Biomechanical Evaluation of Experimental Prostheses

5

5.1 Purpose of Biomechanical Evaluation

We covered in Chaps. 1–3 the role and place of biomechanical research in the process of developing the initial hypotheses and selecting the key characteristics of a new prosthetic device. The designer is better equipped for more efficient work when he uses a biomechanical filter. Once the prototyping and mechanical tests are completed, the stage of evaluation with real patients begins. The safety and effectiveness of a new prosthesis are the two major issues to be addressed by the evaluation.

Safety relates to the mechanical integrity of the device while in use by the patient. It also relates to functional safety. If, for example, a prosthetic knee is not locked adequately during weight bearing, the patient may collapse even with the mechanically intact prosthesis. Another aspect of functional safety is the long-term effect of a new prosthesis on gait and other types of performance. If the use of the new prosthesis results in excessive pressures on the amputee stump, the patient typically develops certain compensatory strategies to avoid overpressure and pain. Such strategies may lead to an overload on the contralateral limb or spine, damage to the joints, and the development of contractures, which also mean insufficient safety. This aspect of functional safety is difficult to distinguish from effectiveness because both categories deal with the performance of the user.

Analysis of stump–socket pressures and forces, as well as the analysis of gait kinematics and dynamics is the component of biomechanical evaluation, which can be conducted for the purpose of both functional safety and effectiveness of the new prosthesis. The problems that have to be addressed in planning the evaluation of the prototype of prosthesis are:

- Is the prototype mechanically safe if tested by a subject?
- What are the characteristics of the functional safety and effectiveness of use by the subject?
- How will the characteristics of effectiveness be measured?
- How will the data be analyzed and interpreted?
- What kinematic and dynamic parameters objectively measured during gait with RJFA (Rolling Joint Foot and Ankle) and conventional prostheses were different, if any?

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- Does the study confirm the initial hypothesis on a link between the prosthesis's design and comfort?
- Which parameters could be predictors of performance?
- Which parameters could be suggested for manufacturing to ensure quality?

5.2 Biomechanical Testing of RJFA

The hypothesis behind the design and development of the Prosthetic RJFA was that a more anatomical moment of resistance in the prosthetics ankle would enable lower limb amputees to ambulate with greater comfort and less pain and fatigue.

During gait at the Gait Laboratory, Peak Motus Motion Analysis System[1] produced kinematic and dynamic data. A Portable Kistler Force Plate was integrated in the Peak system for calculating moments in joints and other dynamic characteristics. Two F-socket sensors were placed on the anterior and posterior surfaces of the stump, and their position did not change when the subject changed the prosthesis. The subjects were asked to walk with their conventional prosthesis and with the RJFA, and to provide a subjective evaluation of the comfort levels with both the prostheses.

Twenty volunteers with transtibial amputations participated in the biomechanical gait trials. The performance of the new *RJFA* was compared with that of the conventional prosthetic feet. Among adults, there were 12 males with an average age of 46.4 years (max – 77, min – 25), and five females with the average age of 48.8 (max – 58, min – 37). One girl of 15 years, and two boys aged 15 and 16 yearsalso participated in the study. The subjects were asked to read and sign an Informed Consent Form approved by the Tufts University and New England Sinai Hospital *Human Investigation Review Boards*. Biomechanical data on ten normal subjects were collected for further comparison with the gait of amputee subjects.

5.2.1 Knee Performance

Statistically significant difference with 95% confidence was found in the angle of knee bending during stance period of gait (Fig. 5.1) when comparing bending in the anatomical knee of the involved leg in transtibial amputees. Observation of data (Fig. 5.1) shows that with the RJ Foot and Ankle prosthesis, maximal angle of flexion in the anatomical knee was closer to normal target (15°) than in SACH and College Park feet. Improvement in knee performance occurred immediately and did not require any training in using the RJ prosthesis.

[1]Peak Performance Technologies, Inc., Englewood, CO.

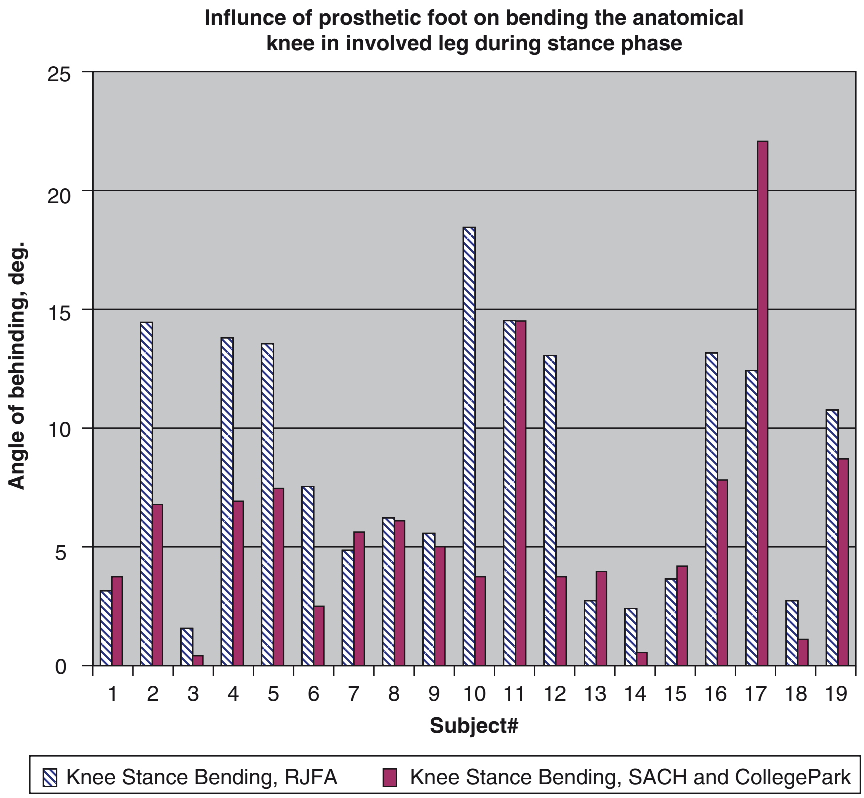

Fig. 5.1 Stance knee flexion while walking with Free-Flow Foot and Ankle, *College Park Foot, and SACH foot*

At the time of trials, pressure/force interface between stump and socket was recorded by Tekscan system.

5.2.2 Forces and Pressures on Residuum

During gait, the amputee's stump transfers loads to the prosthetic leg trough the socket. These loads deform the prosthesis, especially in stance period. The prosthesis resists to the deformation. The pattern of that resistance (moment of resistance to deflection or resistive moment) determines the forces applied backwards to the amputee's stump from the prosthesis by its socket. Excessive forces applied to the stump cause discomfort, fatigue, and pain, as well as skin and tissue complications.

F-socket sensors and the Tekscan Pressure Distribution Measurement System, Tekscan, Inc., South Boston, MA, were used to recording forces applied to the stump during gait.

Paper-thin sensors with 96 independent resistive cells were placed between the stump and socket as shown in Fig. 1.17. After recording data during gait with the subject's existing prostheses, a certified prosthetist installed the *RJFA* without changing the position of the F-sensors. Comparison of forces was conducted as follows. Forces from the first and last steps were omitted since they reflected the initiation and the ending of the pace. A mean of at least three peaks was calculated for both trials with the existing prosthesis and the *RJFA*. The ratio of the existing prosthesis' force means to the RJFA force means, as a percent, was used as an index of influence of prosthetic foot design on the forces and pressures applied to residuum. The methodology allowed us to compensate for the placement sensitivity of Tekscan technology. (If the sensor's position relative to the stump changes during the trial, one should not compare directly data collected.) Typical comparison for one patient who came to the trial with his *College Park* foot is presented in Fig. 5.2. As seen from Fig. 5.2, gait with *RJFA* was associated with fewer forces applied to the anterior surface of the stump when compared to gait with *College Park Foot*. That decrease correlated with the more comfortable performance reported by the subject. How *RJFA* decreased forces on the posterior surfaces of the stump, when compared to gait with SACH foot is seen from Fig. 5.3.

Averaged ratios, percentage of the force, pressure, and peak pressure on anterior and posterior surfaces of the stump for both types of the subjects' existing prosthetic feet are plotted in Fig. 5.4.

Statistical significances of differences (decrease) in these parameters are presented in Table 5.1. From the t-test criterion, the decreases in anterior and posterior force with the *RJFA* when compared with College Park foot, and in anterior force and posterior peak pressure when compared with SACH foot, should be considered statistically significant.

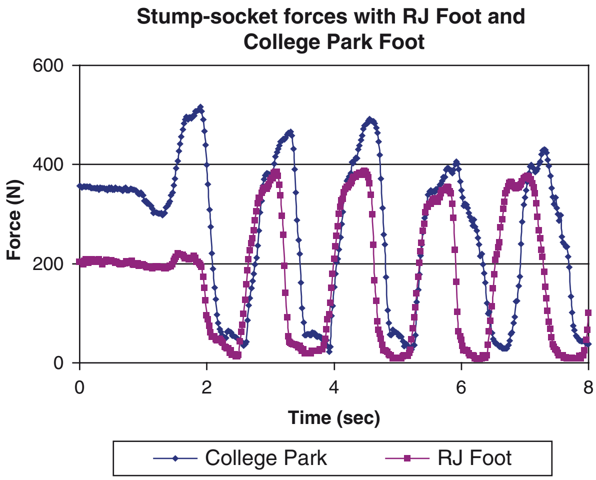

Fig. 5.2 Force applied from socket to the residuum recorded on the posterior F-socket Tekscan sensor during gait of the same with *RJ Foot and College Park foot*. Position of the sensors was unchanged

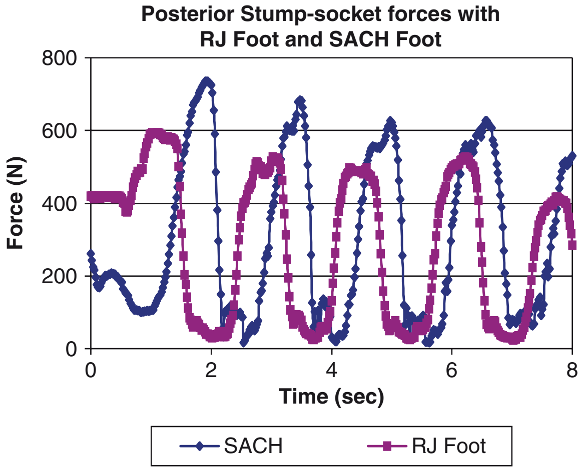

Fig. 5.3 Force applied from socket to the residuum recorded on the posterior F-socket Tekscan sensor during gait of the same with *RJ Foot and SACH foot*. Position of the sensors was unchanged

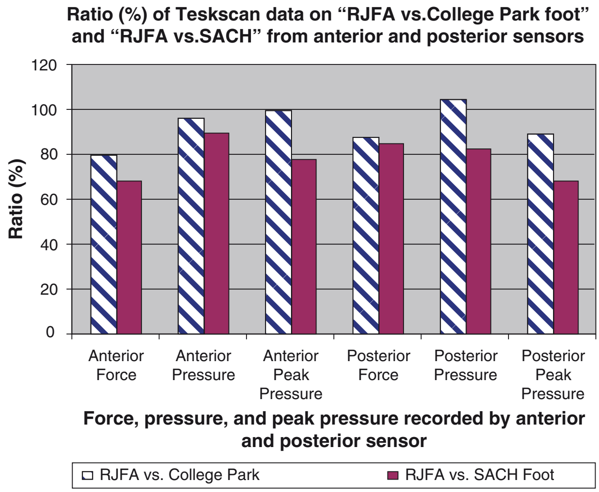

Fig. 5.4 Ration of *forces*, *pressures*, and *peak pressures* on anterior and posterior Tekscan sensors during gait with *RJ Foot and Ankle, College Park foot, and SACH* foot

Table 5.1 Statistical significance* of decrease in force, pressure, and peak pressure on anterior and posterior surface of stump with the RJFA (rolling joint foot and ankle) vs. college park and SACH feet

Type of prosthesis compared with RJFA	Anterior F-socket sensor			Posterior F-socket sensor		
	Force	Pressure	Peak pressure	Force	Pressure	Peak pressure
College park	+(−3.15)	–	–	+(−3.29)	–	–
SACH	+(−3.46)	–	–	–	–	+(−3.62)

*A decrease is considered significant (+) if the t-test value is greater than the t-test threshold

5.2.3 Moment of Dorsiflexion

Moment – angle of dorsiflexion dependencies for the RJFA the College Park foot, and SACH foot are plotted with those obtained for the normal subjects (Pitkin 1999). During the weight bearing event, the ground reaction reaches its first maximum, as well as the forces and pressures applied to the stump. The weight-bearing events are marked with a circle on each of three curves in Figs. 5.5 and 5.6. It is seen from the charts that the value of the moment of resistance in RJFA is lower during weight bearing, than in the College Park and even more notably lower than with the SACH foot.

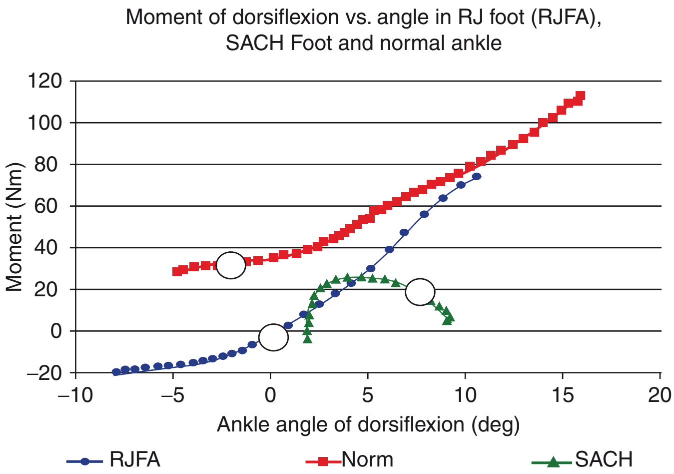

Fig. 5.5 Moment of dorsiflexion in norm, with *SACH foot*, and with *RJ Foot* and *Ankle*. Maximal load bearing event for each trial marked with a *small circle*

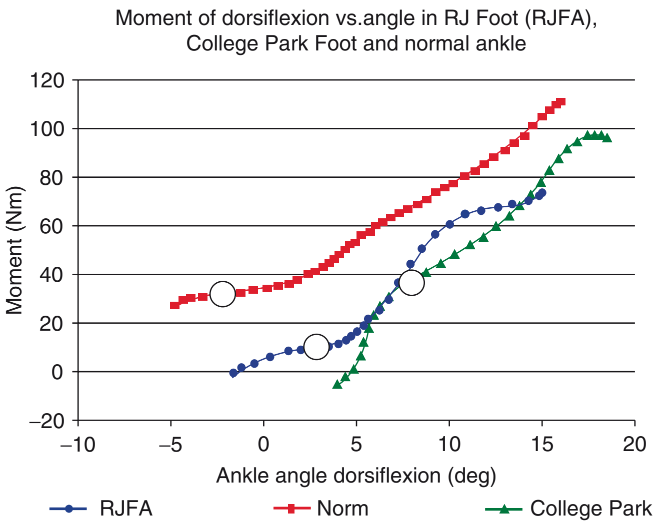

Fig. 5.6 Moment of dorsiflexion in norm, with *College Park foot*, and with *RJ Foot* and *Ankle*. Maximal load bearing event for each trial marked with a *small circle*

5.2.4
Biomechanical Testing of RJFA with Adjustable Stiffness

As described in Sect. 4.2.1.1, the *Free-Flow Foot and Ankle* prosthesis has a mechanism for tuning the initial stiffness in the ankle. Tuning screws 1 (Fig. 4.8) tighten or loosen the bracket, which keeps together the tibial and talar parts of the assembly. That tuning can be performed by a prosthetist working with the patient. A study was conducted whose aim was to develop a practical methodology for prosthesis' adjustment. Tekscan technology was used for recording the force/pressure on amputee residuum during gait with *Free-Flow Foot and Ankle* for developing instructive feedback. Data processing using relative indexes of performance (Pitkin 1999) surpassed the limitations of the measurement procedure.

Adjustment of prosthesis with tuning mechanisms involves an iterative "patient–prosthetist" interaction. However, when sensitivity in the amputee's residuum is reduced, the prosthetist cannot rely on his/her pain-based feedback in the fitting and adjusting process (Levy 1983). This diminishes the options for fine-tuning a prosthesis, even if the feature is a part of the design. Suboptimal tuning can be an additional source of damage to the tissues and skin of the residuum because of its overloading. A prosthesis should have a feature for gradual and controlled change (tuning) of a specific critical parameter (Seelen et al. 2003). Second, each episode of tuning should have an option to be objectively recorded and used for continuing and finalizing the procedure.

We are going to discuss now a methodology of adjustment of initial tension in the *Free-Flow Foot and Ankle* that has a mechanism affecting the moment of resistance to plantar/dorsiflexion (Pitkin et al. 2001). For a feedback signal, force/pressure on the amputee residuum during gait was recorded with Tekscan technology.

The *Free-Flow Foot and Ankle*, used in this study, represents a class of Rolling Joint prostheses (Pitkin 1994, 1995; Pitkin et al. 2001). That class is characterized by employing a higher pair connection of the moving parts (Pitkin 1997). A top view of the control mechanism of the *Free-Flow Foot and Ankle* is shown in Fig. 5.7.

By turning the side medial and lateral screws 1–2, the prosthetist changes the moment, and consequently, the forces applied on the amputee's residuum from the socket. The level of compression, which is set up by the prosthetist, determines the initial moment of resistance to plantar/dorsiflexion to the ankle deflection during gait and other types of performance (Pitkin 1998).

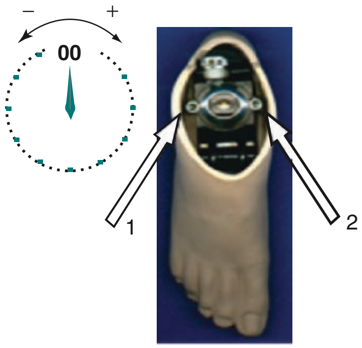

Fig. 5.7 *Top view* of the sided medial and lateral screws *1–2* used for tuning the initial moment of resistance to dorsiflexion in Free-Flow Foot and Ankle

The initial hypothesis was that the peaks of the local pressures on the residuum are responsible for pain and discomfort during gait, and that reduction of these peaks can decrease pain and consequently increase comfort. It was hypothesized further that if peaks could be minimized by tuning the *Free-Flow Foot and Ankle*, the corresponding setting would result in the most comfortable gait.

To verify these hypotheses, the following protocol was developed. Four F-Socket™ 9811 sensors were placed within the socket. The locations of the sensors were not changed during the entire session. Peak pressures on each sensor were collected every 1/60 of a second. Data were exported to Microsoft Excel for further analysis.

The first trial was conducted with the neutral position of the side screws installed by the manufacturer. That position is marked as *OO* in the clock indicators in Fig. 5.7. Then, the certified prosthetist installed screws in three consecutive tightened and loosened positions by screwing or unscrewing them at one revolution. Forces on residuum were recorded for each screw's position. After recording data during gait with the subject's existing prostheses, the certified prosthetist installed the *Free-Flow Foot and Ankle* without changing the position of the F-socket sensors. Overall, seven positions of the side screws in both directions were provided consecutively. With each position of the screws, the subject walked at a comfortable speed along the walkway with four Tekscan sensors between his/her stump and the socket.

The subjects were asked to inform the investigators if one of the screws' positions provided more comfort than others. A trial with the most comfortable gait was marked as such and served as a reference for further comparison.

Twenty unilateral below-knee amputees were enrolled in the biomechanical study at the biomechanics laboratory at the Albrecht Center for Prosthetics and Rehabilitation, St. Petersburg, Russia[2]. Before the trials, each participant read and signed a consent form, approved by the Ethics Committee of the Center and the Institutional Review Board of Tufts University. The subjects reported which position of the screws corresponded to their subjective comfort or discomfort.

Similar to the procedure developed elsewhere (Pitkin 1999), for every *i*th text trial corresponding to a consecutive turn of the tuning screws, we identified five greatest maximal values in peak pressure series from each of the four sensors (*anterior, posterior, medial,* and *lateral*). We calculated the mean maximal values $P_{ant}^{(i)}, P_{post}^{(i)}, P_{med}^{(i)} \; P_{lat}^{(i)}$ and the Indexes of Performance (IP) as the ratios in formulas (5.1):

$$IP_{ant} = \frac{P_{ant}^{i}}{P_{ant}^{comf}}, \; IP_{post} = \frac{P_{post}^{i}}{P_{post}^{comf}}, \; IP_{med} = \frac{P_{med}^{i}}{P_{med}^{comf}}, \; IP_{lat} = \frac{P_{lat}^{i}}{P_{lat}^{comf}}, \qquad (5.1)$$

where $P_{ant}^{comf}, P_{post}^{comf}, P_{med}^{comf}, P_{lat}^{comf}$ related to the trial, which was selected by a subject as the most comfortable.

We determined the statistical significance of the differences between the Indexes of Performance of any given trial and those of the "comfortable" trial. We used a two-sample t-test assuming unequal variances. By definition (5.1), the null hypothesis of "no differences" corresponded to the case when the values of all Indexes equal 1.

[2]The study was partially supported by a CRDF Grant RB1-2382-ST.

For turning the adjustment screws, we used a Mini Click-Style Adjustable Torque Wrench, Model 5853A11[3] (Fig. 5.8), which allows for measuring the torque to be applied to the screw to complete a given turn. At every position of the screws, a subject was asked to evaluate the comfort of the gait using the 10-grade scale, and the corresponding values of a torque on the screws were collected.

The total number of successful trials was 131, including 106 trials with *Free-Flow Foot and Ankle* and 25 trials with the subjects' own feet (Energia 9A010; Energia 9A010.1[4]; Otto-Bock Dynamic 1D10; Otto-Bock Dynamic 1D11[5]; Otto-Bock SACH 1 S70). Results of the two-sample t-test for mean values of the Indexes of Performance are presented in Table 5.2. Indexes of performance calculated for each of four sensors were compared with the Index of Performance for comfortable gait (IP_{comf}) in the right-most column. By

Fig. 5.8 A torque wrench was used to change and to record the pretensed moment of resistance to the ankle's deflection

Table 5.2 t-Test: two-sample t-test assuming unequal variances for indexes of performance on the tekscan sensors when compared with the comfortable gait

Parameters of t-test	IP for anterior sensor (IP_{ant})	IP for posterior sensor (IP_{post})	IP for lateral sensor (IP_{lat})	IP for medial sensor (IP_{med})	IP for comfortable gait (IP_{comf})
Mean	1.07	1.00	1.04	1.17	1.00
Variance	0.07	0.07	0.20	0.49	0.00
Observations	131.00	131.00	131.00	131.00	131.00
df	130.00	130.00	130.00	130.00	
t-Stat	2.88	−0.10	1.07	2.86	
P(T≤t) one tail	0.00	0.46	0.14	0.00	
t Critical one-tail	1.66	1.66	1.66	1.66	
P(T≤t) two-tail	0.00	0.92	0.29	0.00	
t Critical two-tail	1.98	1.98	1.98	1.98	

[3]McMaster-Carr, Dayton, NJ.
[4]Joint Stock Company "Orthopedic Industry Moscow Energy" (JSC OIME): www.oime.ru.
[5]Otto Bock, 119334, Moscow, Russia: www.ottobock.ru.

definition, $IP_{comf} = P_{comf}^{comf} = 1$, therefore, their mean is one and variance is zero. Consequently, the *IP* on each sensor for each trial was paired for comparison with $IP_{comf} = 1$.

An example of the maximal pressure maps on the anterior, posterior, medial, and lateral F-socket Tekscan sensors is shown in Fig. 5.9. The dials indicate the position of a

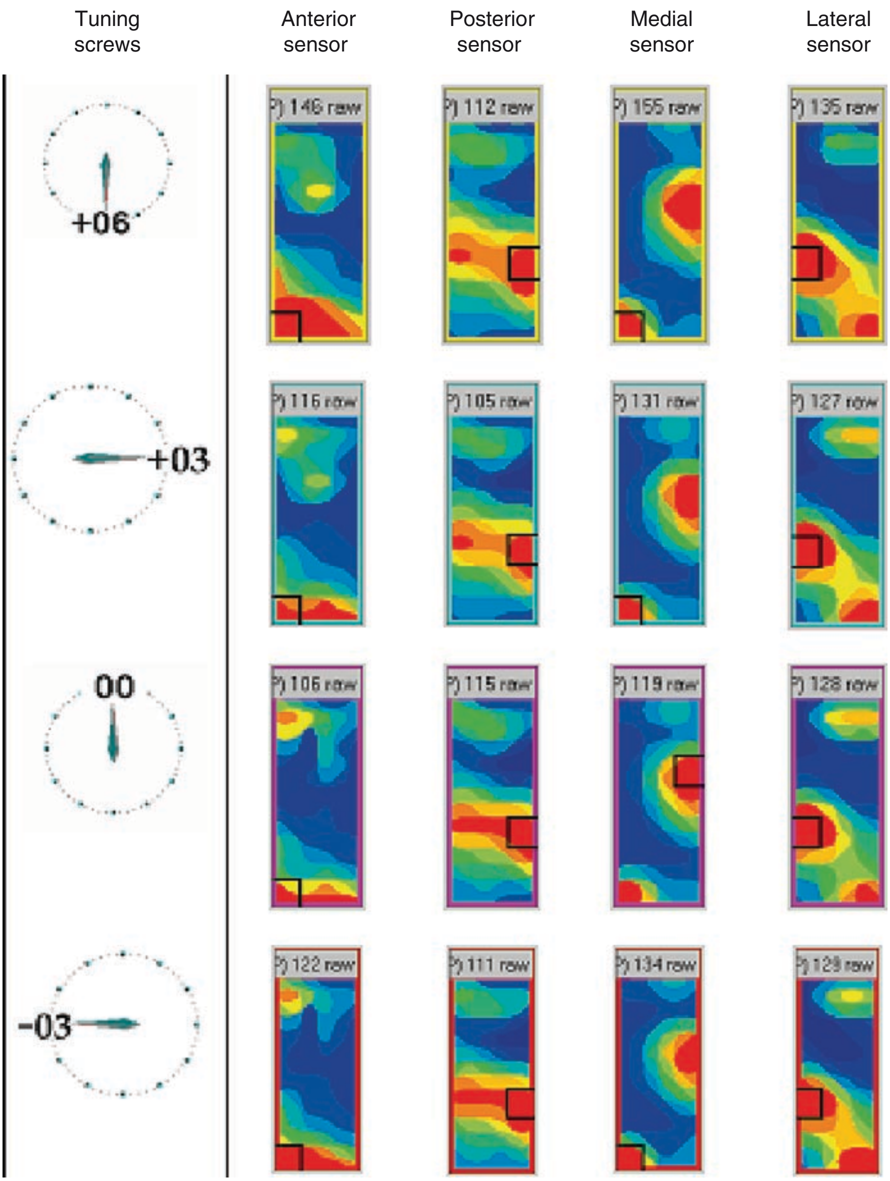

Fig. 5.9 Maximal pressure maps on the *anterior, posterior, medial, and lateral* F-socket Tekscan sensors. The dials indicate position of a mark on the tuning screws, where (+) means tightening and (−) means loosening of the screws

mark on the tuning screws, where (+) means tightening and (−) means loosening of the screws. The maps change according to the frequency of signal collection from the sensors, which was 50 Hz for this study. Each frame shows maximal pressure on a sensor for every position of the tuning screws.

As the data in Table 5.2 demonstrate, compared with comfortable gait, the mean peak pressures on *anterior* and *medial* sensors are greater with statistical significance ($p < 0.05$). The trials, which were identified by the subjects as the most comfortable, were associated with the minimal peak pressures on both *anterior* and *medial* sensors. Analysis of the magnitudes of the torque on the Torque Wrench (Fig. 5.8), yielded the interval 1.69 ± 0.15 Nm of the torques, which corresponded to the most comfortable gaits in all subjects, and which was recommended to the manufacturer for initial in-house installation.

5.2.5
Biomechanical Testing of RJFA: Conclusion

- The biomechanical study demonstrated that the anthropomorphic moment of resistance to dorsiflexion normalizes the stance flexion of existing knee in transtibial amputees, and results in lesser forces on residuum during gait (Pitkin et al. 1999).
- Position of side screws, responsible for the pretensed moment of resistance to the ankle deflection, can be viewed as a tuning parameter, which determines the subject's comfort during gait.

5.3
Biomechanical Testing of the Rolling Joint Leg

A biomechanical study was conducted to answer the following questions:

- If any, what are the differences in kinematical and dynamic parameters objectively measured during gait with the Rolling Joint Leg (RJ Leg), and with conventional prostheses?
- Does the study confirm the initial hypothesis of a correlation between a knee prosthesis design and stump–socket interface as an indicator of comfort?
- Does the study confirm the initial hypothesis that the RJ Leg has the potential to be a more comfortable prosthesis with more anthropomorphic moment of resistance to flexion than the prior art?

One woman, 75 years of age, and two men aged 47 and 52 years of age, participated in the gait study at the Center for Human Performance, New England Sinai Hospital/Tufts University (Pitkin 2004). The participants were unilateral trans-femoral vascular amputees, and good walkers without skin problems. The subjects met the inclusion criteria and signed the consent forms. All combinations of prosthetic components used in the trials are shown in Table 5.3.

Table 5.3 Combinations of prosthetic components used in the trials

KneesFeet	Otto bock safe knee	Total knee	Mauch hydraulic	RJ knee
College park foot	Owned and tested by subject # 1		Owned and tested by subject # 3	Tested by subjects #1, 3
SACH foot		Owned and tested by subject # 2		Tested by subject #2
RJ foot	*Tested by subject #1*	*Tested by subject #2*	*Tested by subject #3*	Tested by subjects #1, 2, 3

The subjects were asked to walk at a self-selected comfortable walking speed with their conventional prosthesis, with the RJ Leg, and with other assemblies indicated in Table 5.3. The subjects provided subjective evaluations of the comfort with both prostheses. After collecting three successful trials in terms of proper positioning of the involved leg on the force plate, the procedure was repeated with the RJ Knee, and the RJ (Free-Flow) Foot and Ankle. The prosthetic knee and foot were changed by a certified prosthetist[6]. Each subject's starting position was adjusted to obtain a "clean" foot strike on the force plate to avoid "targeting" of the force plate, which could result in an excessively short or long stride. The first run with the RJ Leg was assisted by a trained Physical Therapist. After that, the participant did not require any other assistance or accommodation. However, to assure safety, parallel bars were arranged along the walkway.

Foot Kinematic and dynamic data were produced by Peak Motus 3D Motion Analysis System and portable Kistler Force Plates. Pressure/force interface between the stump and socket was recorded by Tekscan pressure Distribution Measurement System (Fig. 5.10).

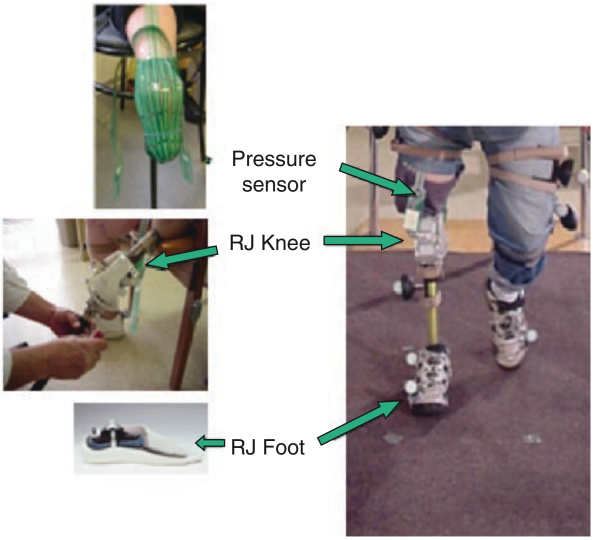

Fig. 5.10 Gait study with RJ Knee with simultaneous recording of the pressure on residuum by Tekscan system

[6]United Prosthetics, Inc., Boston, MA.

For the step length, step time, swing time, stance time, and single support, a symmetry index (SI) percentage was calculated using the formula: SI > (characteristics for involved side/Characteristics for uninvolved side) × 100. A value of 100% for the SI would indicate perfect symmetry between the involved and uninvolved sides.

Before a new trial session, a calibration of each F-sensor was performed. A calibration device provided by the manufacturer consisted of two 10" × 4" × 1" wooden blocks. The blocks were laminated with 1/8" plastic foam with stiffness of 40 U Shore A, aimed to roughly simulate the stump–socket interface. The sensor was placed between the calibration blocks. Then, a subject or other person with known weight stepped on the upper block and stood on one leg for about 3 s with the Tekscan software in "Calibrate" mode.

According to the manufacturer's specifications, a temperature influence on the values of data recorded could be expected at 0.5–0.8% when changing from room temperature of about 70°F to 90–100°F inside the socket. For that reason, the data collection began 15 min after the F-socket sensors were placed inside the socket.

We used two F-socket sensors, placing them on the anterior and posterior surfaces of the residuum of the subject before the trial session. The investigators used visual judgment in their attempts to define both anterior and posterior positions of the sensors on every subject. The position of a sensor was considered anterior if it was not seen from the back of the subject. Similarly, the position of a sensor was considered posterior if it was not seen from the front of the subject. With respect to the socket brims, one-inch of the sensor's upper portion was left above the socket brim to properly record the proximal stump–socket interface. We also tried to avoid wrinkles on the sensors, which could damage the measuring cells. When reasonable positioning was found, the sensor was secured on the stump with medical tape and then covered with a cotton-knitted liner. All patients for all trials used these liners. Then, the subject was asked to put on his or her own prosthetic leg, and to make several steps to ensure that there were no inconveniences associated with two sensors between his/her stump and socket.

5.3.1 Symmetry of Distant-Time Characteristics Between Involved and Uninvolved Sides

The analysis showed asymmetries in distant-time gait parameters between the amputated (involved) and uninvolved sides.

Step length, step time, and swing time were notably longer, while stance time and single support time were shorter on the involved side (Fig. 5.11). Observation of the graph suggests that the RJ Leg provides better symmetry between the involved and uninvolved sides, when compared with all of the other assemblies investigated. A t-test, and an ANOVA analysis confirmed the statistical significance (with 95% confidence) of differences in all five parameters for the RJ Leg vs. the SACH foot + Otto Bock Safe Knee assembly.

5.3.2 Moment of Resistance to Knee Flexion–Extension Moment

A comparison between "moment–knee angle" dependencies in the RJ Leg and the normal group is shown (Fig. 5.12). Both loops should be observed counterclockwise as indicated

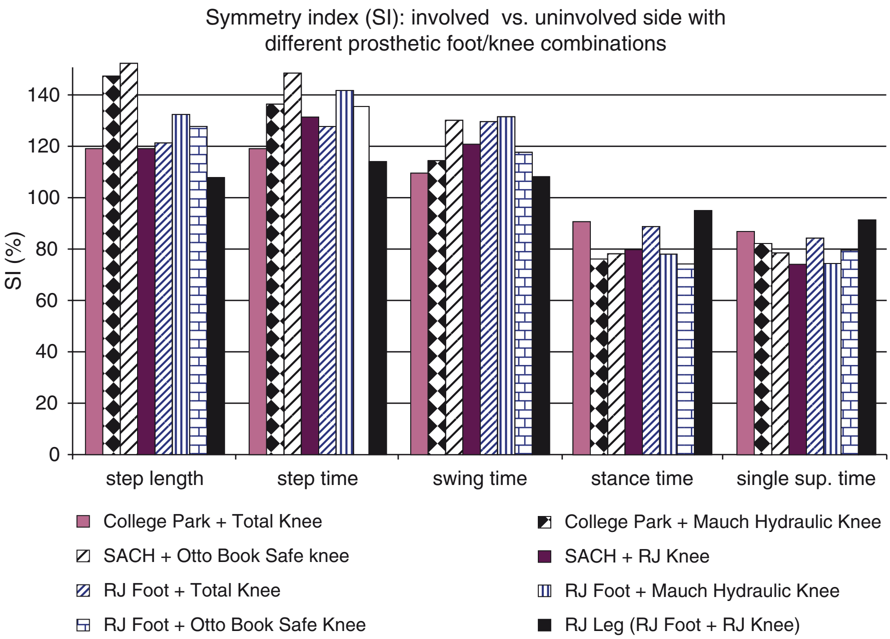

Fig. 5.11 Symmetry index (SI, %): SI > (characteristics for involved side/Characteristics for uninvolved side) × 100

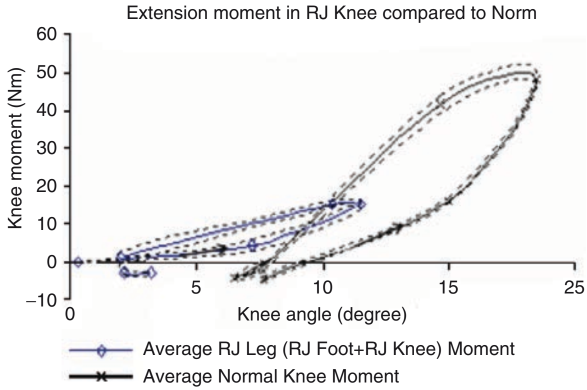

Fig. 5.12 "Moment–knee angle" dependence in the *RJ Leg* when compared with the normal group (± one standard deviation dashed lines are presented). Both loops should be observed counterclockwise as indicated by the *arrows*. The lower part of a loop corresponds to knee flexion, and the upper part – to the knee extension during stance period

by the arrows. The lower part of a loop corresponds to knee flexion, and the upper part corresponds to the knee extension during the stance phase. The data are averaged and ± one standard deviation dashed lines are plotted. The RJ Knee moment of resistance to knee flexion (the lower part of the loop) has a concave shape similar to the normal moment and to the moment recorded in mechanical tests (Fig. 4.21). Other knee units in the study demonstrated an opposite, convex pattern of the "moment–angle" dependence. The amplitude of the angle in the RJ Knee during the stance phase was 11 ± 2.1°, when compared with 13 ± 3.2° in the normal group.

5.3.3
Forces and Pressures on Residuum and Their Link with Ankle Moment

The more compliant RJ-Knee unit was associated with less pressures/forces applied to the stump, when compared with the existing prostheses used in the trials. In Fig. 5.13, averaged ratios, percentage of the force, pressure, and peak pressure on anterior and posterior surfaces of the stump are plotted, with the subjects wearing different combinations of prosthetic components. All statistically significant decreases/increases in these parameters are presented in Table 5.4 using t-test values (nondimensional) that exceeded the t-test threshold of 1.96 for $p=0.05$.

Except for the combination of SACH foot+Otto Bock Safe Knee (anterior pressure) and SACH foot+RJ Knee (posterior force), the gait with the RJ Leg was associated with lower forces, lower pressures, and lower peak pressures, when compared with all other prosthetic assemblies (Fig. 5.13). While not statistically significant, the recorded decrease of anterior pressure in the SACH foot+Otto Bock Safe Knee assembly and decrease of posterior force in the SACH foot+RJ Knee still requires an explanation.

Further analysis indicated that the subject kept the SACH foot+Otto Bock Safe Knee prosthetic leg in a straight position during load bearing. For that reason, the stump was never skewed in the socket. Therefore, forces and pressures on the stump were at a low level, and the subject was able to avoid the S-joint, which was described in Sect. 3.5 (Fig. 3.15). A rigid ankle and a rigid knee required certain compensatory body movements, resulting in gait

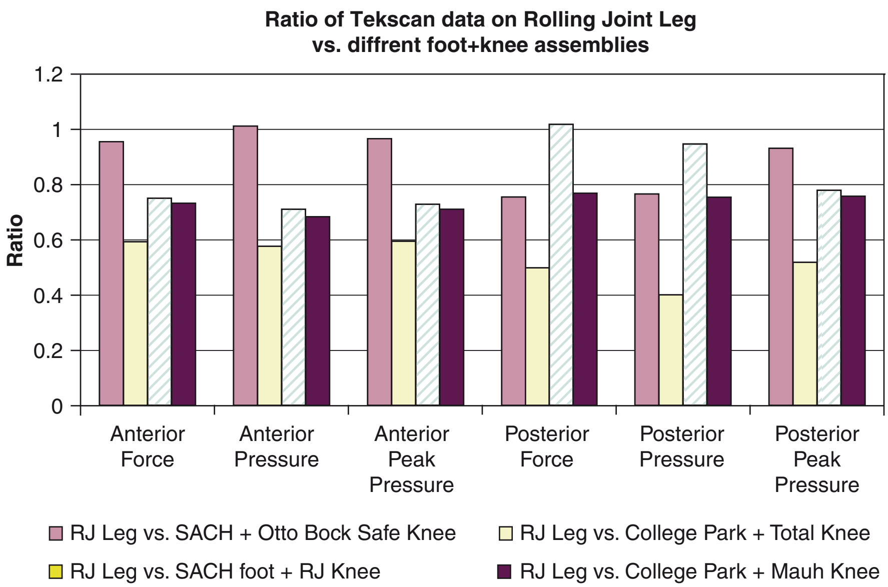

Fig. 5.13 Ratio of Tekscan data on Rolling Joint Leg (RJ Knee+RJ Foot) vs. different foot+knee assemblies

Table 5.4 Statistical significance of decrease/increase* in force, pressure, and peak pressure on anterior and posterior surfaces of the stump with the RJ leg (RJ foot + RJ knee-S) vs. the combinations of prosthetic components used in the trials

Type of prosthesis compared to RJ leg	Anterior F-socket sensor			Posterior F-socket sensor		
	Force	Pressure	Peak pressure	Force	Pressure	Peak pressure
RJ leg vs. SACH + otto bock safe knee	(+)−3.15	–	–	–	–	(+)−2.94
RJ leg vs. college park + total knee	–	(+)−2.98	(+)−3.06	–	(+)−3.50	–
RJ leg vs. SACH foot + RJ knee	–	–	–	(+)2.86	–	–
RJ leg vs. college park + mauch knee	–	(+)−2.87	–	–	–	–
RJ leg vs. RJ foot + total knee	–	–	–	(+)−2.01	(+)−2.22	–
RJ leg vs. RJ foot + mauch hydraulic knee	–	–	–	–	–	–
RJ leg vs. RJ foot + otto bock safe knee	–	–	–	–	–	–

*A decrease (minus sign before the t-test value) is considered significant (+) if the t-test absolute value is greater than the t-test threshold of 1.96 for $p = 0.05$; an increase (plus sign before the t-test value) is considered significant (+) if the t-test absolute value is greater than the t-test threshold

asymmetry. When the more compliant RJ Knee + RJ Foot assembly was provided, the subject was able to maintain the acceptable level of stump stresses without assuming an asymmetric gait strategy.

When we talk about "compliance" in a prosthetic joint, we include the combination of the allowable, more normal range of angulation in a joint, and the nonlinear concave pattern of the moment of resistance to that angulation. The more normal range of angulation without a concave pattern of the moment of resistance is not sufficient for gait improvement. That is confirmed by the outcome of the "College Park + Total Knee" performance. The prosthetic knee angle in this assembly was close to normal, but because of the convex pattern of the moment in Total Knee, higher pressures were applied to the stump. As a result of the subject's attempts to compensate for these stresses, his gait was more asymmetrical.

5.3.4 Contribution of the RJ Knee vs. RJ Foot

The RJ Foot in combination with Total Knee demonstrated a more normal knee angle than with the original combination of "College Park + Total Knee." However, the RJ Foot did not improve the moment in Total knee. The RJ Knee combination with the SACH foot produced a more normal knee angle, and a moment similar to the "College Park + Total

Knee" prosthesis. Thus, we may suggest that the contribution of the RJ Knee without the RJ Foot was more positive than the contribution of the RJ Foot without the RJ Knee.

5.3.5 Biomechanical Testing of Rolling Joint Knee: Conclusion

Results of the biomechanical study suggest that the more compliant knee mechanism in the *RJ Leg* decreases the interfacial forces and pressures between the stump and the socket, normalizes the stance-bending of the prosthetic knee in trans-femoral amputees, improves symmetry in distant-time characteristics, and therefore has potential for greater amputee comfort and less fatigue during gait. All subjects reported that the comfort experienced with the RJ Leg was greater than with their own prostheses.

5.4 Long-Term Outcomes of Rehabilitation with RJFA

Long-term outcomes of rehabilitation with Rolling Joint prostheses were analyzed in a study[7] between the Center for Human Performance at New England Sinai Hospital/Tufts University, Boston, MA, and the Albrecht Rehabilitation Center for Occupational Expertise, Prosthetics and Rehabilitation in St. Petersburg, Russia. It was investigated why ice hockey, an aggressive sport, turns out to be quite comfortable for amputee players.

The first ever ice hockey team of transtibial amputees playing in a standing position was founded in St. Petersburg in 1999 under the program "US-Russian Prosthetic Rehabilitation Bridge" (Pitkin 2002). Since then, Standing Amputee Ice Hockey has been developed in nine countries in Europe, North America, and Australia (www.isihf.org) (Fig. 5.14). The

Fig. 5.14 A game during ISPO 2004 World congress in Hong Kong

[7]Support for the study was provided in part by the CRDF Grant RB1-2382-ST-02; the Ohio Willow Wood Co., Mt. Sterling, OH, and Tekscan Inc., Boston, MA. Roller skates for the study were donated by Scott Harrington, Captain of the US National Amputee Hockey Team and Brent Clemens, Captain of the Canadian National Amputee Hockey Team.

first biomechanical study in standing amputee ice hockey (Pitkin et al. 2003) demonstrated that multiaxial mobility in the ankle zone contributes to better performance on ice, despite the design of hockey boots, in which the rigid heel, and lateral and medial zones are intended to prevent the ankle from sagittal and frontal angulation (Hancock et al. 1999).

Forces and pressures on the stump, as predictors of the amputee's comfort, were recorded with F-Socket sensors, Tekscan, Inc., while the subjects roller-skated, walked, and jumped along a 15-m carpeted wooden path in the Laboratory of Biomechanics of the St. Petersburg Albrecht Center for Occupational Expertise, Prosthetics, and Rehabilitation. Four traumatic below-knee unilateral amputees, three of whom were members of the Russian National Standing Amputee Hockey Team, read and signed the Informed Consent Forms approved by the IRB/Ethics Committee, and agreed to participate in the trials. All subjects used the *Free-Flow Foot and Ankle* prostheses, Ohio Willow Wood, Co., Mt. Sterling, Ohio.

Before the trials, two F-socket sensors were positioned inside the socket, on the anterior and posterior areas of subject's stump. The subjects were asked to start after a signal, skate to the end of the pathway, stop, turn, skate back, and to stop at the initial position. Recording time (10 s) was sufficient to collect data for the whole task, which included all maneuvers and two phases of linear skating. During all the trials, including consecutive walking and jumping on the involved leg, the subjects did not take off the socket, and the positions of the sensors remained unchanged.

Peak pressures on each sensor were collected every 1/60 of a second. Data were exported to format for further analysis. For every trial, we identified five greatest maximal values in peak pressure series from each of two sensors. The mean maximal values $P_{anterior}$ and $P_{posterior}$ were compared, respectively, after linear roller-skating and maneuvering, and after gait and jumping.

Results of the study are illustrated in Figs. 5.15 and 5.16. It is seen that during linear roller-skating, the mean maximal pressure peaks in both sensors were significantly smaller than when subjects were walking in their regular athletic shoes.

During maneuvering, the mean maximal pressure peaks in both sensors were significantly higher than during linear roller-skating, and were similar to jumping in regular athletic shoes. The results of this study suggest that skating contributes to lesser pressure

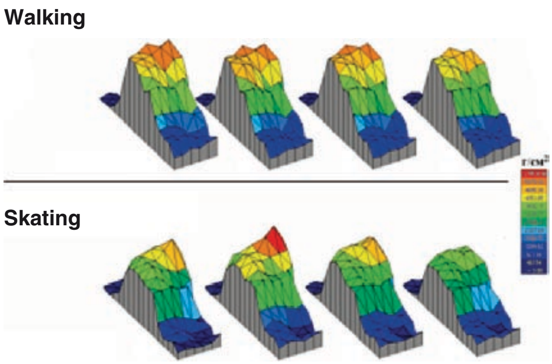

Fig. 5.15 Pressure distribution on anterior surface of stump during *walking and skating*. Diagrams represent maximal pressures for each of four consecutive steps (1–4)

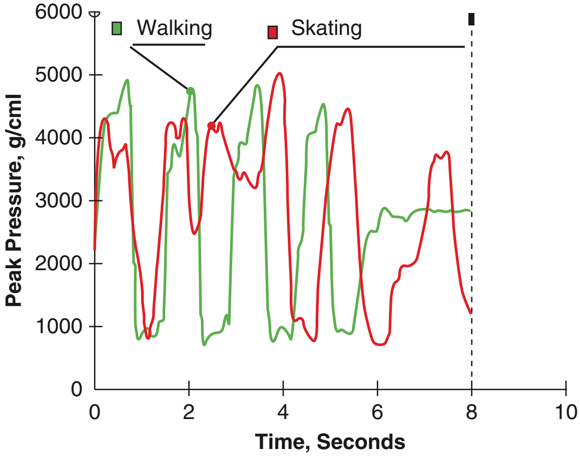

Fig. 5.16 Dynamics of pressure applied to the anterior surface of stump during *walking and skating*

peaks and correspondingly to more comfort when compared with walking, and even more comfort when compared with jumping. It is possible to suggest that the acceptable level of amputees' comfort during hockey play results from both skating biomechanics and specifics of this team sport. First, there is relatively low energy expenditure during skating and gliding, when compared with other competitive sports, such as cycling (Kandou et al. 1987). Second, the most frequently performed skills during the game are skating forward without the puck and gliding forward without the puck (Bracko et al. 1998). The players are exposed to relatively high peak pressures associated with maneuvering for quite a small time. For the rest of the time, they are gliding and skating forward, thus experiencing, as our study demonstrated, more comfort (less pain) than while walking (if players wear the multiaxial prosthetic foot and ankle).

Another reason for the relatively high level of acceptance of standing ice hockey by amputees can be the lower speed of skating, since it decreases impacts due to checking. Preliminary analysis of video data gives an estimate of 30% lower speed in amputees with leg prostheses when compared with able-bodied players. The results of this and a later study (Pitkin et al. 2005) suggest that amputees can participate in a highly motivational and active sport without excesses in pressure peaks on the stump for the larger part of the game.

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