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Braces Designed Using CAD/CAM Combined or Not with Finite Element Modeling Lead to Effective Treatment and Quality of Life after Two Years: A Randomized Controlled Trial.

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Mini

The impact of brace design through CAD/CAM with or without finite element modeling was studied over two years in a randomized controlled trial. Clinical outcomes, 3D correction, compliance and quality of life were satisfactory and equivalent between the computational techniques used, demonstrating the validity of simulations in the design process.

Abstract

Study Design

Single-center prospective randomized controlled trial.

Objective

To assess the computer-aided design/manufacturing (CAD/CAM) brace design approach, with and without added finite element modeling (FEM) simulations, after two years in terms of clinical outcomes, 3D correction, compliance and quality of life (QoL).

Summary of Background Data

Previous studies demonstrated that braces designed using a combination of CAD/CAM and FEM induced promising in-brace corrections, were lighter, thinner and covered less trunk surface. Yet, their long-term impact on treatment quality has not been evaluated.

Methods

One-hundred-twenty AIS patients were recruited following SRS standardized criteria for brace treatment; 61 patients in the first subgroup (CAD) were given braces designed using CAD/CAM; 59 in the second subgroup (CAD-FEM) received braces additionally simulated and refined using a patient-specific FEM built from 3D reconstructions of the spine, rib cage and pelvis. Main thoracic (MT) and thoraco-lumbar/lumbar (TL/L) Cobb angles, sagittal curves, and apical rotations were compared at the initial visit and after two years. Patient compliance and QoL were tracked respectively by using embedded temperature sensors and SRS-22 questionnaires.

Results

Forty-four patients with CAD-FEM braces and 50 with CAD braces completed the study. Average in-brace correction was 9° MT (8° CAD-FEM, 10° CAD, p=0.054) and 12° TL/L (same for both subgroups, p=0.91). Out-of-brace 2-year progression from initial deformity was 4° for all 3D measurements. Sixty-six percent of all cases (30 CAD-FEM, 35 CAD) met the 45° curve progression criterion, 83% (38 CAD-FEM, 43 CAD) stayed below 45° and 6% (5 CAD-FEM, 1 CAD) underwent fusion surgery. 3D correction, compliance and QoL were not significantly different between both subgroups (p>0.05).

Conclusions

After two years, patients with braces designed using CAD/CAM with/without FEM had satisfying clinical outcomes (compared to the BrAIST study), 3D corrections, compliance and QoL. A more comprehensive optimization of brace treatment remains to be accomplished.

Key Words: Adolescent idiopathic scoliosis (AIS); bracing; brace design; simulation; randomized controlled trial (RCT); computer-assisted design and manufacturing (CAD/CAM); finite element modeling (FEM); 3D correction; brace-wear compliance; adherence; quality of life

Level of Evidence:2

Introduction

Adolescent idiopathic scoliosis (AIS) is a three-dimensional (3D) deformation of the spine affecting its normal alignment in the coronal, sagittal and transverse planes.[1,2] A thoracolumbosacral orthosis (TLSO, or orthopedic brace) is the common conservative option to treat moderate curves between 25° and 40°.[3] Recent studies demonstrated the effectiveness of bracing,[4,5] but highlighted insufficient in-brace correction and poor brace compliance as risk factors for treatment failure.[6–8] Other studies have reported weak corrections in the transverse plane and a tendency to flatten sagittal curves.[1,9,10] Bracing was also shown to negatively affect patient quality of life, especially during treatment.[11,12]

Today, surface topography scans and computer-aided design/computer-aided manufacturing (CAD/CAM) are frequently used to replace traditional plaster-cast fabrication methods.[13] CAD/CAM reduces design time, material used and patient discomfort without compromising brace reliability and curve correction.[14,15] Furthermore, numerical finite element models (FEMs) are now used to study brace effects and simulate correction.[16–19] However, the clinical integration of these tools is still limited.

We developed patient-specific FEMs initially to study brace biomechanics,[20–24] they were subsequently improved and combined with the CAD/CAM brace design approach. Today, orthotists can interactively simulate any brace design and compute the in-brace correction, generated pressures and other adjustment features before its fabrication. Our tools' usability in a clinical environment was demonstrated,[25,26] and this innovative approach was validated in a randomized controlled trial (RCT) where the immediate efficacy of braces was evaluated in the coronal plane[27] and in 3D[28] on a small cohort. Braces designed using CAD/CAM and FEM showed promising immediate correction, were lighter, 50% thinner and covered 20% less surface area on the torso than standard CAD/CAM braces. Yet, their long-term effects were never evaluated.

The objective of this study was to assess the validity of the CAD/CAM brace design approach, with and without added FEM simulations, after two years in terms of treatment outcomes, 3D correction, compliance and quality of life.

Materials and Methods

Study design

One-hundred-twenty patients were recruited in a single clinical center over a three-year period (2013-2016). The study was designed to detect a 5° difference with a statistical power of 80%. Inclusion criteria followed the Scoliosis Research Society (SRS) standardized guidelines[3]: patients were at least 10 years of age, diagnosed with AIS with no prior treatment, had a Risser sign for skeletal maturity between 0 and 2 and a primary curve angle between 20° and 45° to account for angle measurement variability.[29,30] The study protocol was approved by the hospital's ethical committee and all participants gave their written consent.

Clinical visits

At the initial visit, patients' height and weight were measured and Risser level was determined by their treating orthopedist. Biplanar radiographs in the coronal and sagittal planes were simultaneously acquired using a calibrated low-dose digital radiography system (EOS, EOS-Imaging, Paris, France). A 3D scan of the external torso geometry was also taken using a surface topography system (3D Capturor II LF, Creaform Inc., Levis, Canada). Patients completed an initial quality of life outcome questionnaire (SRS-22r) before being assigned into the control (CAD) or test (CAD-FEM) subgroup following a block randomization sequence (block size 4) prepared by a biostatistician external to the study. At the end of the visit, patients, families, and orthotists were informed of the randomization assignment while other caretakers and researchers were kept blinded. Experienced orthotists then designed and manufactured the brace following a different protocol for each subgroup, detailed below (Figure 1). All braces were prescribed to be worn between 20 and 23 hours/day, and compliance was tracked using a temperature sensor (iButton, Boston Brace, USA) installed in each orthosis before its delivery.[30]

At each follow-up, biplanar radiographs were taken. The treating orthopedist assessed the evolution of the deformity and asked the orthotists for minor adjustments on the existing brace or, if necessary, for a new one following the assigned subgroup's protocol. Temperature data were collected, and patients completed an SRS-22r follow-up questionnaire.

Brace design for the CAD subgroup

One of the two participating orthotists uploaded the patient's torso scan in a CAD software (Rodin4D, Merignac, France). He/she designed a TLSO brace following his/her experience by symmetrizing the trunk, adding pressure or relief areas and sculpting the shape. The final model was exported to a numerical milling machine (Model C, Rodin4D) that carved a polyurethane foam block for subsequent thermoforming. Upon delivery to the patient, the orthotist added foam pads to maximize the biomechanical action of pressure areas, and manually adjusted the fit to improve correction and comfort.

Brace design for the CAD-FEM subgroup

As described by Cobetto et al,[27] the patient's biplanar radiographs were used to build a 3D reconstruction of the spine, rib-cage and pelvis.[31] Affixed fiducial radiopaque markers visible on the X-rays and on the torso scan were used to register the internal and external geometries, which were then imported in the Ansys 14.5 software (Ansys Inc., Canonsburg, PA, USA) to create a patient-specific FEM.[24,28] Intervertebral discs and osseous structures such as thoracic and lumbar vertebrae, ribs, sternum, and pelvis were represented by 3D elastic beam elements. Ligaments, soft tissues and joints were modeled by tension-only springs. External soft tissues and their interaction with the brace were represented by shells and surface-to-surface contact elements respectively. Mechanical properties of all anatomical structures were taken from cadaveric studies and an estimation of patient flexibility was factored in. A

previously described optimization process computed the gravitational and stabilizing forces to obtain a loaded geometry corresponding to the standing X-rays.[23]

One of the two participating orthotists designed a first version of the brace as described for the CAD cohort. The brace geometry was then imported in the FEM and modeled by quadrilateral linear elastic shell elements with the mechanical properties of polyethylene, and a surface-to-surface contact interface with friction for the interface between the torso and the interior of the brace.[23] The donning and full tightening of the brace was simulated. The program computed the in-brace 3D geometry of the spine with associated deformity measurements, the pressures exerted on the trunk, and the skin-to-brace distances. Results were reported via a graphical user interface. This previously validated FEM was shown to appropriately simulate a correction within 5° of the in-brace radiographic Cobb angle.[25]

The orthotist then modified the design according to his/her interpretation of the results and simulated it again, aiming to increase correction with appropriate pressures on the torso, to avoid the use of an inner lining, and to create large openings in areas distant by more than 6mm from the skin since their biomechanical contribution to the correction was considered negligible.[27] The final design was manufactured similarly to the CAD braces. At delivery, adjustments were made to ensure comfort and fit, but no corrective pads were added since the depth of pressure points had already been determined numerically.

Measurement and analysis of brace effectiveness

Biplanar radiographs were taken at three time-points: 1) out-of-brace at the initial visit before the start of treatment; 2) in-brace at brace fitting; 3) out-of-brace at the 2-year visit (25±4 months). Clinical outcomes were evaluated following SRS criteria.[3] In-brace corrections were calculated by subtracting the initial measurements with their subsequent corresponding values.

Coronal main thoracic (MT) and thoraco-lumbar/lumbar (TL/L) Cobb angles were measured blindly by a trained observer,[32] and further validated by three additional ones until consensus. Three-Dimensional reconstructions at each time-point were built by a blinded expert and validated by a second for all subjects in both subgroups. T4-T12 thoracic kyphosis (TK) and L1-L5 lumbar lordosis (LL) were computed along with the vertebral axial rotation (AR) at each curve's apex, defined as the angle between the frontal plane and the vector joining the center of the pedicles, projected on the transverse plane. Considering the documented accuracy of 4.5°,[33] apical rotations with initial values under 2° were neglected.

Mean hours of brace worn by each patient were calculated and tracked over the 2-year period. Average daily wear was analyzed for the timespans between fitting and the first follow-up, and between the 2-year visit and the one prior. SRS-22r scores at the 2-year visit were compared to the initial ones.

Paired and two-sample bilateral Student's t-tests (95% significance level) evaluated the statistical significance of differences observed respectively between the initial and the 2-year visit, and between each subgroup.

Results

Patient populations

Five patients withdrew voluntarily from the study. Thirteen were removed because of a subsequent spondylolisthesis diagnosis. One was removed because of an initial Risser level corrected to 3, one was removed because of infantile scoliosis misdiagnosis and two were lost during follow-up. Four cases (3 CAD-FEM, 1 CAD) received surgery before their two-year visit and were therefore considered in the treatment outcome assessment but not in other analyses. In the end, 44 and 50 patients in the CAD-FEM and CAD subgroups were kept respectively. At the initial visit, both cohorts were similar in terms of age (13yrs [10,16]), weight (43kg [27,88]), height (153cm [134,178]), and Risser [0,2].

Curve evolution and 3D correction

For all patients, the resulting out-of-brace average MT Cobb had increased at the 2-year visit (31°[9,67], p=0.002), as compared to the pretreating deformity. Differences observed in all curves and rotations in the three planes were not statistically significant except for LL which was higher for the CAD-FEM subgroup at the 2-year follow-up (55°[37,71] CAD-FEM vs 49°[16,80] CAD, p=0.01) (Table 1).

Sixty-six percent of all cases had a 2-year out-of-brace Cobb angle that improved or did not progress >5° (Table 2). 34% progressed >5° but 16% were still below 45°; therefore, 83% of all cases were <45° out-of-brace at two years. Overall, 11 patients (11%) required surgical treatment, of which 3 CAD-FEM subjects received an Anterior Vertebral Body Growth Modulation (AVBGM) before they reached 45° and 2 CAD subjects received an AVBGM over 45°. Therefore, only 6 patients (6%) overall (5 CAD-FEM, 1 CAD) underwent instrumentation and fusion surgery.

All curves and rotations were reduced in-brace for all patients (reduction of MT Cobb: 9°[-9,21](32%), TL/L Cobb: 12°[-4,28](46%), TK: 4°[-23,25], LL: 9°[-14,41], MT AR: 2°[-7,16], TL/L AR: 3°[-7,15]; a negative value mean an increase in curve/rotation severity). After two years, out-of-brace deformity reductions were within 4° on average for all patients (reduction of MT Cobb: 3°[-37,12], TL/L Cobb: 0°[-36,18], TK: 1°[-20,20], LL: 2°[-25,28], MT AR: 0°[-17,10], TL/L AR: 1°[-16,11]). None of the differences between the two subgroups were statistically significant (Table 3).

Compliance

Two patients in each subgroup had faulty compliance data due to a recording malfunction and were removed for the analysis. The daily brace mean wearing time for the 90 remaining patients was 13.4±5.9 hours (64% compliance) and similar in both subgroups (Table 4). Over the 2-year period, 16% of patients wore their brace on average more than 20 hours/day, 29% between 15-20 hours/day, 24% between 10-15 hours/day and 31% less than 10 hours/day. Average wear was 14.6 hours/day in the first recorded timespan between brace fitting and first follow-up (5.7±1.6 months). It dropped steadily over time to reach a significantly lower

average of 11.8 hours/day (p<0.001) at the last recorded timespan between the 2-year visit and the one prior (6.9±1.3 months). The recorded compliance was not statistically different between the subgroups.

Quality of life

Initial SRS-22r scores were similar in both cohorts, except for the mental health domain (4.35±0.50 (CAD-FEM) vs 4.06±0.70 (CAD), p=0.01) (Table 5). Overall SRS-22r scores in all categories did not vary significantly between the initial and the 2-year visit. Only in the self-image/appearance domain did patients from the CAD subgroup scored significantly higher at the 2-year visit than at the initial one (4.01±0.58 vs. 3.83±0.54, p=0.048). After two years, scores averaged 4.20±0.46 with no statistical difference measured between the subgroups in all domains.

Discussion

This study is the first to evaluate the efficacy of CAD/CAM approaches with and without FEM after two years of treatment. The presented FEM is also, to our knowledge, the only one to be clinically integrated in the brace creation process.

The documented outcomes are consistent with similar published studies,[5,34] although comparisons are difficult to establish due to discrepancies between protocols and methodologies. Studies adhering to SRS criteria reported rates of progression (>5°) for rigid TLSOs ranging from 30% to 85%,[35,36] with most remaining around 40%, similarly to our results.[37-39] In a multicentric RCT (BrAIST study), Weinstein et al. showed that 28% of patients who underwent bracing progressed to 50° or more before skeletal maturity,[4] which is higher than our 17% using a more conservative threshold of 45°. A systematic review by Dolan et al. pooled surgical rates during bracing at 23% ranging from 12 to 41% for Boston-type TLSOs,[40] which is also higher than our 11% overall rate with 6% of spinal fusion. However, some subjects did not yet reach skeletal maturity after two years of bracing, so rates of progression and surgery could possibly increase before all patients end their treatment.

CAD-FEM braces (CAD/CAM+FEM) were not found to be different from CAD braces (CAD/CAM) in terms of clinical efficacy and 3D correction. Similarly in both subgroups, the main corrective action was in the coronal plane where thoracic main curves progressed more frequently than lumbar ones, with the increased stiffness[41] added by the rib cage impeding proper correction in turn compromising long-term effectiveness.[21] In the sagittal plane, TK and LL were initially reduced in-brace but ended up similar to the initial curvatures after two years, which differs from old findings of Labelle et al.[1] reporting early anti-kyphotic and anti-lordotic designs of the Boston brace. LLs were significantly greater for the CAD-FEM vs. CAD subgroup (p<0.05) after two years: CAD-FEM braces successfully maintained a higher lordosis over the documented period. In the transverse plane, we measured only a slight immediate correction, which has been often reported in studies assessing the 3D effectiveness of braces.[10,20,28,42]

FEM simulations allowed the removal of unnecessary material, leading to the creation of lighter braces with large openings. However, it did not affect the compliance and quality of life measurements, which remained similar for both subgroups. The average compliance of 64% is consistent with some previously published results using similar temperature-logging sensors (69.9% reported by Rahman et al[43]; 77.5% by Takemitsu et al[44]), and better than others (47% measured by Morton et al[45]; 27%-35% by Katz et al[8]). In Katz's study, the highest overall recorded average wear was 9.1 hours/day for non-progressive patients (<6°), with 10.2 hours/day in the first year and 7.1 hours/day in the subsequent ones. Similar trends were observed in our study but with a higher recorded compliance that might be related to braces' improved design features. Weaning may also have contributed to the decline of brace wear over time, since some patients ended their treatment soon after two years. Donzelli et al[46] reported 91.7% compliance, which could be related to a patient-centric team management strategy not included in our study. The merging of an ideally designed brace with a comprehensive multidisciplinary follow-up is an interesting avenue to explore to improve compliance and the overall performance of bracing.

SRS-22r outcomes were globally satisfying with total scores above 4.1/5. Evolutions and differences between cohorts fall below the minimum clinically important difference previously established by Crawford et al[47]. Quality of life metrics are difficult to compare, and questionnaire scores in different treatment groups often result in non-significant differences[4].

This study has several limitations. One of them is the bias coming from the orthotists who also participated in the previous development of the FEM integrated in the CAD/CAM software[25,26]. The knowledge gained from its extensive use may have positively impacted their overall design skills. Furthermore, adjustments permitted only in the CAD orthoses, such as the addition of pads, allowed for an immediate slightly higher relative correction in the thoracic region, which difference was not maintained over time. Similar adjustments at delivery combined with simulation might be an interesting avenue to further improve brace effectiveness. The evolution of practices is another limitation: in our center, AVBGM surgery was offered to patients over 40° with sufficient remaining growth potential. As a result, five subjects switched to AVBGM treatment even if bracing was not completed or the principal curve did not reach 45°.

Overall, a CAD/CAM approach with or without added improvement steps through a patient-specific FEM has shown value. Relying on validated biomechanical simulations to guide design choices should result in treatments of more consistent quality, not entirely dependent on orthotist skill and caregiver expertise. The advantages of simulating and predicting the effect of braces before their fabrication already enabled to improve their design[27], but the full capacity to determine the optimal correction, combined with a comprehensive interdisciplinary management of the treatment, remains to be established.

Braces designed using CAD/CAM with or without FEM induced adequate immediate in-brace corrections that limited curve progression over two years.

Patients treated with braces designed through CAD/CAM with or without FEM present similar or better clinical outcomes than the ones in previously reported clinical trials like the BrAIST study.

Brace-wear compliance was clinically satisfactory and comparable with similar previously published studies.

Quality of life (SRS-22r scores) did not vary significantly over two years for all patients, in every domain.

Adding FEM refinement steps created lighter, thinner braces with less covered surface on the torso, but did not significantly impact immediate 3D correction, long-term deformity evolution, brace-wear compliance nor total SRS-22r scores.

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Figure 1: Brace design and follow up protocol for the CAD/CAM (CAD) and the CAD/CAM+FEM (CAD-FEM) subgroups

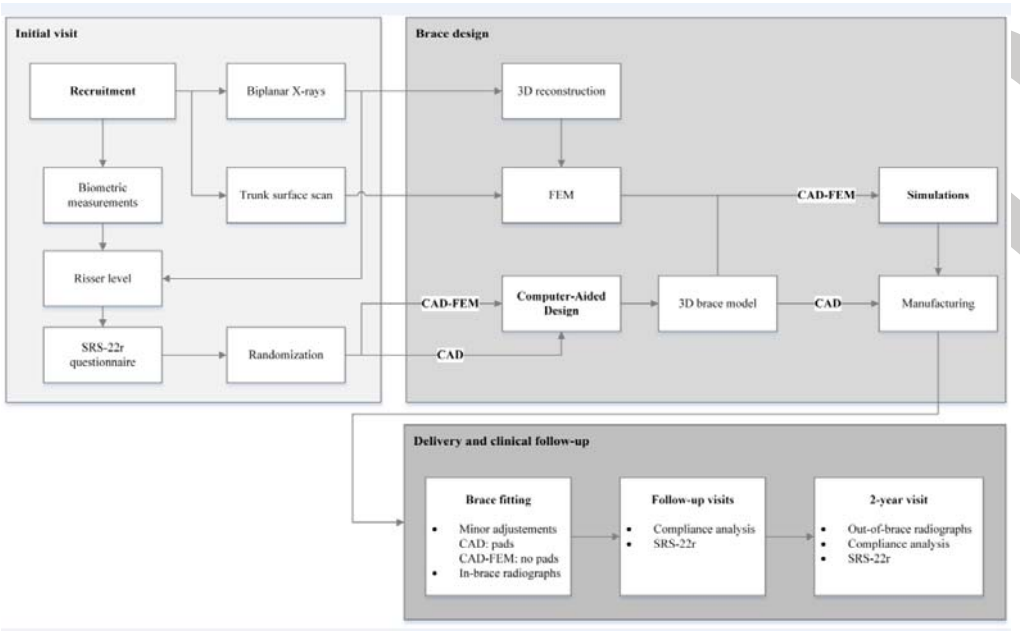

Table 1: Out of brace patient data at initial and 2-yr visits: average values ± std; all rangula measurements are in degrees. Statistically significant p-values (p<0.05) marked with *.

	ALL patients; N = 94			CAD-FEM group; N = 44			CAD group; N = 50			CAD-FEM vs. CAD	
	initial	2-yr	p	initial	2-yr	p	initial	2-yr	p	initial p	2-yr p
Cobb – MT	28 ± 7	31 ± 12	0.002*	28 ± 8	32 ± 13	0.009*	28 ± 6	30 ± 11	0.07	0.87	0.59
Cobb – TL/L	26 ± 7	25 ± 11	0.80	26 ± 6	27 ± 12	0.81	25 ± 7	24 ± 10	0.48	0.43	0.36
TK – T4-T12	27 ± 11	26 ± 11	0.24	29 ± 11	27 ± 11	0.11	26 ± 12	26 ± 11	0.96	0.16	0.50
LL – L1-L5	54 ± 13	52 ± 12	0.05*	56 ± 9	55 ± 9	0.25	51 ± 15	49 ± 13	0.10	0.05	0.01*
Apical rotation – MT	8 ± 4	8 ± 6	0.74	8 ± 5	8 ± 7	0.50	7 ± 4	8 ± 6	0.75	0.57	0.98
Apical rotation – TL/L	9 ± 4	8 ± 6	0.16	9 ± 5	8 ± 6	0.18	8 ± 4	7 ± 6	0.56	0.43	0.92

Table 2: Treatment outcome after two years: number of patients (% of population)

Treatment status	Criteria of effectiveness - Principal curve	ALL patients; N = 98	CAD-FEM group; N = 47	CAD group; N = 51
Improved	Cobb angle reduction > 5° (2-yr vs. initial)	24 (24%)	11 (23%)	13 (25%)
Unchanged	Cobb angle ± 5° (2-yr vs. initial)	41 (42%)	19 (40%)	22 (43%)
Progressed	Cobb angle progression > 5° (2-yr vs. initial)	33 (34%)	17 (36%)	16 (31%)
Failed	≥ 45° at 2 years	17 (17%)	9 (19%)	8 (16%)
	Surgery (AVBT or fusion)	11 (11%)	8 (17%)	3 (6%)

Table 3: Immediate (in-brace) and 2-year (out-of-brace) corrections in the three planes: average values ± std; statistically significant values marked with *. All angles are in degrees. A negative value means a worsening.

			ALL patients; N = 94	CAD-FEM group; N = 44	CAD group; N = 50	CAD-FEM vs. CAD p-value
Immediate in-brace	Coronal deformity correction	MT Cobb	9 ± 6	8 ± 7	10 ± 5	0.05
		TL/L Cobb	12 ± 6	12 ± 6	12 ± 7	0.91
	Sagittal curve reduction	T4-T12 TK	4 ± 8	5 ± 7	4 ± 9	0.43
		L1-L5 LL	9 ± 10	9 ± 9	10 ± 11	0.70
	Transverse apical rotation reduction	MT	2 ± 5	2 ± 5	2 ± 4	0.67
		TL/L	3 ± 4	3 ± 5	3 ± 4	0.85
2-year out-of-brace	Coronal deformity correction	MT Cobb	-3 ± 10	-4 ± 10	-3 ± 9	0.43
		TL/L Cobb	0 ± 8	0 ± 9	1 ± 7	0.55
	Sagittal curve reduction	T4-T12 TK	1 ± 7	2 ±7	0 ± 7	0.24
		L1-L5 LL	2 ± 10	2 ± 10	2 ± 10	0.80
	Transverse apical rotation reduction	MT	0 ± 5	1 ± 6	0 ± 5	0.46
		TL/L	1 ± 5	1 ± 6	0 ± 5	0.51

Table 4: Compliance tracking results and patient distribution for average daily wear time: average values ± std; statistically significant p-values marked with *; number of patients (% of population)

	ALL patients N = 90	CAD-FEM group N = 42	CAD group N = 48	CAD-FEM vs CAD p-value
Daily wear (hrs) – 2 years	13.4 ± 5.9	13.3 ± 5.8	13.6 ± 6.0	77 0.
Daily wear (hrs) – first recorded timespan	14.6 ± 6.2	15.0 ± 6.0	14.3 ± 6.3	0.60
Daily wear (hrs) – last recorded. timespan	11.8 ± 6.8	11.0 ± 6.7	12.5 ± 6.8	0.37
First vs last recorded. timespan p-value	< 0.001*	< 0.001*	0.04*	-
n > 20 hrs/day	14 (16%)	4 (10%)	10 (21%)	-
15 < n < 20 hrs/day	26 (29%)	14 (33%)	12 (25%)	-
10 < n < 15 hrs/day	22 (24%)	11 (26%)	11 (23%)	-
n< 10 hrs/day	28 (31%)	13 (31%)	15 (31%)	-

Table 5: SRS-22r scores: average values ± std; statistically significant p-values marked with *

	ALL patients; N = 94			CAD-FEM group; N = 44			CAD group; N = 50			CAD-FEM vs CAD	
	initial	2-yr	p	initial	2-yr	p	initial	2-yr	p	initial p	2-yr p
Total score	4.19 ± 0.39	4.20 ± 0.46	0.68	4.26 ± 0.34	4.25 ± 0.40	0.78	4.12 ± 0.42	4.16 ± 0.51	0.44	0.08	0.37
Function/activity	4.34 ± 0.42	4.34 ± 0.42	0.91	4.38 ± 0.45	4.38 ± 0.37	0.94	4.31 ± 0.39	4.30 ± 0.46	0.83	0.37	0.32
Pain	4.39 ± 0.58	4.43 ± 0.57	0.51	4.40 ± 0.51	4.48 ± 0.52	0.45	4.38 ± 0.65	4.39 ± 0.61	0.91	0.84	0.45
Self-image/appearance	3.91 ± 0.54	4.00 ± 0.57	0.18	4.01 ± 0.54	3.98 ± 0.57	0.80	3.83 ± 0.54	4.01 ± 0.58	0.05*	0.38	0.84
Mental health	4.19 ± 0.63	4.12 ± 0.75	0.29	4.35 ± 0.50	4.23 ± 0.62	0.22	4.06 ± 0.70	4.03 ± 0.84	0.77	0.01*	0.20
Satisfaction	3.90 ± 0.69	3.99 ± 0.78	0.34	4.02 ± 0.67	4.02 ± 0.81	1.00	3.80 ± 0.70	3.97 ± 0.77	0.15	0.28	0.75