CALL FOR A CONSENSUS ON VERTEBRA TESTS

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ABSTRACT:

In recent years, the number of tests performed on vertebrae and the number of related papers have increased in such a manner that a proper assessment of all the data that have been gathered seems to be difficult. There is now a need for standardization studies. The problems are (i) the criteria to be followed in the material selection, (ii) the choice of the parameters to be studied and (iii) the interpretation of the test results. Experimental studies are mainly performed on calf spines, polyester imitations and fresh cadaver speciments. It is commonly stated that calf spines exhibit uniformity in stiffness among speciments. There is, however, no definition of uniformity. In addition, there is no universal consensus on the number of samples and the number of vertebrae to be tested. Accordingly, we need a standard describing "determination, verification and application of precision data" and "the requirements for laboratories". The temperature and the humidity of the laboratory and the pre-test freezing temperature of the spinal speciment should be standardized. Cross-head speeds, number of cycles, maximum applied load values, upper and lower limits of loads or displacement in cyclic loading, preload values, measures taken to decelerate biological deterioration during tests, test time, etc. largely differ from laboratory to laboratory. In order to see the effect of the above mentioned parameters in axial and cyclic loading of vertebrae, we have performed a series of tests in our laboratory. We believe that if a consensus is reached for (i) the criteria for the selection of test materials and (ii) the test conditions, the interpretation of the test results will be more uniform and the conclusions will be more dependable.

Key Words: *Spine, Biomechanics, Consensus*

INTRODUCTION

In recent years, the number of tests performed on vertebrae and the number of related papershave reached such a large number that a proper assessment of all the data that have been gathered in indeed difficult. Besides, every research takes into account different parameters and considers them as essential in the comparison of different techniques and fixation devices employed in the stabilization of the spinal column. There is now a need for a consensus on:

i) The criteria to be followed while selecting the material and the spine model
ii) Preparations preliminary to test
iii) The choice of the parameters to be considered as essential
iv) The key parameters that have to be considered in the interpretation of the test results and of the assessment of spinal implants.

MATERIALS

Experimental studies on vertebra are mainly performed on calf spines, polyester and fresh cadaver specimens. Many researchers (1) have claimed that calf spines, in addition to the similarity in size to adolescent spine, exhibit uniformity in stiffness among samples. They, therefore, can be regarded as appropriate in the comparison studies of spinal implants. This common assumption was perplexing to us and we have tested 14 calf spines (Seven of them consisting of three vertebrae, (3V), the remaining seven of five vertebrae (5V) in compression. As can be seen in figures 1 and 2 nonuniformity, present, especially at the level of physiological loads, observed in the response curves seems to be a noteworthy characteristic of vertebrae. Unless a plastic vertebra is used, non uniformity among specimens is unavoidable. Accordingly, the common basic assumption mentioned above should be further investigated.

SPINE MODELS

In posterior stabilization case, fixation from three vertebrae above to two or three vertebrae below the fractured region is usually preferred. Accordingly, in general we encounter with tests performed with five or more vertebrae. There are also a few studies in which 3V sets are used. A remark relevant to the choice of the number of the vertebra levels to be tested is in order: Even though energy absorption capacity of 5V set is greater than that of 3V set, 5V set is more susceptible to lateral motion. The eccentricity of the system (load and vertebral column) will be more ef-

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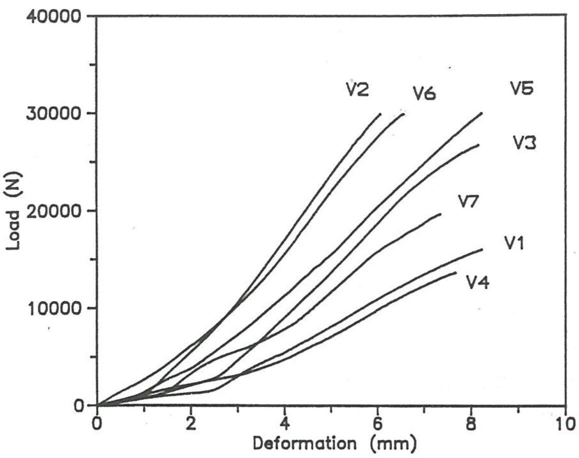

Figure 1. Load-Deformation curves of three intact vertebra (RL = 10 mm/minute)

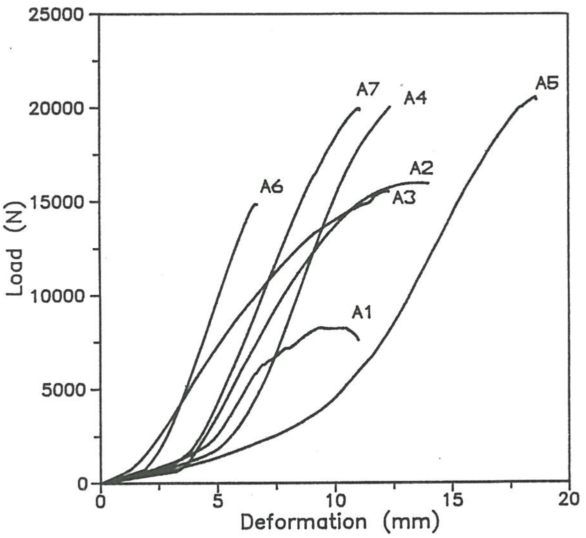

Figure 2. Load-Deformation curves of five intact vertebra (RL = 10 mm/minute)

fective in the 5V model. In other words, imperfect buckling behavior is unavoidable in 5V set. It is advisable to use 3V models in order to simulate a pure axial compressive loading as closely as possible.

In choosing a model for a destabilized spine, the type of fracture that is going to be simulated plays an important role. Till now, in order to have a clinical relevance to burst fracture, a model having bone graft (3, 4) in the dissected region of the vertebra is utilized in the vertebra tests. In our studies we have placed. instead, a cylindricon rubber (diameter = 5 cm and height ~5 cm) of 30 shore hardness into the dissected

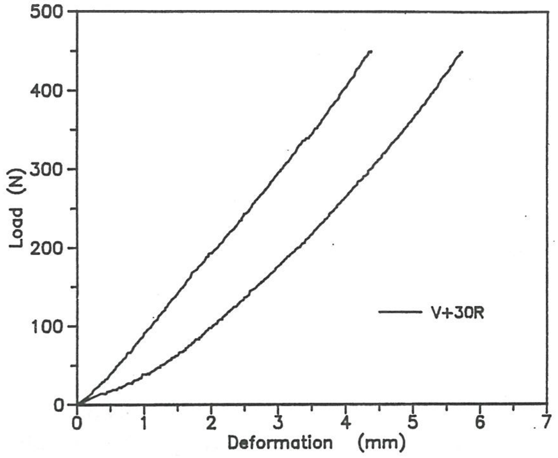

Figure 3. Load-Deformation curves of destabilized vertebra

region which involves the transaction of the central vertebral body, half of the adjacent disk spaces and anterior-posterior longitudinal ligaments. As can be seen in figure 3, nonlinearity in P - Δ curves, which is characteristics of intact vertebra'is preserved also after the placement of rubber spacers.

PREPARATIONS PRELIMINARY TO TEST

There is more or less consensus on the preparations undertaken prior to tests. The specimens are kept at -20°C till the time of testing, then thawed to room temperature. Testing period (thawing included) does not last more than three hours (4, 5, 6). In static tests, it is not difficult to obey this maximum limit but in fatigue loading (or cyclic loading) to satisfy this limit is very difficult. Thawing (i.e. when vertebral discs return to their natural color) usually takes more than one hour. The preparation of the specimen (i.e., dissection operations, screw placement, capping) requires at least an additional 40 minutes and then testing (even at the rate of loading of 50 mm/minute) takes at least 40 minutes more (if, for example, cyclic resting up to 1000 cycles at RL = 50 mm/minute is performed). To shorten the thawing period we have applied three stages of storage. After the specimens are taken from the slaughterhouse, they are kept frozen at -20°C. 16 hours before testing they are moved to the refrigerator shelves (4°C). Three hours before testing they are taken out and wrapped in wet towels until complete thawing is maintained. This process of storage reduces the thawing period considerably. A remark relevant to capping is now in order: The end conditions at the time of test, the capping method and the end conditions before capping may have pronounced effect upon the compressive strength of the vertebrae. The higher the compressive strength of the capping material, the higher the indicated strength of the vertebrae. Irregular ends and capping with low strength material may reduce the strength. Irregular ends have more pronounced effects on the strength. In our experiments, ends are cut by saw machine and plane capping is done using bone cement.

TEST PARAMETERS

Apart from a few papers (1, 2) the rate of loading employed in the test is usually not indicated by the researchers. Energy absoption capacity and even stiffness of a spinal construct may, however, be affected by an increase in rate of loading (RL) (Figure 4). Figure 4 displays the response of intact 3V and Alıcı instrument when subjected to compressive loading. Spinal construct of curve (b) is subjected to two cycles (load between 0 and -400 N) of loading before loaded to ~ 500 N. Even though the difference in the material characteristics of vertebrae is important in the stiffness and energy absorption capacity of a spinal construct. The effect of an increase in RL can not be ignored and results may be considered as dependent on RL (1). For compressive axial static testing. RL of 10 mm/minute seems to be appropriate. Ashman gives RL in terms of N/second as 15 N/second for pure axial loading (2).

The parameters of dynamic loading (i.e. cyclic loading) are either number of cycles (n) or number of cycles per second, frequency (7, 8). Depending upon the rate of loading, however, variation of hysteresis lost with respect to number of cycles will be different (Figure 5). Therefore apart from stating n and/or f, RL should also be stated (even though it can be expressed either in mm/minute or N/second, it is advisable to use deformation rate).

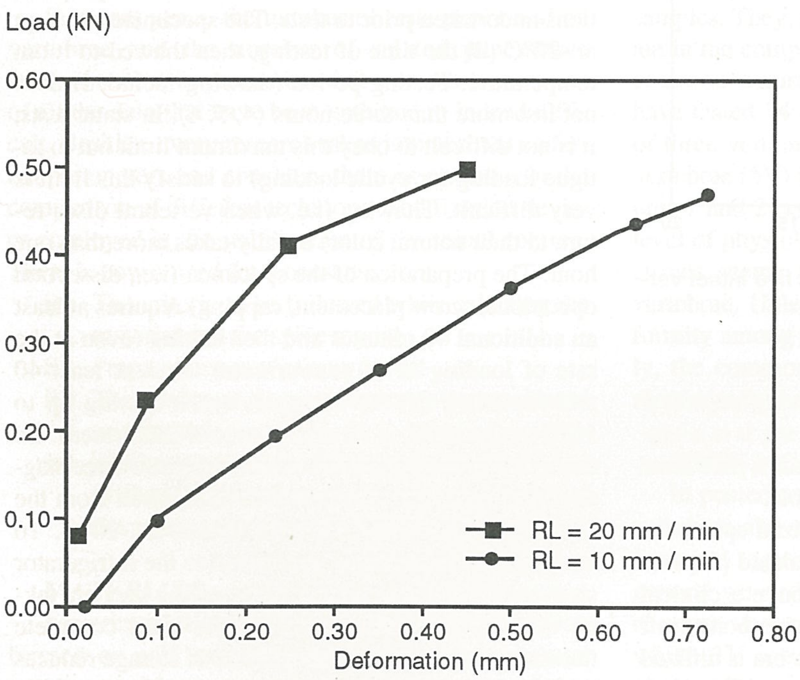

Figure 4. Effect of RL on load-deformation relations of 3V and Alıcı construct

COMPARISON CRITERIA FOR SPINAL IMPLANTS

As is well known, response of vertebra to axial loading is of nonlinear nature (Figure 1). Therefore, simultaneous satisfaction of the two criteria given below should be required:

i) After the application of the spinal implant, stiffness of the spinal construct must increase.

ii) Energy absorbed by the spinal construct must be lower than the energy absorbed by destabilized spine and must be as close as possible to the energy absorption capacity of the intact vertebra.

CONCLUSIONS

No range, neither relevant to the increase in stiffness that has to be achieved nor reduction in the energy absorbed by the destabilized spine, are indicated. The only restriction stated so far is relevant to interlaminar motion (1). If interlaminar motions exhibit less then 10 % strain, the fusion is not prevented or decelerated. Upper and lower bounds for the extra stiffness provided by spinal implants have to be given. It is a well known fact that too stiff implants may cause stress concentrations, in the adjacent vertebra and may accelerate osteoporosis at the spinal fracture site. To achieve the reproducibility of the original vertebra, its original

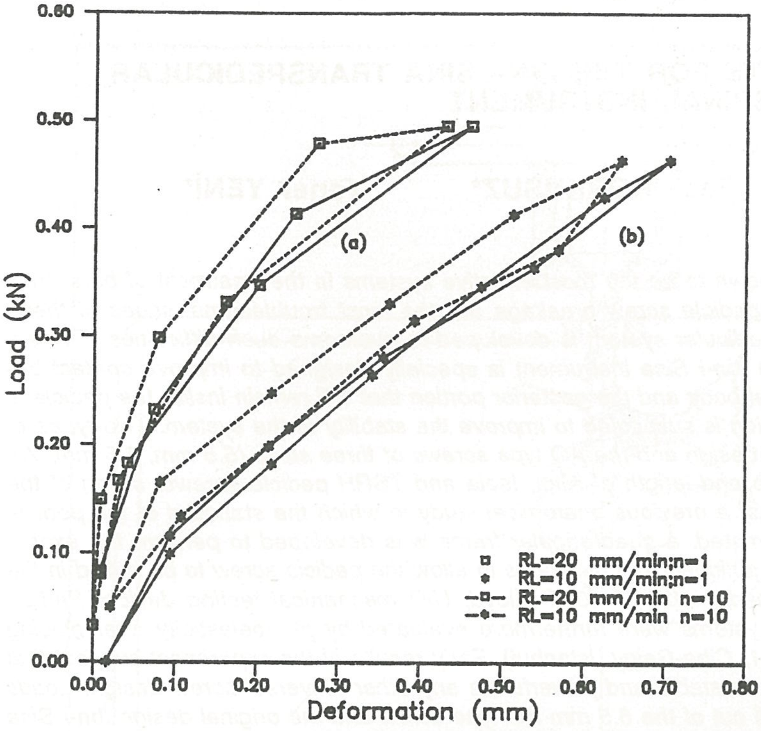

Figure 5. Hysterisis curves

resistive characteristic to sudden load has to be restored also, which can expressed by a factor indicating the contribution of the spinal column to energy absorption capacity of the spinal implant. This factor can easily be determined from the test results as

$$EF = 1 - \frac{(A)_{DV}}{(A)_{T}}$$

where (A)DV is the are under P-Δ curve of destabilized vertebra and (A)T is the area under P-Δ curve of instrumented vertebra. EF factor will take values between zero and one and indicates the ameliorative effect of the spinal implant. EF defined here is somewhat different from RΔ (9) where RΔ indicates the rigidity gained by the instrumented spine with respect to uninstrumented intact one. By assessing the test results done all over the world a consensus be reached on the lower and upper limits of this factor. In addition to these percentage load that can be allowed to be transferred across injured section can also be a factor in the asessment of spinal implants, but to obtain these values is not so easy as the two above mentioned values.

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