, Exley C, Steele J, Vale L. Developing Effective and Efficient care pathways in chronic Pain: DEEP study protocol. *BMC Oral Health* 2014;**14**:6) data conducted for this project. There was no additional risk of mortality, and the whole cohort, regardless of treatment arm, was exposed to general population all-cause mortality risks. The model was run over a lifetime horizon, with costs and quality-adjusted life-years occurring in the future being discounted at a rate of 3.5% per annum.

When possible, meta-analysis of clinical effectiveness studies was used to obtain mean differences (splints vs. no splints) in the alternative pain measures. Mean differences were translated into assumed relative risks in pain tertiles and applied to the transition probability data obtained from the DEEP study. DEEP study data were also used to inform the costs and utilities of different pain states in the model. All model input data were sampled probabilistically from respective sampling distributions for transition probabilities, mean differences in pain, costs and utilities.

The model was, therefore, fully probabilistic. Expected values of costs and quality-adjusted life-years were obtained using Monte Carlo simulation (1000 repetitions) and used to calculate incremental cost-effectiveness ratios. Results were reported using scatterplots of the cost-effectiveness plane, and cost-effectiveness acceptability curves were used to illustrate the decision uncertainty regarding the optimal strategy. It was assumed that the threshold value of willingness to pay for a quality-adjusted life-year gained was £20,000. Expected value of perfect information and expected value of perfect parameter information analyses were used to determine whether or not further research was worthwhile, and, if so, what model parameters should be researched to reduce future decision uncertainty.

Results

Fifty-two trials were included in the systematic review. Fifty trials were assessed as being at high risk of bias and the remaining two trials had an unclear risk of bias. Therefore, no studies were deemed to have a low risk of bias in this review.

Comparing splints with no splints/control or placebo splints/minimal intervention in patients with temporomandibular disorders (all subtypes of temporomandibular disorder pooled into one group)

From 35 studies comparing splints with no splints or a minimal intervention, there was no evidence that providing splints reduced pain (measured on continuous/discrete graded scales) in patients with temporomandibular disorders when all subtypes of temporomandibular disorder were pooled into one group [standardised mean difference (up to 3 months) −0.18, 95% confidence interval −0.42 to 0.06; substantial heterogeneity $I^2 = 70\%$; very low-quality evidence; 13 studies; 1076 participants]. There were fewer studies and patients contributing to the standardised mean difference estimates at the other time points and, similarly, no evidence that splints reduced pain. The standardised mean difference effect size at up to 3 months was considered to be small and we undertook an analysis for current pain measured on a visual analogue scale or numerical rating scale (scored from 0 to 100) to look at the effect size in standard units. Eleven studies and 874 patients were included and the mean difference during the 0- to 3-month time period was −4.48 (95% confidence interval −11.59 to 2.64; $I^2 = 94\%$), with insufficient evidence of any difference at the other time points. Data for the secondary outcomes of the review also failed to provide any evidence that splints improved these outcomes. There was no evidence of adverse events associated with splints, but reporting was poor regarding this outcome.

The literature review did not identify any studies evaluating the cost-effectiveness of splints for temporomandibular disorder; therefore, the results of the decision-analysis model are reported to address the clear gap in the evidence base. There was substantial uncertainty regarding the optimal treatment strategy. The base-case incremental cost-effectiveness ratios for splints versus no splints were £39,216 and dominated (i.e. splints were, on average, more costly and generated fewer quality-adjusted life-years) for the current pain and Characteristic Pain Intensity configurations, respectively. However, these incremental cost-effectiveness ratios were surrounded by considerable uncertainty and it is most informative to consider the decision uncertainty as reported for the probabilistic analysis. Assuming that society is willing to pay a maximum of £20,000 to achieve a one-unit quality-adjusted life-year gain, there was only a 58% and 29% chance that splints are the optimal (i.e. most cost-effective) treatment strategy using the current pain and Characteristic Pain Intensity configurations, respectively. Deterministic sensitivity and scenario analyses indicate that the cost-effectiveness results are most sensitive to assumptions made about (1) the long-term benefits of splints (mean differences in pain intensity), (2) long-term transition probabilities and (3) the frequency of splint replacement.

Comparing splints with no splints/control or placebo splints/minimal intervention in patients with bruxism

There were no studies measuring tooth wear in patients with bruxism. One small study looked at pain and found a reduction in the splint group (mean difference −2.01, 95% confidence interval −2.62 to −1.40; very low-quality evidence). There was no cost-effectiveness evidence in the literature. Furthermore, it was not possible to populate a decision-analysis model to determine cost-effectiveness because of a paucity of data regarding transition probabilities between tooth wear states, utilities or costs.

Comparing prefabricated and custom-made splints

As there was no evidence that splints reduced pain or improved other outcomes in the clinical effectiveness review, this comparison between different splint types became irrelevant. However, exploratory cost-effectiveness analyses were conducted to identify the main drivers of cost-effectiveness in a three-way comparison of custom-made versus prefabricated versus no splints. Results were highly uncertain and the model indicated an approximately equal chance of custom-made, prefabricated and none being the most cost-effective strategy, further emphasising the need for future research.

Limitations

There are a number of substantial limitations in this evidence synthesis due to the large variation in the diagnostic criteria, splint types and methods of outcome measurement and reporting. We performed sensitivity analyses based on these limitations, but did not demonstrate a reduction in pain.

Owing to a lack of relative risk data from the clinical effectiveness review to match the economic model structured around pain tertiles, assumptions were required to map mean differences to tertile-specific relative risks. This process was based on assumptions about the feasible changes in tertile for each possible mean difference. This assumption raises uncertainties in the model, as the results are not based on true relative risks. Furthermore, there were no data available to inform the long-term effectiveness of splints and assumptions were required about the impact of splints beyond 6–12 months. An advantage of the modelling approach taken is that, for the base-case analysis, different assumptions were incorporated probabilistically, meaning that each assumption had an equal chance of being applied in each Monte Carlo simulation.

Conclusions

The very low-quality evidence identified did not demonstrate that splints reduced pain in temporomandibular disorder as a group of conditions; data were poorly reported for different temporomandibular disorder subtypes. There is insufficient evidence to determine whether or not splints reduce tooth wear in patients with bruxism. It remains unclear whether or not splints offer value for money to the NHS.

Future work

There is a need for well-conducted trials to determine the clinical effectiveness and cost-effectiveness of splints in patients with carefully diagnosed and subtyped temporomandibular disorder, and patients with bruxism, using agreed measures of pain and tooth wear.

The value-of-information analysis revealed a very high expected value of perfect information, indicating that future research to resolve decision uncertainty regarding the optimal, most cost-effective strategy (splints or no splints) is beneficial. The expected value of perfect parameter information analysis identified future research priorities and indicated that further research regarding the clinical effectiveness of splints (in the short and longer term) is particularly worthwhile. In addition, the expected value of perfect parameter information analysis indicated that further research should be carried out to determine the long-term impact of temporomandibular disorders on pain states (beyond 2 years), as well as the frequency of splint replacement.

Study registration

The study is registered as PROSPERO CRD42017068512.

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