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Relevance of a novel external dynamic distraction device for treating back pain

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Abstract

Low back pain is a common, expensive, and disabling condition in industrialized countries. There is still no consensus for its ideal management. Believing in the beneficial effect of traction, we developed a novel external dynamic distraction device. The purpose of this work was to demonstrate that external distraction allows limiting the pressure exerted in standing-up position on the lower intervertebral discs. Numerical and cadaveric studies were used as complementary approaches. Firstly, we implemented the device into a numerical model of a validated musculoskeletal software (Anybody Modeling System) and we calculated the lower disc pressure while traction forces were applied. Secondly, we performed an anatomical study using a non-formalin preserved cadaver placed in a sitting position. A pressure sensor was placed in the lower discs under fluoroscopic control through a Jamshidi needle. The intradiscal pressure was then measured continuously at rest while applying a traction force of 200 N. Both numerical and cadaveric studies demonstrated a decrease in intradiscal pressures after applying a traction force with the external device. Using the numerical model, we showed that tensile forces below 500 N in total were sufficient. The application of higher forces seems useless and potentially deleterious. External dynamic distraction device is able to significantly decrease the intradiscal pressure in a sitting or standing position. However, the therapeutic effects need to be proven using clinical studies.

Keywords

Back pain, actuators, traction, disc pressure, Anybody Modeling System

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Introduction

Back pain is becoming an increasing concern in most industrialized countries. Indeed, it is estimated that 80% of the adult population suffers or will suffer from low back pain with an annual prevalence of 30%.[1,2] This frequency more than tripled in Europe and in the US between 1980 and 2000.[1,2] Chronic low back pain, evolution of which is by definition longer than 3 months, concerns only 20% of these patients, that is to say 10% to 20% of the general population with a preferred age ranged between 35 and 45 years old. In industrialized countries, low back pain is a major public health problem as it generates significant costs in healthcare and is one of the leading causes of disability and sick leave.[3,4] The etiology of the pain can be difficult to determine, although it can often be due to degenerative changes in the intervertebral disc and articular joints,[5,6] the lower segments being the most frequently and severely affected in clinical practice (L4L5 and L5S1 segments). Many risk factors have been highlighted such as smoking, overweight, sedentary lifestyle, and some occupations that require heavy loads carrying.[7,8] The exaggerated mechanical stresses are clearly identified to accelerate the degeneration and

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thus aggravate the symptoms. In clinical practice, the source of pain can be diverse (disc, facets, muscles), sometimes combined and often difficult to determine. However, some patients present pain that is clearly related to an excess of mechanical stress on the intervertebral disc.

In spite of its frequency and its social impact, there is no consensus for the treatment of chronic low back pain.[9,10] Surgery failed to show its effectiveness in the absence of radicular pain, except in very particular situations.[11,12] In the same way, the majority of conservative treatments have not shown clear evidence of their effectiveness.[13] Among them, lumbar traction is a commonly used method to treat patients with low back pain with or without sciatica, aiming to reduce the mechanical stresses exerted on the lumbar structures, and more particularly the intervertebral disc. In most industrialized countries, lumbar traction is used routinely by outpatient rehabilitation providers.[14,15] Thus, there is a discordance between the lack of evidence-based recommendation and how lumbar traction is regarded in current clinical practice, which is explained by the great heterogeneity of practices and the methodological problems found in most clinical studies.[16] Believing in the beneficial effect of traction, we developed an external distraction device. The purpose of this work is to demonstrate that external distraction allows to limit the pressure exerted on standing up position on the lumbar spine and mainly on the lower intervertebral disc.

Methods

We have carried out two complementary studies as follows. The first study consists on a predictive evaluation of the device effect using a validated numerical model. The second study aims to measure on a cadaver model, the effect on the intradiscal pressure, using an external distraction device with a non-invasive fixation.

Numerical assessment

Anybody model. Anybody Modeling System (AMS, AnyBody Technology, v.6.0.6, http://www.anybodytech.com/) is a validated musculoskeletal software revolving around inverse dynamic simulations, able to calculate individual muscle forces, joint contact forces and pressures.[17] Each body part is implemented using validated cadaveric or anatomical data ensuring high accuracy and anatomical fidelity of the model. Every bones, joints, muscles, ligaments and tendons are represented (Figure 1). We decided to use a full body model offered by AnyBody (full-body, AnyBody Managed Model Repository, AMMR). Very widespread model in the world of research, more than fifty scientific publications refer to it (AnyBody Technology) to study the efforts in the various joints and in particular in the spine. Finally, AMS allows the importation of Computer Assisted Design (CAD) components in order to study their effects in interaction with the body. Note that anthropometric measures can be modified.

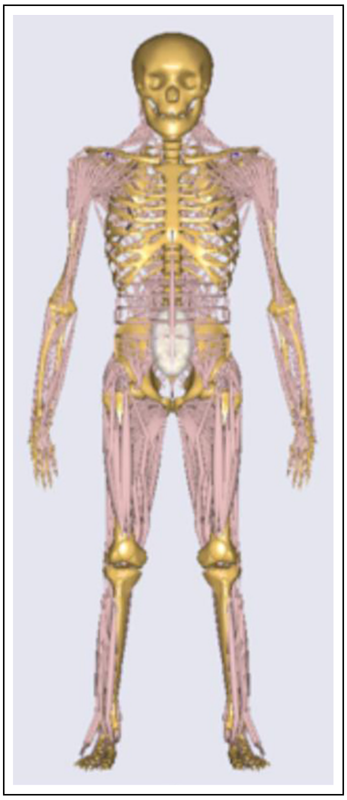

Figure 1. Anybody Modeling System default model.

Exoskeleton model. The aim of the exoskeleton (prototype of Japet.[W], Japet Medical Devices, https://www.japet.eu/) is to apply vertical traction forces to reduce pressure on the lumbar spine in the upright position (Figure 2(a)). In order to preserve both proper spinal alignment and freedom of motion, the device is composed of two sets of actuators positioned on both side of the body. The actuators are supported on plastic supports. The traction is produced by these four actuators, each of them represented by a pivot joint between the upper part and the lower part of the device (Figure 2(b)). These joints are activated by electric motors thanks to worm screws and controlled by on-board electronics. At the end of each one, a ball joint preserves the motion of the trunk. Each actuator can generate a force of 80 N, ensuring a maximum distraction force of 320 N. The outer part of the device is made of textile. The overall weight is < 2 kg and its dimensions are $1 \times 0.3 \times 0.1$ m.

Implementation of the exoskeleton in Anybody. As the simulation does not include the skin, we used the torso on which the exoskeleton was designed to position the device in the simulation. The torso used for the prototype design is a standard morphology transmitted by a local orthoprosthetist. A skeleton was then fitted inside

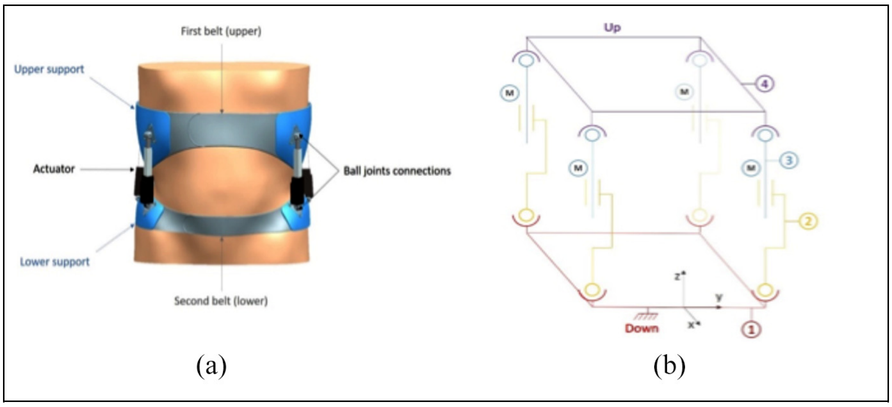

Figure 2. Conceptual design of the device (a). The exoskeleton is composed of two belts respectively tightened at the base of the thorax and on the waist (over the iliac crests), and linked by four actuators able to apply a traction force of 80 N each. The kinematic of the exoskeleton is schematized (b).

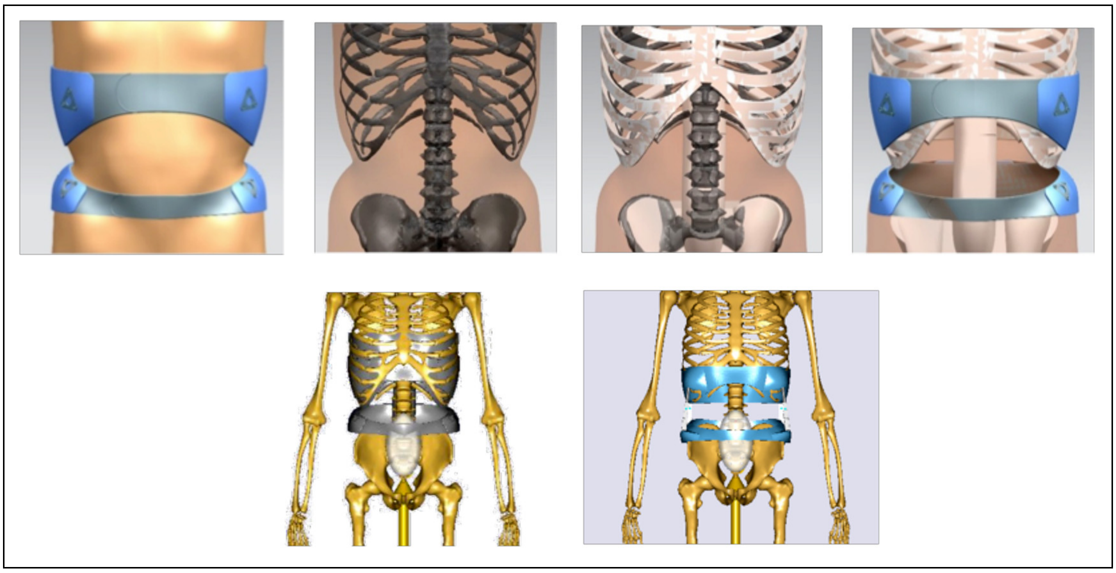

Figure 3. Implementation of the exoskeleton in Anybody. As the simulation does not include the skin, we used the torso on which the exoskeleton was designed to position the device in the simulation. The torso used for the prototype design is a standard morphology transmitted by a local orthoprosthetist. A skeleton was then fitted inside the CAD of the body with size adaptation relative to the body dimension. The skeleton was obtained from a free CAD on GrabCAD (GrabCAD Inc, https://grabcad.com). The skeleton inside the CAD was then fitted to the Anybody model to position the torso, therefore fitting the position of the exoskeleton in the simulation. Finally, the connection points were visually fitted to the solid part of the pelvis and the thorax.

the CAD of the body with size adaptation relative to the body dimension. The skeleton was obtained from a free CAD on GrabCAD (GrabCAD Inc, https://grabcad.com) (Figure 3). The skeleton inside the CAD was then fitted to the Anybody model to position the torso, therefore fitting the position of the exoskeleton in the simulation. Finally, the connection points were visually fitted to the solid part of the pelvis and the thorax.

Therefore, it was necessary to simplify the model to allow the software to perform the calculation. In addition, some data stay unknown and are subject specific such as device slippage (skin, fat) and friction in actuators (depending on materials, tightening, etc.). It is thus very difficult to take all parameters into account. Firstly, a perfect model was applied for the actuators (no friction) to simplify the calculations. Secondly, as the AMS software performs the simulations by inverse dynamics operations, we had to constrain the degrees of freedom. The top ball joint was replaced by a universal joint to avoid rotation in the actuators along the z axis. Similarly, the pivot joint between the two parts of each actuator was replaced by a slide joint to limit rotation. Finally, the connection between the body and the belts was simplified as a housing to prevent movement.

Study protocol. For this study, we chose morphometric data to get closer to the European average for a man. We parameterized a height of 1.68 m, a weight of 85 kg and a lumbar disc area of 19.8 cm^2. The intradiscal pressure (P) was estimated by dividing the force (F) with the corresponding disc area applying a correction factor. The correction factor considered the non-uniform load distribution in the disc. In accordance with the Nachemson study[18,19] and as confirmed by Brinckmann and Grootenboer[20] and Cripton et al.,[21] we applied a correction factor of 0.66. Thus, the final formula to calculate the intradiscal pressure was $P = F/(0.66 \times S)$. Even if the actuators of our device cannot develop more than 80 N of traction force, we decided to realize extreme simulations from 0 to 1000 N (250 N per actuator) in order to define the optimal traction force and to analyze changes of disc pressure during extreme traction. The measurements were performed for the three lower discs L3L4, L4L5 and L5S1, which are most frequently affected in clinical practice. We also decided to analyze the activity of the lumbar muscles to detect and measure any possible reaction contractile activity.

Anatomical study

Cadaver characteristics. The full body of a 62-year-old woman (height 1.62 cm, weight 70 kg) was used for the study. The cadaver was prepared using a solution without formalin, rich in glycerin, making the soft tissues similar to those of living people, except for the bleeding. She had no history of spinal surgery or spinal injection. Radiological evaluation confirmed a disc high superior to 10 mm from L3 to S1. Similarly, there was no sclerosis of the endplates or voluminous osteophytes, overall confirming the absence of severe disc degeneration at those levels.

Measurement technique. A table of maintenance was made for this study. It was very complicated to position the cadaver in a standing position. The fixing systems did not make it possible to stabilize it without supporting it. Thus, the cadaver was kept in a sitting position, in rectitude, avoiding any support under the arms, which would have been likely to reduce the body weight. Due to the elasticity of tissues, we waited 30 min before starting any measurement to reach the plateau phase. A Jamshidi needle (13 Gauge, 150 mm length) was inserted percutaneously through a strict midline posterior approach. The placement was performed under a strict anteroposterior and lateral fluoroscopic control (Figure 4). On the lateral radiograph, the disc was divided into three zones: posterior, middle and anterior (Figure 4(c)). The needle was placed respectively in the three zones beginning with the posterior, then middle and finally anterior. Due to the bony overlapping of the iliac wing, it was difficult to certify the proper positioning of the needle at L5S1 level and measurements were thus made on the L3L4 and L4L5 discs. The device consists of two belts respectively tightened at the base of the thorax and on the waist (over the iliac crests). No rigid attachment to the cadaver was performed, in order to maintain the potential effects of slips that could be encountered in therapeutic condition.

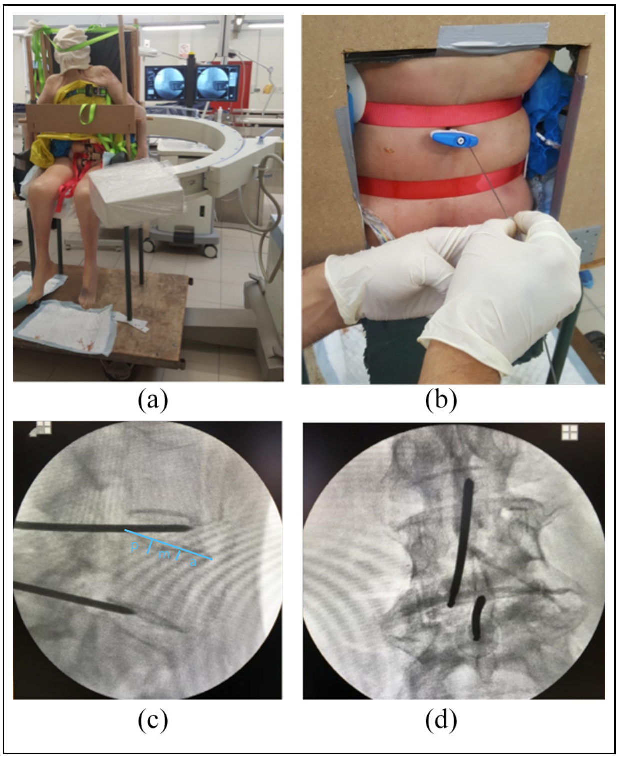

Figure 4. Anatomical protocol. The cadaver is placed in a sitting position under strict fluoroscopic control (a). The Jamshidi needle (13 Gauge) is inserted percutaneously under anteroposterior and lateral fluoroscopy (b). On the lateral view (c) the disc is divided into three zones (posterior, middle, anterior). On the anteroposterior view, we ensure the strictly median placement (d).

Measurement protocol. After placing the needle, a pressure sensor was inserted through. We used a high pressure needle CTN/4F-HP (Gaeltec Devices Ltd., http://www.gaeltec.com), 145 mm long with a domed tip. The distance from the tip to the middle of the sensor is 5 mm. The sensor is mounted in a 3.5 mm long window. This type of needle is often used to measure intradiscal pressure on cadavers. The needle is coupled to the GBA Amplifier (Gaeltec Devices Ltd., Bridge Amplifier System, http://www.gaeltec.com) and to the PicoLog analysis software (Pico Technology, v.6., https://www.picotech.com). Once the sensor was introduced, awaiting time of 5 min was respected in order to reach an equilibrium, because of the minimal tissue lesions induced by the puncture. We then performed five measurements for each zone and for each disc. For each measurement the same protocol was respected. After recording the base pressure, we applied a force of 50 N per actuator (total of 200 N) for 2 min. We then recorded the baseline pressure for 5 min to regain balance before starting a new measurement. We then

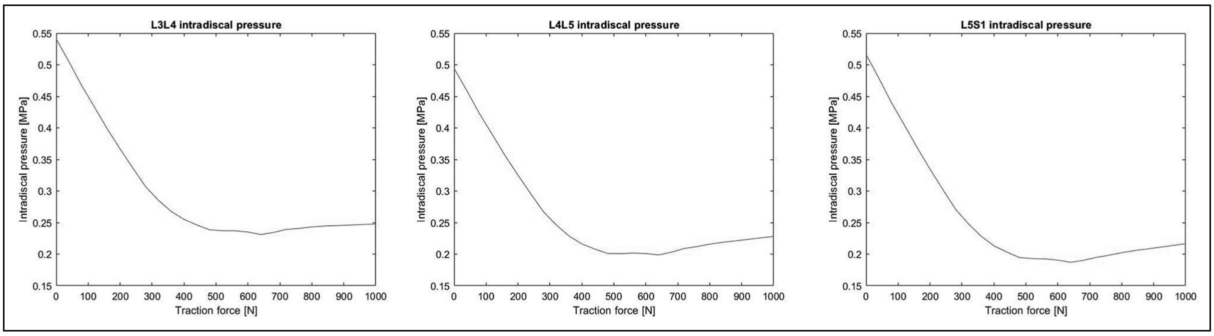

Figure 5. Numerical simulation. Evolution of the simulated intradiscal pressure in L3L4 (a), L4L5 (b) and L5S1 (c) as a function of the total traction force applied (Traction forces are in Newton and intradiscal pressures in MegaPascal).

performed a prolonged recording to measure the evolution of the disc pressure when a prolonged distraction is applied. We placed the sensor in the middle of the disc and after observing a latency of 5 min, we measured the disc pressure while a force of 50 N per actuator for 30 min is applied.

Results

Numerical results

Development of the intradiscal pressure. For the L3L4 disc, it was found that the disc pressure gradually decreased from 0.54 to 0.24 MPa for a total traction force closes to 600 N. Paradoxically, when increasing the tensile force, a rise in the disc pressure was observed (Figure 5(a)). For the L4L5 disc, it was also found that the disc pressure gradually decreased from 0.48 to 0.2 MPa for a total traction force closes to 500 N. As for the above disc, when increasing the tensile force, a rise in the disc pressure was observed (Figure 5(b)). For the L5S1 disc, the intradiscal pressure decreased from 0.52 to 0.17 MPa for a total traction force close to 600 N. Similarly, when increasing the traction, we observed a rise in the discal pressure that reached 0.22 MPa for 1000 N of traction (Figure 5(c)). Under the conditions of this simulation, the optimum total traction force seems to be close to 500 N. In addition to safety concerns, a higher traction force seemed useless or even deleterious.

Muscles activity. At the lumbar level, we have three powerful and stabilizing muscles that are inside and outside, the multifidus, the longissimus and the iliocostalis acting in compression.[22] The activity of these muscles was recorded in parallel with the disc pressure (Figure 6). We found that there was little muscle activity for traction forces below 400 N. Beyond 500 N, we observed a significant and progressive increase in these three muscles activity, exceeding twice the basis activity for the longissimus and three times the basis activity for both multifidus and iliocostalis.

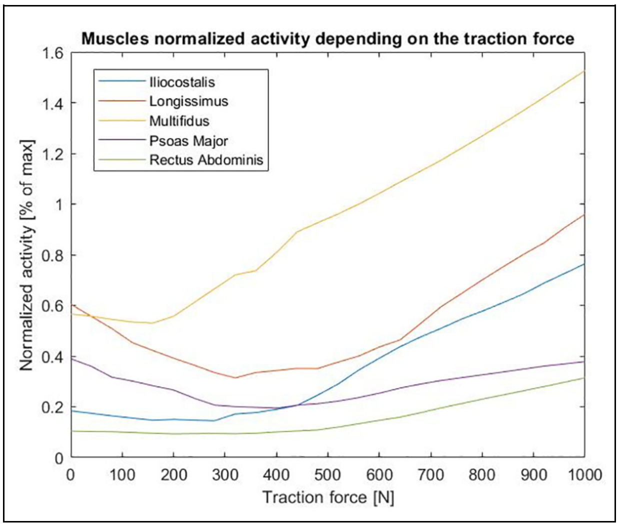

Figure 6. Numerical simulation. Evolution of the activity of the main erector and torsi flector muscles of the trunk as a function of the total traction force applied.

Anatomical results

As stated previously, the measurements were performed on L3L4 and L4L5 discs, as L5S1 disc was not easily identifiable on the fluoroscopic control, because of bony overlapping of the iliac wing, which did not allow confirming with certainty the proper positioning of the sensor.

For the L3L4 disc, we measured a significant decrease in intradiscal pressure during the distraction phase which remained stable. This decrease was reproducible in the five completed registrations. Standardized results are shown in Figure 7 (the measured pressures were divided by the base value). We found that the decrease in pressure was greater in the middle and at the back of the disc, whereas it was less significant at the front of the disc. Indeed, the pressure drop reaches 43.96% in the middle, 27.82% in the back and only 17.90% in the front of the disc. For the L4L5 disc, we also measured a significant drop in pressure after the actuators were activated. This decrease was stable and significant in the five recordings made. We

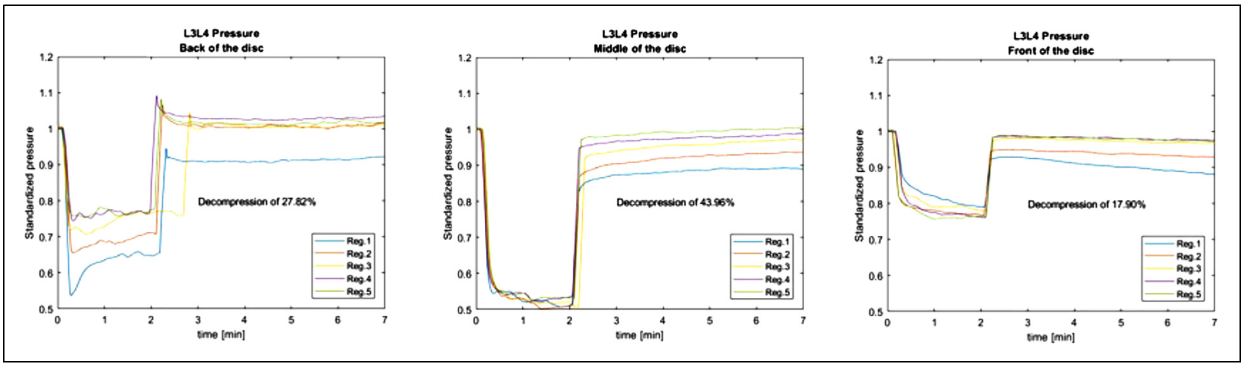

Figure 7. Anatomical measurements. The intradiscal pressure has been measured in the three different zones of the L3L4 disc (back, middle, front). The five registrations for each zone have been reported. The results have been standardized (divided by the base pressure). After a few seconds of measurement, a traction force of 200 N was applied for 2 min.

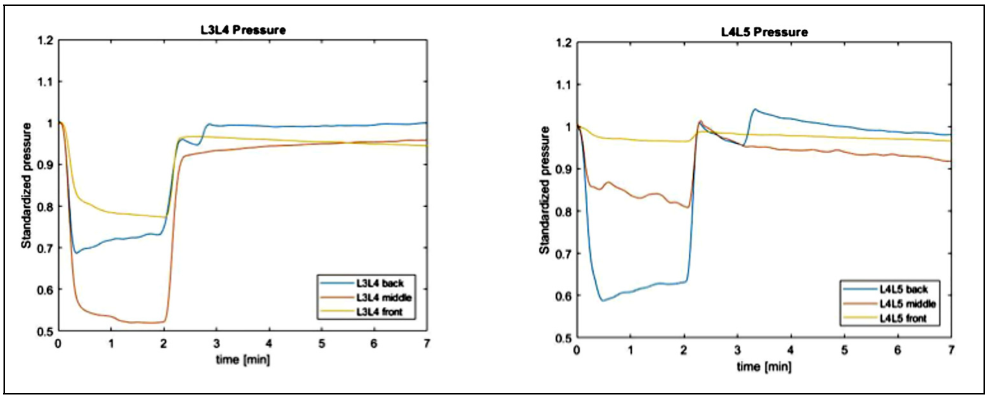

Figure 8. Anatomical measurements. The intradiscal pressure has been measured in the three different zones of the L3L4 (a) and L4L5 (b) discs. For each zone, we calculated and reported the average of the results obtained (average of the five successive recordings). After a few seconds of measurement, a traction force of 200 N was applied for 2 min.

found that the pressure drop was more significant at the back and the middle of the disc while it was minimal at the front of the disc. The normalized averages obtained for each zone of each disc are shown in Figure 8.

We also found that the pressure drop obtained under the effect of traction was durable over time. Indeed, the decrease in pressure recorded in the middle of the L3L4 disc remained significant (up to 40%) beyond 30 min of continuous traction (Figure 9).

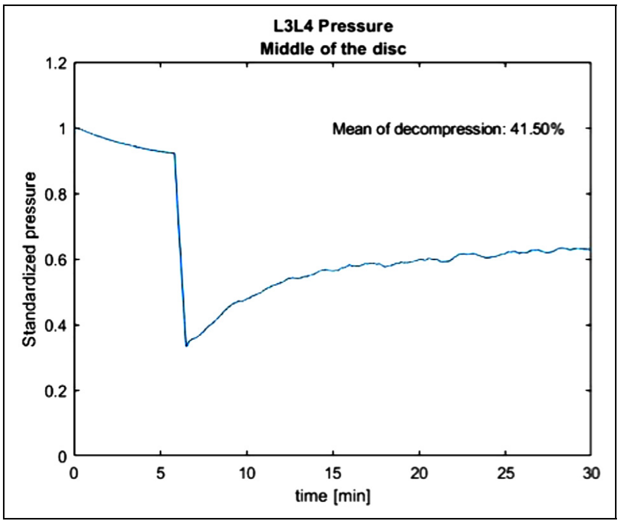

Figure 9. Anatomical measurements. Prolonged recording in the middle of the L3L4 disc. We placed the sensor in the middle of the disc and after observing a latency of 5 min, a traction force of 200 N was applied during 30 min. There is a prolonged and significant decrease in pressure when traction is maintained.

Discussion

Low back pain is a common, expensive and disabling condition in industrialized countries.[1–4] The pathophysiology is complex, but the exaggerated mechanical stresses were clearly identified as a main deleterious factor. Many structures can be variously involved and further aggravated by muscle deconditioning, socio-professional and psychological factors. Using a proper clinical and radiological evaluation, excess of mechanical stress into the disc space can be considered as the main cause of pain in some patients, so called disco genic pain. The existing therapeutic solutions are multiple but to date the prognosis is still often unfavorable, reflecting the need for new therapeutic tools.[23] Till now, only physical exercise is considered as being a way of avoiding muscle deconditioning, the latter is a aggravating factor for chronic back pain. Physical exercise allows indeed to improve functional capacity and to decrease disability, however, its efficiency in pain managing in the mid and long term has not been demonstrated. Among the existing solutions, traction is very popular, but no study has been able to demonstrate its clinical effectiveness in the medium or long term.[16] However, experimental studies have shown that traction tables are likely to increase the height of the intervertebral disc and even reduce the conflicts between the disc and the nerve roots in case of associated sciatica.[24–27] To date, the lack of evidence of effectiveness is likely to be related to a lack of technical solutions, rather than a lack of concepts. In this perspective, we developed an exoskeleton to obtain a distraction in standing up position. Thus, the traction can be applied more prolonged, on a subject in a position of function and potentially in motion and in activity insofar as the actuators allow the maintenance of the amplitudes of movement. The objective would be to reduce the mechanical stress exerted on the lumbar disc (L4L5 and L5S1 being the most frequently affected), while maintaining the activity of the patient (recreation or professional). It would also aim to limit the muscular deconditioning caused by the inactivity or by rigid contention belts that are sometimes proposed.

In our study we demonstrated that an external distraction was able to induce a significant decrease in intradiscal pressure. Using the numerical model, we have shown that tensile forces below 500 N in total were sufficient. The application of higher forces is useless because it is accompanied by a deleterious increase of the disc pressure. This effect can be explained in large part by the reflex muscular activity (simulated in our study) but also by the elastic properties of the ligament and tendinous structures not represented in the Anybody model. Indeed, the developers stated: "*when building the lumbar spine model the original idea was to include ligaments as well. But at some point, we decided not to include the ligaments in the model, because of lack of readily available information about the mechanical properties and slack lengths. We were in fear that ligaments with wrong properties might give worse results than excluding them.*" Note that the majority of traction tables have the technical ability to apply traction forces up to 1000 N in a supine position. Even in the absence of standard protocol, such forces are note applied routinely in clinical practice.[27,28] The absence of representation of the ligaments is not the only limit of this model. The skin is also not represented in AMS, and the device had to be attached to the skeleton. As a result, the sliding of the device on the skin and the soft tissues is not considered, which may increase the physiological effects observed. In addition, the disc pressure is not directly measured but calculated according to the defined surface and by means of a chosen correction factor, which can be a source of approximation. The biomechanics of the disc soft tissues should be considered in furthermore accurate models[30,31] along with deeper understanding of the disc functionality.[32–34] In the current study, it was therefore necessary to carry out direct measurements "in vivo" in order to limit these biases.

Unlike cadavers prepared with formaldehyde, we used a BIOMET cadaver, in order to preserve much of the elasticity of the tissues. This cadaveric study has demonstrated that the application of external traction significantly reduces disc pressure. This pressure drop is significant, reproducible and durable over time, as demonstrated during the prolonged recording of 30 min, allowing to appreciate the potential therapeutic effects. Note that we measured larger effects in the back and middle of the disc while the pressure drop was lower at the front of the disc at the L3L4 and L4L5 levels. This is probably related to a postural effect. Indeed, the cadaver was sitting slightly leaning forward, which can induce a slight inversion of curvature (lower lordosis) and increase the stresses exerted on the front of the disc.[27–29]

This cadaveric study has certain limitations. First, muscle activity is non-existent, and its effect cannot be measured. Indeed, the muscles have a very important role in postural control and in the regulation of intradiscal and facet pressures. Thus, even if the effect of external distraction is demonstrated, the measurements may be not accurately estimated in the absence of muscle contractions. This limitation must be balanced by the study of Cholewicki et al.,[35] who demonstrated that the muscle activity (measured by electromyography) remains low when applying a standard traction force of 25 N on a traction table. In addition, it would have been useful to perform measurements on several subjects to confirm reproducibility. However, the combination of a simulation on a validated model and a cadaveric study with direct measurements, makes it possible to validate the effect of external distraction on the decrease in intradiscal pressure. The therapeutic effect of this device deserves to be carefully studied, and for this purpose an observational clinical study is currently ongoing.

Conclusion

In summary, external dynamic distraction device is able to significantly decrease the intradiscal pressure in a sitting or standing position. The effects are obtained using traction forces lower than 500 N. The application of higher forces seems useless and potentially deleterious. However, the therapeutic effects need to be proven using clinical studies.

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Declaration of conflicting interests

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