

Response of Headgear Release Mechanisms to Nonaxial Force Application

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Abstract: Safety products have been developed to help reduce the incidence of trauma caused by headgear. Previous studies have reported the characteristics of breakaway type headgear release mechanisms with axial force application. Not all accidental releases are triggered by an axial force and it is necessary to understand the characteristics of these mechanisms with nonaxial force application. Thirteen headgear release mechanisms were tested as part of a complete headgear system. With the system attached to a plaster head and neck model a tensile force was applied to the system at 30 degrees to the sagittal plane at 2 rates. The force of activation at release and the distance traveled were determined and analyzed statistically. Force values ranged from 4.6 to 36.7 pounds and facebow travel before release ranged from 0.97 to 3.42 inches. No consistent pattern of rate dependence was observed. Several devices demonstrated the desirable combination of low force and facebow travel at release. (*Angle Orthod* 2000;70:377–382.)

Key Words: Headgear; Release mechanism; Nonaxial pull; Force; Extension

INTRODUCTION

Extra-oral traction has been used by orthodontists for over a century and is still routinely used to produce dental and orthopedic changes and to increase anchorage.^{1,2} The results of headgear wear can be very beneficial to the patient, but documented reports of headgear trauma to the face and eyes demonstrate the potential for serious injury.^{3–6} Although their incidence is relatively low, the morbidity associated with penetrating eye injuries is especially high due to saliva contamination of the inner bow. As such, it is essential that steps be taken to improve headgear safety and reduce the risk of injury to patients.

In 1975 the American Association of Orthodontists (AAO) issued a special bulletin to its members urging them to take precautionary measures to eliminate accidental patient injuries. In that same year, the AAO also contacted manufacturers to explore the feasibility of making a safer headgear design. Since that time, various safety headgear products have been made available which can be categorized into 3 groups: breakaway systems, safety facebows,

and miscellaneous safety products. Additionally, various authors have proposed mechanisms for improving headgear safety.^{8–13} This study focused on breakaway headgear systems, which operate on the principle of a release mechanism, generally made of metal or plastic, that is built into the traction module and connects the facebow to the head cap or neck strap. The system is designed to release the traction module from the neck strap when a sufficient displacement force is applied to the system. As such, the risk of a displaced facebow catapulting back at the patient is reduced.

In 1984, the California State Society of Orthodontists highly recommended the exclusive use of safety facebows and breakaway headgear systems.¹⁴ The results of several published surveys in recent years demonstrate the rising popularity of safety headgear system usage.^{2,15} The number of survey respondents using safety mechanisms rose from 27% in 1982 to 68% in 1996.

The ideal safety release module should release at low force and extension.^{16,17} It should not release, however, until forces greater than those used at therapeutic levels are applied to the system. In addition, it should detach at an appropriate extension so that the free ends of the facebow remain in the mouth at the time of disengagement to reduce the risk of injury to the face and eyes. Currently no safety standards are established for the release mechanisms available.

There is limited information that objectively reports the characteristics of the various headgear safety release mechanisms commercially available. In 1989, Postlethwaite reported her findings of the range and effectiveness of safety

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Accepted: March 2000. Submitted: August 1997.

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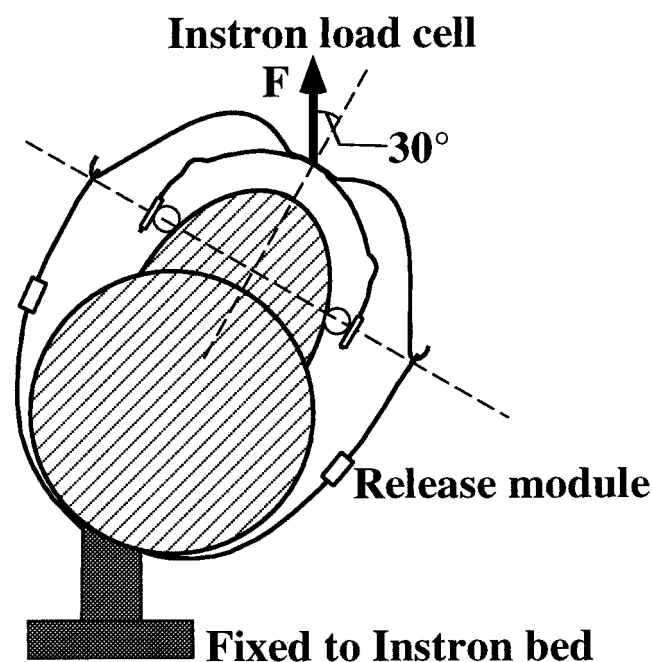


FIGURE 1. Diagrammatic representation of test system.

headgear products in which a tensile force at constant speed was applied to individual safety release modules.¹⁷ Subsequently Stafford et al¹⁸ tested the characteristics of release mechanisms as part of a complete headgear system including a facebow, neckstrap, and safety release module. An anteriorly directed tensile force was applied to the systems that were tested at 2 rates of pull. To date there is no information available that objectively describes the characteristics of safety release mechanisms using a nonaxial direction of pull. In situations where headgear might be displaced, it is unlikely that the direction of pull will always come from straight on. For this reason it is necessary to know if the release mechanisms perform differently with changing vectors of force. The purpose of this study was to test the characteristics of headgear release mechanisms using nonaxial force application.

MATERIALS AND METHODS

Thirteen commercially available release mechanisms were tested as part of a complete headgear system consisting of a neck strap, facebow (Series 5, size 3, 3M Unitek, Monrovia, Cal), and release module. Five mechanisms of each type were tested in the study. The headgear system was attached to a life-size head and neck model fabricated of yellow plaster, which was rigidly fixated to the bed of an Instron machine (Model 1122, Instron Corporation, Canton, Mass) (Figure 1). The direction of pull was set at 30 degrees to the sagittal plane and with the facebow attached to the Instron at the center of the inner bow, the appliance was activated until the mechanisms released. The ends of the inner bow inserted into headgear tubes affixed to the

model with plaster. As the facebow was distracted, the inner bow became mildly distorted but was corrected after each test to maintain a passive insertion of the facebow with each test. Each of the 5 samples of each release mechanism was tested 5 times at 2 rates of pull, 5 inches per minute and 50 inches per minute. Additionally, 1 each of the 13 mechanisms was tested 3 times at both rates of pull with an anteriorly directed force for use in comparing the 2 vectors of pull.

The Instron recorded the applied force in pounds at the time of mechanism release. A stopwatch was used to record the time from start to release and the recorded time and rate of pull were used to calculate the distance the facebow traveled in inches.

A component of variance analysis was performed for both force and extension at 5 inches per minute and 50 inches per minute for each of the appliances. This was done in order to determine the absolute and relative between and within sample contribution to the total variation around the mean. An analysis of variance for force and another for extension was used to determine significant variation between the 13 systems. A *t*-test was performed to determine whether statistically significant differences exist between the pull rates of 5 and 50 inches per minute for the force and extension variables. A *t*-test was also performed to determine whether statistically significant differences exist between the axial and nonaxial directions of pull.

RESULTS

The 13 appliances are described in Table 1. The descriptive statistics for each of the appliances are presented in Tables 2 and 3. For the force variable, Table 2 displays the values at 5 inches per minute and at 50 inches per minute and compares the 2 rates. Of the 13 mechanisms, 11 released at force levels that were lower when the rate of pull was 50 inches per minute. Eight of the 13 mechanisms released at significantly different force levels ($P < .05$) when the rate of pull increased. And, of those 8, all force values were lower when tested at 50 inches per minute.

Table 3 displays the extension values at 5 inches per minute and at 50 inches per minute and compares the 2 rates. Nine of the mechanisms released at smaller extensions at 50 inches per minute, 2 showed an increase in extension and 2 remained the same. Three of the mechanisms showed a significant change with a change in rate of pull ($P < .05$). Of those 3 mechanisms, 2 had extension values that decreased and 1 increased at 50 inches per minute.

The R square values in Tables 2 and 3 are a ratio of the between sample variance to the total variance and indicate what proportion of the total variation is attributed to between sample variation. For example, in Table 2, TP at 5 inches per minute has an R square value of 0.19. This indicates that 19% of the total variation is due to between

TABLE 1. Appliances Tested

Code	Appliance	Type	Manufacturer
3MC	3M Unitek traction release cervical module, medium	Plastic, C-clip	3M Unitek, Monrovia, Calif
3MH	3M Unitek traction release high-pull module, medium	Plastic	3M Unitek
A	"A" Company safety release mechanism	Metal, C-clip	"A" Company Orthodontics, San Diego, Calif
EQ	Equa-Pull module, heavy	Metal "constant force"	Dr Roger Wolk, Malibu, Calif
GB	GAC blue safety module	Plastic	GAC International Inc, Central Islip, NY
GS	Sof Gear breakaway module	Plastic, C-clip	GAC International Inc
NW	NorthWest Snap-Way cervical force module (10–22 oz)	Metal	3M Unitek
OC	Ormco C-type release module, heavy	Plastic, C-clip	Ormco Corp, Orange, Calif
OR	Ormco release module, heavy	Plastic	Ormco Corp
OS	Ormco Sentry Headgear system	Plastic, strap part of device	Ormco Corp
OO	Ortho Organizers safety system release module	Metal, C-clip	Ortho Organizers Inc, San Marcos, Calif
PZ	Pozzi safety module, medium	Plastic, C-clip	Pozzi Orthodontics, Tolleson, Ariz
TP	TP safety mechanism	Plastic, C-clip	TP Orthodontics Inc, LaPorte, Ind

TABLE 2. Comparison of Force Variable at 5 in/min and 50 in/min^a

Variable	5 in/min			50 in/min			P Value
	Mean	SD	R ²	Mean	SD	R ²	
3MC	18.83	1.00	.18	18.56	0.93	.62	.62
3MH	10.68	0.65	.51	10.09	0.72	.64	.02
A	16.08	2.87	.73	14.92	3.43	.53	.04
EQ	4.84	0.40	.61	4.62	0.36	.25	.19
GB	20.38	3.23	.94	18.84	2.31	.83	.04
GS	13.95	1.16	.55	13.22	0.57	.52	.04
NW	11.93	1.01	.19	13.71	1.50	.79	.08
OC	25.11	2.16	.00	22.37	1.89	.25	.01
OO	36.66	2.57	.62	36.26	2.25	.64	.72
OR	29.30	3.33	.00	25.66	2.01	.16	.01
OS	11.94	1.10	.56	10.92	0.79	.67	.01
PZ	15.57	1.10	.21	14.72	0.73	.00	.03
TP	17.88	1.10	.19	18.19	1.27	.73	.55

^a SD indicates standard deviation; 3MC, 3M Unitek traction release cervical module; 3MH, 3M Unitek traction release high-pull module; A, "A" Company safety release mechanism; EQ, Equa-Pull module; GB, GAC blue safety module; GS, Sof Gear breakaway module; NW, NorthWest Snap-Way cervical force module; OC, Ormco C-type release module; OR, Ormco release module; OS, Ormco Sentry Headgear system; OO, Ortho Organizers safety system release module; PZ, Pozzi safety module; and TP, TP safety mechanism.

sample variation and the remaining 81% is due to within sample variation.

The force means at both rates of activation are graphically displayed in Figure 2. They range from 4.84 to 36.66 pounds at 5 inches per minute and from 4.62 to 36.26 pounds at 50 inches per minute. The EQ mechanism released at the lowest force levels at both rates of pull and was the only mechanism to release at a force value less than 10 pounds. Only 4 appliances, 3MH, NW, OS, and GS, had force levels measuring between 10 and 15 pounds. At 5 inches per minute 3 mechanisms had force levels measuring above 25 pounds and at 50 inches per minute 2

TABLE 3. Comparison of Extension Variable at 5 in/min and 50 in/min^a

Variable	5 in/min			50 in/min			P Value
	Mean	SD	R ²	Mean	SD	R ²	
3MC	2.29	0.11	.71	2.25	0.08	.18	.28
3MH	0.97	0.07	.08	0.97	0.06	.00	.98
A	1.81	0.30	.94	1.79	0.21	.65	.67
EQ	1.60	0.21	.75	1.64	0.14	.32	.59
GB	2.19	0.24	.96	2.19	0.18	.79	.97
GS	2.75	0.08	.63	2.66	0.09	.33	.04
NW	1.22	0.07	.13	1.30	0.08	.12	.03
OC	2.04	0.15	.00	1.96	0.12	.45	.06
OO	3.42	0.44	.92	3.27	0.19	.66	.42
OR	2.43	0.32	.24	2.30	0.34	.87	.18
OS	1.31	0.14	.82	1.29	0.10	.47	.71
PZ	1.38	0.09	.44	1.33	0.05	.48	.12
TP	2.17	0.13	.73	2.11	0.13	.66	.03

^a SD indicates standard deviation; 3MC, 3M Unitek traction release cervical module; 3MH, 3M Unitek traction release high-pull module; A, "A" Company safety release mechanism; EQ, Equa-Pull module; GB, GAC blue safety module; GS, Sof Gear breakaway module; NW, NorthWest Snap-Way cervical force module; OC, Ormco C-type release module; OR, Ormco release module; OS, Ormco Sentry Headgear system; OO, Ortho Organizers safety system release module; PZ, Pozzi safety module; and TP, TP safety mechanism.

mechanisms had values above 25 pounds. OO had the highest force values at both rates of pull.

The extension means for both rates of pull are graphically displayed in Figure 3. They range from 0.97 to 3.42 inches at 5 inches per minute and from 0.97 to 3.27 inches at 50 inches per minute. Appliance 3MH was the only one to release at an extension of less than 1 inch. At both rates of pull NW, OS, PZ, and EQ released at distances less than 1.5 inches. All other appliances except OO and GS released at extension values between 1.5 and 2.5 inches. OO was

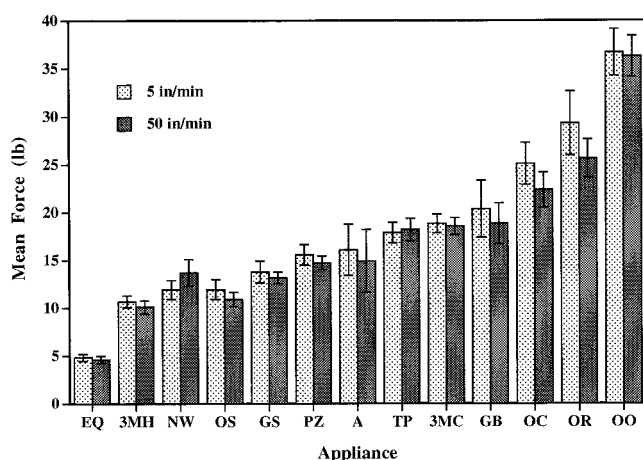


FIGURE 2. Summary of mean force values.

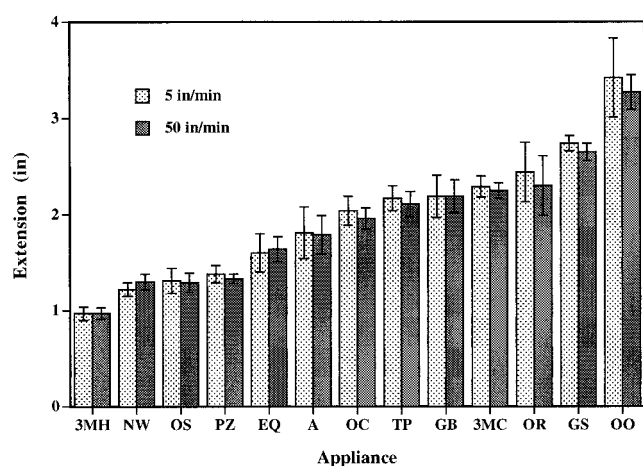


FIGURE 3. Summary of mean extension values.

the only appliance to release at an extension greater than 3 inches at both rates of pull.

Tables 4 and 5 compare data from the tests using an angular vector of pull with those using a straight vector of pull for force values at 5 and 50 inches per minute. At 5 inches per minute, 9 of the 13 mechanisms released at lower force levels with a straight pull. Seven mechanisms released at significantly different force levels at $P < .05$. Of those 7 mechanisms, 6 of the force values were lower with a straight vector of pull. At 50 inches per minute, 12 appliances released at significantly different force levels. Of the 12 appliances, 8 released at force values that were lower when tested with a straight vector of force.

Tables 6 and 7 compare the straight and angular pull data for extension values at 5 and 50 inches per minute. Eight of the 13 mechanisms released at extensions which showed significant differences at $P < .05$ at 5 inches per minute. Of the 8 mechanisms, 4 extension values were higher and the other 4 were lower when using a straight vector of force. At 50 inches per minute, 11 mechanisms released at significantly different extensions at $P < .05$. Five of these

TABLE 4. Comparison of Straight and Angular Directions of Pull for Force Variable at 5 in/min^a

Variable	Angular		Straight		P Value
	Mean	SD	Mean	SD	
3MC	18.83	1.00	16.53	0.02	.00
3MH	10.68	0.65	14.37	0.55	.00
A	16.08	2.87	14.63	1.16	.15
EQ	4.84	0.40	4.83	0.15	.96
GB	20.38	3.23	17.10	0.61	.00
GS	13.95	1.16	13.63	0.35	.68
NW	11.93	1.01	13.37	1.22	.19
OC	25.11	2.16	19.07	1.90	.01
OO	36.66	2.57	42.43	3.79	.12
OR	29.30	3.33	20.97	1.38	.00
OS	11.94	1.10	14.67	2.02	.15
PZ	15.57	1.10	11.90	0.26	.00
TP	17.88	1.10	15.03	0.55	.00

^a SD indicates standard deviation; 3MC, 3M Unitek traction release cervical module; 3MH, 3M Unitek traction release high-pull module; A, "A" Company safety release mechanism; EQ, Equa-Pull module; GB, GAC blue safety module; GS, Sof Gear breakaway module; NW, NorthWest Snap-Way cervical force module; OC, Ormco C-type release module; OR, Ormco release module; OS, Ormco Sentry Headgear system; OO, Ortho Organizers safety system release module; PZ, Pozzi safety module; and TP, TP safety mechanism.

extension values were higher and 6 were lower when incorporating a straight vector of pull.

DISCUSSION

Although no safety standards have been established for the manufacture of headgear release mechanisms, it is the authors' opinion that the ideal mechanism should release at low levels of force and extension. The force levels at release would need to be greater than therapeutic levels of force. The extension values also should be as low as possible so that, at a minimum, the ends of the facebow remain in the mouth at release. Ideally, they should remain within the headgear tubes at release to minimize the risk of injury. Additionally, the ideal release mechanism should perform consistently, with little between- and within-sample variation for both force and extension values at release.

All 13 mechanisms tested were of a bilateral design, incorporating a release mechanism on both sides of the headgear system. In all the tests performed for all the mechanisms in the study, mechanism release occurred on only 1 of the 2 mechanisms in the system. Regarding the results for the force variable, there was significant variation between the 13 mechanisms tested. EQ released at force levels of 4.8 pounds and OO released at 36.6 pounds. These values are 3.7 and 35.5 pounds higher than recommended therapeutic levels, respectively.¹⁹ Nine of the 13 mechanisms had force means between 10 and 20 pounds, and the remaining 2 were in the 20- to 30-pound range. The 5 mechanisms with the lowest force levels at release are, in rank

TABLE 5. Comparison of Straight and Angular Directions of Pull for Force Variable at 50 in/min^a

Variable	Angular		Straight		P Value
	Mean	SD	Mean	SD	
3MC	18.56	0.93	14.83	0.21	.00
3MH	10.09	0.72	14.07	0.03	.00
A	14.92	3.43	12.50	0.30	.00
EQ	4.62	0.36	5.13	0.06	.00
GB	18.84	2.31	16.17	0.90	.01
GS	13.22	0.57	12.50	0.10	.00
NW	13.71	1.50	14.23	0.68	.34
OC	22.37	1.89	18.93	0.60	.00
OO	36.26	2.25	39.17	4.05	.35
OR	25.66	2.01	20.53	1.01	.00
OS	10.92	0.79	14.87	0.78	.01
PZ	14.72	0.73	12.93	0.31	.00
TP	18.19	1.27	14.80	0.21	.00

^a SD indicates standard deviation; 3MC, 3M Unitek traction release cervical module; 3MH, 3M Unitek traction release high-pull module; A, "A" Company safety release mechanism; EQ, Equa-Pull module; GB, GAC blue safety module; GS, Sof Gear breakaway module; NW, NorthWest Snap-Way cervical force module; OC, Ormco C-type release module; OR, Ormco release module; OS, Ormco Sentry Headgear system; OO, Ortho Organizers safety system release module; PZ, Pozzi safety module; and TP, TP safety mechanism.

TABLE 6. Comparison of Straight and Angular Directions of Pull for Extension Variable at 5 in/min^a

Variable	Angular		Straight		P Value
	Mean	SD	Mean	SD	
3MC	2.29	0.11	1.88	0.02	.00
3MH	0.97	0.07	1.42	0.01	.00
A	1.81	0.30	1.99	0.17	.02
EQ	1.60	0.21	1.67	0.02	.01
GB	2.19	0.24	1.59	0.02	.00
GS	2.75	0.08	2.65	0.07	.15
NW	1.22	0.07	1.35	0.02	.00
OC	2.04	0.15	1.81	0.11	.06
OO	3.42	0.44	4.52	0.70	.12
OR	2.43	0.32	1.74	0.05	.00
OS	1.31	0.14	1.60	0.03	.00
PZ	1.38	0.09	1.54	0.06	.03
TP	2.17	0.13	1.98	0.06	.01

^a SD indicates standard deviation; 3MC, 3M Unitek traction release cervical module; 3MH, 3M Unitek traction release high-pull module; A, "A" Company safety release mechanism; EQ, Equa-Pull module; GB, GAC blue safety module; GS, Sof Gear breakaway module; NW, NorthWest Snap-Way cervical force module; OC, Ormco C-type release module; OR, Ormco release module; OS, Ormco Sentry Headgear system; OO, Ortho Organizers safety system release module; PZ, Pozzi safety module; and TP, TP safety mechanism.

order from lowest to fifth lowest, as follows: EQ, 3MH, OS, NW, and GS.

The safety implications of using an appliance that releases at force levels of 20 or 30 pounds or more are of major concern. In some patients in whom early corrective

TABLE 7. Comparison of Straight and Angular Directions of Pull for Extension Variable at 50 in/min^a

Variable	Angular		Straight		P Value
	Mean	SD	Mean	SD	
3MC	2.25	.08	1.72	.09	.01
3MH	0.97	.06	1.33	.00	.00
A	1.79	.21	1.83	.17	.68
EQ	1.64	.14	1.89	.10	.03
GB	2.19	.18	1.56	.10	.00
GS	2.66	.09	2.44	.10	.04
NW	1.30	.08	1.44	.10	.14
OC	1.96	.12	1.72	.09	.03
OO	3.27	.19	4.22	.19	.01
OR	2.30	.34	1.72	.09	.00
OS	1.29	.10	1.83	.00	.00
PZ	1.33	.05	1.61	.10	.04
TP	2.11	.13	1.83	.00	.00

^a SD indicates standard deviation; 3MC, 3M Unitek traction release cervical module; 3MH, 3M Unitek traction release high-pull module; A, "A" Company safety release mechanism; EQ, Equa-Pull module; GB, GAC blue safety module; GS, Sof Gear breakaway module; NW, NorthWest Snap-Way cervical force module; OC, Ormco C-type release module; OR, Ormco release module; OS, Ormco Sentry Headgear system; OO, Ortho Organizers safety system release module; PZ, Pozzi safety module; and TP, TP safety mechanism.

therapy is indicated, force levels of this magnitude approach half their total body weight. Of equal concern are the extension values at release, which were sometimes greater than 2 or 3 inches. Again, there was significant variation between the 13 mechanisms tested. The 3MH mechanism released at 0.97 inches and was the only mechanism to release at an extension of less than 1 inch. Six of the 13 mechanisms released at distances greater than 2 inches. In many patients, a facebow distracted 2 inches would be out of the mouth and in position to recoil into the face or eyes. The 5 mechanisms with the lowest extension values at release are, in rank order from lowest to fifth lowest, as follows: 3MH, NW, OS, PZ, and EQ.

In real life situations, the rate of pull or distraction of the facebow could vary greatly from one occurrence to another. It is difficult to say what the rate of pull would be on the playground with a quick yank on the headgear. It would, however, probably be much different from the rate of distraction which occurs during sleep or when a child is carefully but improperly removing the headgear. For this reason, the mechanisms were tested at 2 rates of pull. When comparing force values, 8 of the 13 mechanisms performed significantly different ($P < .05$) when the rate of pull changed. However, these differences do not appear to be clinically significant and the data does not suggest the mechanisms would respond differently at even higher rates of pull. For example, 3MH released at 10.68 pounds at 5 inches per minute and at 10.09 pounds at 50 inches per minute, $P = .02$. This difference of 0.59 pounds may or may not make a difference in affecting the safety of pa-

tients. When comparing extension values, only 3 of the 13 mechanisms performed significantly different with a change in the rate of pull. Practically speaking, however, all mechanisms performed similarly at both rates of pull. For example, TP released at 2.17 inches at 5 inches per minute and at 2.11 inches at 50 inches per minute, $P = .03$. In some patients, the 0.06-inch difference may make a difference and in others the facebow would have exited the mouth before reaching either extension. This is an example of why the establishment of safety standards is a difficult task: there is variation in size and shape of the mouth from patient to patient.

A 30-degree angle to the sagittal plane was selected for the vector of force during testing for several reasons. As the angle increases between the sagittal plane and the origination of the displacing force, there is increasing movement of the patient's head in the direction of pull. It is difficult to account for this movement in laboratory tests. Additionally, as the angle increases there is more binding of the inner bow inside the headgear tubes, which interferes with distraction of the facebow.

The characteristics of all 13 release mechanisms changed significantly for at least 1 variable when the vector of force was altered from nonaxial to axial. However, many of the statistically significant changes seem to be of little practical significance and would have little or no impact on the safety of the mechanism or the selection process of the orthodontist in choosing an appliance. For example, at 50 inches per minute GS released at 13.17 pounds with an angular vector of force and at 12.5 pounds with a straight vector, $P = .00$. Although statistically significant, this mechanism performed within a range that may be considered acceptable for both force vectors. The greatest variation was seen with the OO mechanism whose force values increased more than 5 pounds and extension values increased by 1 inch with a straight vector of force. In this case, as well as with several other mechanisms tested, the values are much higher than would be considered ideal for either vector of force. Such appliances are not recommended for clinical use due to the excessive force and extension values required to trigger mechanism release.

CONCLUSIONS

The characteristics of 13 commercially available headgear release mechanisms were evaluated as part of a complete headgear system. The vector of force used to trigger mechanism release measured 30 degrees to the sagittal plane. All mechanisms were tested at 2 rates of pull, 5 and 50 inches per minute. The findings were as follows:

1. The mean force values at release ranged from 4.62 pounds to 36.66 pounds.

2. The extension means ranged from 0.97 to 3.42 inches at release.
3. Most of the tested mechanisms did not meet the suggested ideal standards of release at low force and extension.
4. Statistically significant differences existed at different rates of pull, which were small and seem to be of little clinical significance.
5. There were statistically significant differences between the angular force vector data and the straight force vector data that were also small and appear to be of little clinical significance.

In the absence of established standards for the manufacture of these mechanisms, this data should allow the clinician to better evaluate some of the commercially available headgear release mechanisms.

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