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The effects of custom-made mouthguard design on physiological parameters and players' perception in rugby union

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Abstract

Some sports participants are often reluctant to wear a mouthguard due to issues with comfort, breathing and communication. However, there is limited evidence that investigates the use of custom-made mouthguards and variations in design as key factors to minimise these issues. Therefore, the aim of this study was to examine the effect of custom-made mouthguard design on cardiopulmonary function, exercise performance and perception of comfort in rugby union players. Fourteen rugby players (aged 20.2 ± 1.19 years) were recruited to undertake a rugby-specific exercise protocol on a treadmill over four conditions (no mouthguard and three custom-made mouthguard designs). Cardiopulmonary responses were assessed using breath-by-breath analysis, in conjunction with blood lactate (BLa) and rating of perceived exertion (RPE). Maximum oxygen uptake (VO_{2max}) was assessed before and after the study to identify any changes in players' level of performance. Participants scored each mouthguard in relation to preference, comfort, breathing, protection and retention. There were no differences in oxygen uptake ($p = 0.785$, $\eta_p^2 = 0.021$), ventilation ($p = 0.952$, $\eta_p^2 = 0.007$), respiratory exchange ratio ($p = 0.564$, $\eta_p^2 = 0.039$) and heart rate ($p = 0.830$, $\eta_p^2 = 0.017$), whilst participants performed with the selected custom-made mouthguards. However, RPE was higher without a mouthguard than whilst using two of the mouthguards during the first 3 min of exercise, in combination with higher BLa accumulation ($p \leq 0.05$). Although there was no statistical difference between mouthguard designs in the ratings around comfort, there was a preference towards mouthguards with reduced palatal coverage. Individual preference in design may improve compliance of wearing a mouthguard without affecting physiological parameters.

KEYWORDS
cardiorespiratory, lactate, mouthguard, rugby

Highlights

- Wearing any of the three selected custom-made mouthguards had no impact on cardiorespiratory parameters, such as oxygen uptake, minute ventilation, respiratory exchange ratio, heart rate and blood lactate.
- In terms of participants' perceived comfort, there were no differences between the selected mouthguard designs.
- The findings of the present study may lead to encouraging the use of custom-made mouthguards amongst rugby players as no negative influence on the examined physiological parameters was found.

1 | INTRODUCTION

Epidemiological studies assessing the prevalence of dental trauma within adult and junior rugby players have highlighted the need for personal protective equipment (Ilia et al., 2014; Jagger et al., 2010; Muller-Bolla et al., 2003; Nicol et al., 2011; Schildknecht et al., 2012). Ilia et al. (2014) reported that 64.9% of rugby union players ($n = 240$; 24.1 ± 5.7 years) had sustained a dental injury, similar to the findings of Schildknecht et al. (2012), who reported 54.4% within a larger population ($n = 517$; 23.1 years). In relation to all orofacial traumas, 41.9% were related to the dentition (i.e. avulsion, luxation, crown or root fracture), with more than a half of them affecting the upper anterior teeth (Schildknecht et al., 2012). However, despite the strong recommendation of wearing mouth protection, players often raise issues, such as impedances in communication, breathing and comfort (Boffano et al., 2012; Ilia et al., 2014). An investigation of mouthguard awareness and compliance within rugby players in Italy reported that only 53.9% ($n = 65$; males; 22.2 ± 5.66 years) of the participants used mouthguards during training and competition (Boffano et al., 2012). In addition, 32.5% reported that they had never used a mouthguard. The most common issues were impedances in communication (79.6%), difficulty to close the lips (22.2%) and breathing obstruction (16.7%). Participants' acceptance of mouthguards could be increased if they were provided with a well-fitted device (Ilia et al., 2014). It is important that dental practitioners not only promote the advantages of customised mouthguards but also educate their patients about variations in design which may affect user compliance.

Previous findings have suggested that wearing a mouthguard during training and/or competition could potentially affect physiological variables (i.e. oxygen uptake [VO_2] and ventilation [V_E]). Previous research examining field-based team-sports, such as rugby, have primarily focused on the influence of 'boil-and-bite' (self-adjusted) mouthguards compared to no mouthguard and/or custom-made mouthguards on physiological variables (Bourdin et al., 2006; Drum et al., 2016; Duarte-Pereira et al., 2008; Queiroz et al., 2013; Schulze et al., 2019). Whilst past research denotes less interference with performance when custom-made mouthguards are used compared to using stock (cannot be self-adjusted) or 'boil-and-bite' types (Bourdin et al., 2006; Drum et al., 2016; Duarte-Pereira et al., 2008), there are limited studies that assess the influence of differences in design of custom-made mouthguards on physiological performance, comfort, communication and adherence in rugby union players. Although Lässing et al. (2021) observed some changes in cardiopulmonary and metabolic parameters when two different custom-made mouthguards were used, their randomised crossover study included healthy participants (seven males and six females; 23.5 ± 14 years) but their testing protocol was not sport-specific. Following this, the importance of performing a sport-specific exercise protocol was not highlighted. This is recommended in order to achieve more valid findings and contribute to the current knowledge within mouthguard research. Therefore, the aims of the present study were to use a novel testing protocol, which mimicked the aerobic and anaerobic demands of a rugby game (i.e. intermittent running and sprinting, combined with walking and jogging) to examine the influence of different custom-made mouthguard designs on physiological parameters and players' preference in rugby union players. It was hypothesised that there will be no mouthguard effect observed for the physiological and perceptual measures recorded.

2 | MATERIALS AND METHODS

Prior to commencing any experimental work, participant consent and ethical approval were obtained from the University Ethics committee (Number: SE151683) in accordance with the Declaration of Helsinki (WMA, 2013). Participants were provided with detailed information about the study objectives, full protocol and the possible risks and benefits of taking part prior to obtaining informed consent. All participants had the right to withdraw at any time during the study.

2.1 | Participants

A priori sample size calculation was conducted via G*Power (v3.1.9.4, Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany), using $\alpha = 0.05$ and an effect size of 0.8, resulting in a minimum requirement of 12 participants. Statistical significance was set at $p \leq 0.05$. Fourteen men (age 20.2 ± 1.19 years; body mass 91.2 ± 13.53 kg; height 182.1 ± 8.65 cm) were recruited from a Premier B British University and Colleges Rugby Union team. All participants trained for 5–10 h per week, with 11 ± 3.9 years of experience in rugby and 10 ± 3.8 years of competing.

Medical and dental assessments were completed to ensure none of the participants had any present injuries, related cardiovascular problems, temporomandibular disorder or any trauma of the oral and facial structures that would affect their involvement within the study. Participants were excluded if taking any form of medication, which could affect airflow, muscle fatigue and heart rate (HR) or were diagnosed anaemic (haemoglobin <13 g/dL) or hypertension (systolic ≥140 mm Hg or diastolic ≥90 mm Hg).

2.2 | Fabrication of mouthguards

A dental clinician took alginate dental impressions (Tropicalgin®; Zhermack SpA) of both the maxillae and the mandible for each participant. Three mouthguard devices were then fabricated for each participant by the same technician. All mouthguards were thermoformed on a Biostar machine (BIOSTAR®; SCHEU-DENTAL GmbH) at 4.8 bars applied pressure and made of clear ethylene vinyl acetate (EVA) blanks of 120 mm Ø (diameter) (Bracon Ltd.). Figure 1 shows the selected mouthguard designs (MG1, MG2 and MG3), which had previously demonstrated higher retention levels than other designs (Karaganeva et al., 2019). MG1 was fabricated from a 5 mm single EVA blank and it had a 4 mm gingival flange, similar to the mouthguard proposed by Gebauer et al. (2011). In comparison, MG2 and MG3 were fabricated with two EVA layers (2 and 4 mm) and were trimmed around the palatal gingival margins. The designs of MG2 and MG3 were adapted from Morales et al. (2015) and Takeda et al. (2014). MG2 consisted of a double layer at the occlusal surfaces of the posterior region only, whereas MG3, which was designed for a rugby player with mal-aligned teeth, had a double EVA layer covering all anterior teeth and the occlusal surfaces of the posterior teeth. MG1 and MG2 were finished at the distal surfaces of the first maxillary molars, whereas MG3 extended over the second maxillary molars. All devices had a full buccal flange.

2.3 | Baseline measurements and aerobic fitness assessment

To control for variability in the data, participants recorded their dietary intake and physical activity 24 h prior to attending each laboratory session, whilst abstaining from caffeine and fasting 2 h before testing. Primary baseline measurements included: height, body mass, blood pressure, HR and level of blood lactate (BLa). Capillary finger prick blood samples were taken twice to measure Hb and BLa levels. A portable analyser (Lactate Pro, Arkray) was used to analyse the BLa samples.

Maximal aerobic fitness (VO_{2max}) was assessed by a breath-by-breath analyser (METALYZER® 3B; CORTEX) following an incremental testing protocol on a motorised treadmill (Pro Woodway). This was completed at the start and at the end of the study to ensure aerobic fitness levels were stable during the testing period. The test started at 0% treadmill incline, which was increased by 1% every minute, whilst the speed for each individual (11 ± 0.70 $km{\cdot}h^{-1}$) remained unchanged. The period between the first and the second VO_{2max} session varied from 5 to 12 weeks. The variation was due to participants' availability attending the testing session.

2.4 | Rugby specific protocol

Following completion of the VO_{2max} protocol, participants undertook four laboratory-based test sessions on a weekly basis. During each session, the participants performed a rugby-specific protocol (Figure 2) with randomly allocated mouthguard or without a mouthguard. Randomisation was performed in advance by the primary researcher using a standard Microsoft Excel Spreadsheet and colour-coded cells to indicate the type of session. The choice of speeds (5 and 20 $km{\cdot}h^{-1}$) was based on proposed speed zones that were recorded previously during elite rugby union games (Cunniffe et al., 2009). Respiratory parameters were measured throughout the whole protocol using breath-by-breath analysis (METALYZER® 3B; CORTEX). Following manufacturer's instructions, volume sensor precalibration of the gas analyser was performed prior to each session using a 3-L calibration syringe (Hans Rudolph™, Inc, Series 5530). Additionally, HR (bpm) was monitored with a chest strap HR sensor (Polar H7, Polar Electro Ltd.). Capillary finger prick BLa samples were taken at rest, post warm-up, alongside the end of the third, sixth and tenth sprints and 3 min post-exercise in line with previous research (Gharbi et al., 2014). Participants were asked to provide their perceived rate of exertion (RPE) on a standard Borg scale (6—No Exertion to 20—Maximal Exertion) immediately following each sprint.

2.5 | Assessment of participants' preference

Following each test session, participants were asked to wear the mouthguard provided during training and competitions until their

FIGURE 1 Customised mouthguards (MG1, MG2 and MG3) used by all participants.

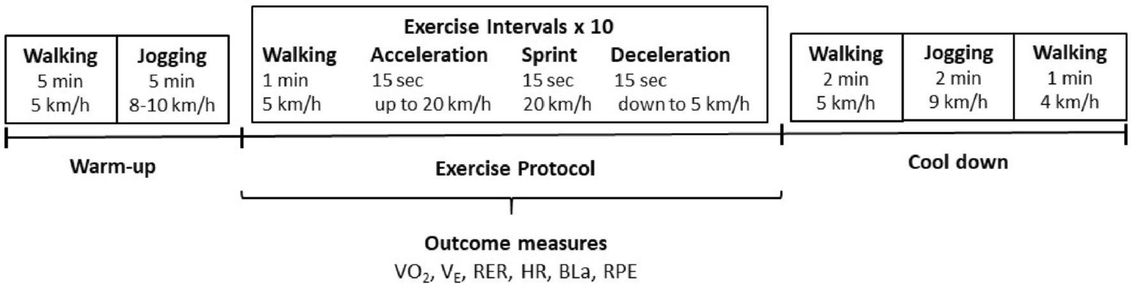

FIGURE 2 Exercise protocol performed by all participants with each of the three mouthguards and without a mouthguard (BLa, blood lactate concentration; HR, heart rate; RER, respiratory exchange ratio; RPE, rating of perceived exertion; V_E, minute ventilation; VO_2, oxygen uptake).

next laboratory visit. They were then given a questionnaire that was designed to assess their perception of comfort, thickness, retention, breathability, communication, effect on concentration, protection and the likelihood of wearing the mouthguard again, which have also been addressed in previous research studies (Brionnet et al., 2001; Duarte-Pereira et al., 2008; Duddy et al., 2012; Lee et al., 2013; Liew et al., 2014; von Arx et al., 2008). The questionnaire used a scale of 1–10 to rate each of the characteristics, with 1 scoring the lowest and 10 scoring the highest. No information about the differences in mouthguards characteristics and design was provided in order to avoid any bias.

2.6 | Statistical analysis

Cardiopulmonary measurements were analysed using rolling 30 s averages for each walking interval and rolling 5 s averages for the duration of each sprint, acceleration and deceleration intervals. Data are presented as means and standard deviation. Statistical analyses were performed using IBM SPSS Statistics® (Version 24, IBM Corp.). To determine parametricity, both the Shapiro–Wilk and Levene's tests were utilised. Statistical significance was set at $p \leq 0.05$. Repeated measures ANOVA (within subjects) with post-hoc (Bonferroni) were performed to identify the effect of different mouthguards on the following parameters: VO_2, V_E, respiratory exchange ratio (RER), HR, BLa and RPE. The effect size was determined using the partial eta squared statistic (η_p^2) with values of 0.01, 0.06 and 0.14 indicating small, moderate and large, respectively (Cohen, 1988). To compare the ratings around comfort between the mouthguard designs, an independent-sample Kruskal–Wallis test with pairwise comparisons was used with the significance level set at $p \leq 0.05$.

3 | RESULTS

3.1 | Participants' aerobic fitness (VO_{2max})

Participants' level of aerobic fitness in terms of VO_{2max} measurements did not differ between the start and the end of the study (pre-study test $VO_{2max} = 50 \pm 5$ mL · kg^{-1} · min^{-1} vs. post-study test $VO_{2max} = 53 \pm 6$ mL · kg^{-1} · min^{-1}, $p = 0.193$).

3.2 | Cardiopulmonary parameters

Table 1 shows that the intensity of the rugby specific protocol varied between 84% and 93% relative to VO_{2max} and 92%–96% relative to HR_{max}. When within subjects data analysis were performed, no statistical differences were found in VO_2 ($F = 0.375$, $p = 0.785$ and $\eta_p^2 = 0.021$), V_E ($F = 0.112$, $p = 0.952$ and $\eta_p^2 = 0.007$), RER ($F = 0.686$, $p = 0.564$ and $\eta_p^2 = 0.039$) and HR ($F = 0.239$, $p = 0.830$ and $\eta_p^2 = 0.017$) whilst participants performed with either of the three custom-made mouthguards or without a mouthguard (Table 1). The partial eta squared during each of the four intervals (walking, acceleration, sprint and deceleration) indicated that the presence or type of mouthguard explained 0.04%–4.3% (<small) of the variances observed.

3.3 | Blood lactate

BLa accumulation significantly increased post warm-up and after the third sprint when no mouthguard was worn in comparison to wearing any of the mouthguards (31.0%–44.0%, $p = 0.001$) (Figure 3A). Despite the lack of statistical significance throughout the rest of the protocol, the lowest accumulation of BLa was recorded when using MG1 (up to 14.0% lower than MG2 and 8% lower than MG3).

3.4 | Perceived exertion

Participants' RPE demonstrated that exercising without a mouthguard was significantly harder than whilst using MG1 or MG2 ($p \leq 0.05$). Although these differences were recorded only during the first half of the rugby protocol, Figure 3B illustrates that the same trend was followed throughout the remainder of the session. In contrast, wearing the three mouthguards demonstrated similar perceived exertion; starting with a rating of 9.0 ± 0.00 ('Very Light'), which increased to 15.33 ± 0.58 ('Hard/Heavy') after the last sprint.

3.5 | Assessment of participants' preference

There was no statistical difference in the ratings of comfort ($X^2 = 1.747$, $F = 2$ and $p = 0.418$), thickness ($X^2 = 5.707$, $F = 2$ and

TABLE 1 Intensity of rugby exercise protocol relative to participants' maximum oxygen uptake (VO_{2max} mL/kg/min) and maximum heart rate (HbR_{max} bpm) ($N = 14$).

Variable	No MG	MG1	MG2	MG3	η_p^2	F	p
$\%VO_{2max}$	84% ± 4.88	93% ± 10.67	88% ± 9.04	84% ± 5.57			
$\%HR_{max}$	93% ± 3.17	96% ± 5.21	95% ± 5.74	92% ± 3.36			
VO_2 ($L\cdot min^{-1}$)							
Walking	2.81 ± 0.43	2.87 ± 0.57	2.87 ± 0.43	2.73 ± 0.40	0.016	0.275	0.843
Acceleration	2.70 ± 0.43	2.76 ± 0.57	2.77 ± 0.57	2.59 ± 0.42	0.023	0.406	0.749
Sprint	3.16 ± 0.39	3.27 ± 0.39	3.26 ± 0.44	3.12 ± 0.44	0.018	0.307	0.820
Deceleration	3.58 ± 0.46	3.77 ± 0.65	3.72 ± 0.46	3.59 ± 0.46	0.027	0.471	0.704
Total	3.06 ± 0.42	3.17 ± 0.60	3.15 ± 0.44	3.01 ± 0.42	0.021	0.357	0.785
V_E ($L\cdot min^{-1}$)							
Walking	84.8 ± 16.1	82.6 ± 17.5	80.6 ± 24.7	83.1 ± 15.9	0.007	0.118	0.949
Acceleration	106.7 ± 21.4	103.7 ± 20.6	103.2 ± 29.5	103.9 ± 19.9	0.004	0.066	0.978
Sprint	122.1 ± 22.4	118.5 ± 22.1	116.1 ± 32.7	119.7 ± 20.9	0.008	0.135	0.939
Deceleration	115.8 ± 19.1	115.1 ± 19.7	110.1 ± 32.0	114.8 ± 18.5	0.010	0.171	0.915
Total	107.8 ± 19.1	105.1 ± 19.5	102.5 ± 29.3	105.4 ± 18.2	0.007	0.112	0.952
RER (AU)							
Walking	0.98 ± 0.04	1.00 ± 0.05	1.00 ± 0.03	1.01 ± 0.04	0.041	0.731	0.538
Acceleration	1.09 ± 0.05	1.10 ± 0.07	1.12 ± 0.06	1.12 ± 0.06	0.043	0.763	0.520
Sprint	1.02 ± 0.05	1.03 ± 0.05	1.03 ± 0.04	1.03 ± 0.04	0.006	0.098	0.961
Deceleration	0.93 ± 0.04	0.94 ± 0.04	0.94 ± 0.02	0.94 ± 0.02	0.039	0.687	0.564
Total	1.01 ± 0.03	1.02 ± 0.05	1.02 ± 0.03	1.03 ± 0.04	0.039	0.686	0.564
HR ($b\cdot min^{-1}$)							
Walking	154 ± 12	150 ± 12	149 ± 11	149 ± 11	0.031	0.549	0.651
Acceleration	146 ± 14	142 ± 13	142 ± 12	142 ± 12	0.023	0.395	0.757
Sprint	162 ± 12	160 ± 12	160 ± 11	159 ± 11	0.012	0.206	0.892
Deceleration	175 ± 10	174 ± 11	173 ± 10	173 ± 10	0.005	0.094	0.963
Total	159 ± 12	157 ± 12	156 ± 11	156 ± 11	0.017	0.293	0.830

Note: Mean ± SD for VO_2 (oxygen uptake), V_E (minute ventilation), RER (respiratory exchange ratio) and HR (heart rate) recorded during the rugby-specific protocol, whilst participants performed with three custom mouthguards (MG1, MG2 and MG3) and without a mouthguard (No MG). The total value represents the overall data during the four exercise intervals (walking, acceleration, sprint and deceleration).

$p = 0.058$), retention ($X^2 = 0.226$, $F = 2$ and $p = 0.893$), breathing ($X^2 = 2.658$, $F = 2$ and $p = 0.265$), speech ($X^2 = 3.795$, $F = 2$ and $p = 0.150$), concentration ($X^2 = 1.434$, $F = 2$ and $p = 0.488$) and how likely they are to wear them again ($X^2 = 4.641$, $F = 2$ and $p = 0.098$).

4 | DISCUSSION

To the authors' knowledge, this is one of the first studies to examine the effects of three different custom-made mouthguards on physiological parameters and player preference in rugby union. The reported findings did not demonstrate any trend in significant statistical differences in terms of consumption of VO_2, V_E, RER and HR. Therefore, it could be concluded that wearing any of the three mouthguards did not obstruct respiratory flow during performance of the rugby exercise protocol. However, it was noted that the levels of BLa accumulation and perceived exertion were significantly higher whilst participants performed without a mouthguard than with mouthguards. Although not statistically different, it is worth mentioning that both MG2 and MG3 were reported to provide greater retention and aid concentration. This suggests that using a double EVA layer design, which is trimmed around the palatal gingival margins, as used in MG2 and MG3 could be considered effective designs for rugby. However, further studies are required to support these findings.

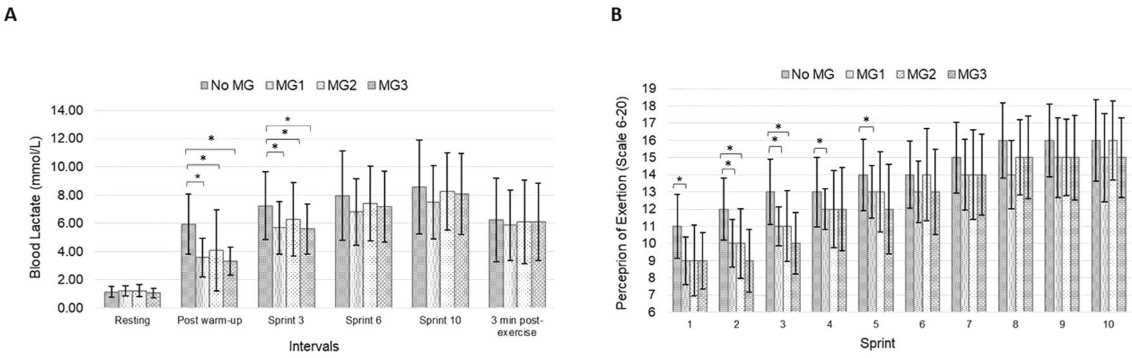

FIGURE 3 Changes in blood lactate levels and participants' perception of exertion. (A) Blood lactate levels measured at rest, throughout the rugby protocol and 3 min post-exercise whilst wearing no mouthguard (No MG) and the three selected designs (MG1, MG2 or MG3). (B) Participants' perception of exertion following each sprint (1–10). Error bars represent the standard deviation. (*) = Statistical differences ($p < 0.05$).

4.1 | Exercise protocol and participants' aerobic fitness

Primarily, it is important to note that the novel designed exercise protocol used within the study replicated performance levels observed during a game of elite rugby union (~80%–85% VO_{2max}; ~81%–90% HR_{max} [Blair et al., 2018; Cunniffe et al., 2009]; BLa 5.1–9.8 mmol/L [Deutsch et al., 1998; McLean, 1992] versus 84%–93% VO_{2max}; 92%–96% HR_{max}; BLa 8.10 mmol/L reported in the present study). Similarly, participants' aerobic fitness in relation to VO_{2max} was closely matched within professional rugby union players demonstrating its applicability to sub-elite/elite cohorts (VO_{2max} 55.3 ± 1.2 mL·kg^{-1}·min^{-1} (Dubois et al., 2018) versus 53 ± 6 mL·kg^{-1}·min^{-1} reported in the present study).

4.2 | Cardiopulmonary results, BLa and HR

By breaking down the rugby-specific exercise into distinct movement categories (walking, acceleration, sprinting and deceleration) provided a novel interpretation of the cardiopulmonary results. Although previous studies (Bourdin et al., 2006; Duarte-Pereira et al., 2008; Schulze et al., 2019) have attempted to examine changes in physiological performance of rugby players, they have not managed to address some of the essential elements of the game. For example, examining acceleration has been proposed to be more important than sprinting due to the short sprint duration (85% of all sprints under 30 m) (Johnston et al., 2014). Therefore, breaking down the exercise protocol allowed reflection on valuable activity elements and identifying potential effects. By using a global positioning system, Cunniffe et al. (2009) determined that elite rugby union players spend 66.5%–77.8% of their time standing or walking (0–6 km·h^{-1}) and about 2.5% high-speed running (18–20 km·h^{-1}) and sprinting (>20 km·h^{-1}). Most commonly, improvements in speed and distance covered are monitored through submaximal or maximal shuttle runs and intermittent sprint intervals (Dubois et al., 2018). These types of exercises should be considered when studies examine the effects of mouthguards in order to achieve valid measurements in relation to the sport.

The physiological results revealed beneficial effects of all three mouthguards at early stages of the exercise protocol versus no mouthguard with lower levels BLa and RPE in the first 3 min of exercise commencement (Figure 3). This may potentially be due to jaw repositioning during mouthguard usage. Schultz Martins et al. (2018) demonstrated a significant interaction between jaw repositioning, volumetric change and an increase in both aerobic and anaerobic performance. In addition, there was a non-significant trend throughout the protocol of a lower BLa accumulation whilst wearing MG1 compared to all other conditions. However, these minimal differences alone would not suggest a preferable mouthguard design to be worn by rugby players, but an important message that custom-made mouthguard designs utilised in the study did not hinder physiological performance; yet in part enhanced performance through reduced BLa accumulation and RPE at the commencement of performance.

Three previous studies have examined the effects of 'boil-and-bite' and custom-made mouthguards in rugby participants (Bourdin et al., 2006; Duarte-Pereira et al., 2008; Schulze et al., 2019). As with the present research, they both included only men and performed an exercise activity during randomised sessions with and without mouthguards. Bourdin et al. (2006) tested 19 team players (only 16-played rugby; 27 ± 4.8 years) utilising a maximal 6 s cycling sprint protocol to assess maximal power, followed by a maximal exhaustion cycle test, with no effect reported between mouthguard types. In comparison to the present study, they lacked sport-specificity in their exercise protocol and did not use breath-by-breath analysis, leading to limited analysis in terms of cardiopulmonary parameters. Interestingly, similarities were observed in the design of their custom-made mouthguard to MG2, as both mouthguards had an increased thickness over the occlusal surfaces of the posterior teeth. However, Bourdin et al. (2006) used polymethyl methacrylate on a metal framework to construct their mouthguard, instead of the much more commonly used EVA. In contrast, the custom mouthguard utilised by Duarte-Pereira et al. (2008) was a laminated pressure-formed mouthguard, made of EVA, where they evaluated the performance of

10 rugby players (21–23 years) through counter-movement jumps and rebound jumps of 15 s over a force platform with no differences reported within the players' power or spirometry parameters with/without the mouthguard. Similar to the present study, Schulze et al. (2019) followed a treadmill protocol and recorded breath-by-breath gas exchange as well as BLa measurements. However, the participants, who wore 'boil-and-bite' and custom mouthguards, ran until exhaustion and performed sprints and countermovement jumps. Nevertheless, the findings agree with the present results that mouthguards have no negative effects on rugby-specific performance or respiratory parameters.

4.3 | Assessment of participants' preference

Participants' perception of comfort could be a defining factor for their compliance and frequency of using the device. Prior to the start of the study, all participants had past experience of wearing different mouthguard types (i.e. 'boil-and-bite' and custom-made), possibly contributing to a more accurate individual perception of comfort level. Overall, there were no significant differences in terms of mouthguard design preference. Rugby is a sport where communication with teammates is important, and the present findings showed that although there was no statistical significance, there was a tendency to favour a mouthguard design with reduced palatal flange up to the gingival margin, which may influence communication. This was in agreement with previous findings (Gebauer et al., 2011; Gomez-Gimeno et al., 2019; Maeda et al., 2006; Nozaki et al., 2013). In terms of retention, it was good to see that designs with trimmed palatal flange were rated similar to a mouthguard design with a palatal flange. This supports the findings of a previous study (Karaganeva et al., 2019), which performed a retention test of the same mouthguard designs. Similar to the current study, Collares et al. (2014) used a scale of 1–10 (with 10 giving the highest score) to examine participants' opinion on a custom-made device fabricated with 3 mm EVA blank. The mouthguard design was identical to MG1 from this study (4 mm palatal flange; extending up to the distal surfaces of the first molars). However, their participants did not have previous experience of wearing any mouthguard type. Collares et al. (2014) reported a much lower score compared to the present study in terms of communication (pre 2.12 ± 1.55; post 3.83 ± 2.50) and breathing (pre 5.63 ± 2.52; post 6.80 ± 2.56). These findings should be considered by dental practitioners and suppliers of mouthguards in order to provide suitable devices for individuals participating in sports. User compliance with mouthguards may increase if participants are made aware of the variations in custom-made designs and their benefits.

4.4 | Study limitations and future directions

Whilst 'boil-and-bite' devices are popular in the sport due to their low cost, bespoke custom-made mouthguards were selected for the present investigation as no other studies have previously examined the effects of having three different custom designs in rugby. In addition, it was decided to limit the study to one gender as it has been established that males have different metabolic and respiratory rates to females that lead to variation in responses to exercise and higher aerobic power (Harms, 2006; Sheel et al., 2004). Hence, future studies should examine a female sample size with relevant intensity of the exercise protocol. Furthermore, a portable gas analyser can be used to assess the cardiopulmonary responses during a rugby game when participants wear different types of mouthguards.

5 | CONCLUSION

The present study is one of the first to report the effects of three customised mouthguard designs on breath-by-breath gas exchange parameters, HR, BLa concentration and RPE in rugby participants following a newly designed rugby-specific exercise test. Additionally, the participants' perspective in terms of preferences towards mouthguard design was assessed. Wearing any of the three selected custom-made mouthguards had no impact on VO_2, V_E, RER, HR and BLa. In terms of participants' perceived comfort, there were no differences between the selected mouthguard designs. However, there was a tendency among participants to favour the inclusion of two EVA layers that are trimmed around the palatal gingival margins. This information may be used by mouthguard manufacturers to ensure they provide mouthguards that players would find more comfortable, without compromising the level of protection.

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CONFLICT OF INTEREST STATEMENT

The authors report there are no competing interests to declare.

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