1	Analysis of compression/release stabilized transfemoral prosthetic socket by
2	finite element modelling method
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17 Abstract

18 This project aimed to investigate the residual limb stress of a transfermoral amputee's 19 Compression/Release Stabilized (CRS) socket by finite elemental modelling. The model was 20 constructed from magnetic resonance images of the left residual limb of a 48-year-old male 21 transfemoral amputee. Two conditions were simulated. In the donning condition, the prosthetic 22 socket under the residual limb moved proximally until it reached the required donned position. 23 The weight-bearing condition was subsequently simulated by applying body weight (800N) at 24 the femoral head while keeping the distal end of the socket fixed. The maximum contact pressure 25 was concentrated at the proximal anterior-medial regions of the residual limb surfaces in both 26 conditions. In the donning condition, the maximum von Mises stress and the maximum contact 27 pressure were 277.7 kPa and 254 kPa respectively. The respective values were 191.9 kPa and 28 218.5 kPa when body weight was applied. The CRS socket demonstrated higher stress and 29 contact pressure as compared to that of other designs reported in the literature. Nevertheless, the 30 higher stress and contact pressure may be acceptable since the values are tolerable and below the 31 pain threshold of the previous study. Our findings provide important biomechanical information 32 on the CRS socket that may help future design optimization.

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Keywords: compression/release; transfemoral amputee; socket design; finite element

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35 Introduction

36 Lower limb prostheses are designed to substitute the functions of the amputated limb and play an 37 important role in facilitating daily activities such as standing and locomotion. The prosthetic 38 socket, a crucial component of the prosthesis, makes direct contact with the residual limb and 39 influences prosthetic fit and comfort. Inappropriate design or fitting may lead to various 40 complaints, especially in those who use a prosthesis with a more conventional socket design 41 (e.g., Quadrilateral or Ischial-ramal containment socket) [1-3]. These complaints include pain, 42 abrasion, sweating, poor prosthetic control, and inconvenient donning and doffing. Improvement 43 of socket design could hopefully alleviate some of these problems, which commonly arise during 44 rehabilitation and activities of daily living.

45 The quadrilateral prosthetic socket (Quad) has a quadrilateral brim that is narrower in the 46 anterior-posterior direction compared to the medial-lateral direction. The ischial tuberosity rests 47 on the posterior brim for weight-bearing and force transfer [4]. Since the ischium is not secured, 48 the ischial bone may medially slide on the posterior surface of the prosthetic socket during 49 weight bearing causing femur abduction. As a result, the distal end of the residual limb would be 50 pressed against the socket wall, leading to pain, discomfort and lateral lurch gait. The ischial-51 ramal containment (IRC) socket was developed in the 1980s aiming to remedy this problem [5-52 8]. The IRC socket extends the posteromedial brim of the socket to cover the medial border of 53 the ischial tuberosity and ramus by an oblique and sloping contours design. Compared with the 54 Quad socket, it is narrower in the medial-lateral dimension. The Quad and IRC Sockets share 55 similar design features and can both compromise hip range of motion [9-11]. The IRC socket 56 design was further modified to become the Marlo Anatomical Socket (MAS). Instead of 57 containing the ischium, the MAS surrounds the ischio-pubic ramus and allows a release on the

posterior gluteal portion. Improved comfort, stability and reduced energy cost of walking werereported [12,13].

60 Sufficient compression on the residual limb can reduce the relative motion between soft tissue, 61 bone and the socket, which is essential for prosthetic control [14]. Traditional socket designs 62 (Quad, IRC, MAS) may produce insufficient tissue compression and thus prosthetic control. The 63 compression/release stabilization (CRS) socket design was recently introduced that features four 64 longitudinal pre-compression bars and four adjacent release regions. The release regions allow 65 some room to accommodate the compressed tissue for better comfort and reduced chance of 66 ischemia while maintaining adequate compression on the residual limb through the pre-67 compression bars. Subsequently, a more compressed residual limb enables a higher efficiency of 68 momentum transfer from the femur bone to the socket [15]. There may be no need for a proximal 69 brim design to stabilize the socket around the ischial region and therefore no loss of hip range of 70 motion. The control stability, sitting, donning and doffing comfort may be improved by the CRS 71 design [16,17]. However, the condition of the residual limb under further compression is not 72 clear. This study aimed to evaluate the pressure and stress distribution on the transfemoral 73 residual limb using the CRS socket by the finite element (FE) modelling method.

74 Methods

75 Subject

A 48-year-old male transfermoral amputee (left side) was recruited for this study. His limb was amputated 28 years ago due to a bone tumor and has used a prosthesis ever since. He was active in daily activities and walked independently every day. Before the experiment started, the subject signed an informed consent and the study was approved by the institutional ethics committee.

80 Geometric reconstruction of the residual limb and design of CRS socket

MR images of the subject's residual limb were taken (GE Signa HDxt 1.5T, Canada). Image parameters were: slice thickness, 2mm; acquisition time, 0.42s/35mins; matrix, 320×160, Field of view, 40×32cm, 1-mm pixel size. The patient was supine lying on the MRI patient table with the hip in a neutral position. An unmodified plaster cast was worn to minimize gravity induced residual limb tissue distortion [18]. Soft tissue and bone segmentation were carried out using image segmentation software Mimics v10 (Materialise, Leuven, Belgium).
The CRS socket was constructed by offset the surface of the 3D geometry of residual limb in

SolidWorks (Corporation, MA, USA). The compression was started 40mm below the upper brim of the socket. Four compression areas with an equal compression width (the upper circumference of residual limb divided by 8) were centered between median sagittal and coronal plane with the adjacent openings for the soft tissue displacement. The compression depth was set to 15mm (Figure 1).

93 Material properties and mesh creation

94 The material properties of the bone encapsulated soft tissue and socket were assumed to be linear 95 elastic, homogeneous, and isotropic. As the CRS socket is a new socket design approach, the 96 simplification of material properties can quickly assess the CRS socket biomechanics and the 97 results can be a starting point for further study. The Young's modulus of the bone and socket 98 were 15,000 MPa and 1,500 MPa respectively [19]. The Poisson's ratio for the bone and socket 99 was 0.3 [20,21]. As reported by Malinauskas, the average modulus from nine transfermoral 100 amputees ranged from 53.2 to 141.4 kPa [22]. However, the underlying muscles would be in 101 tension during the socket donning, which increased the soft tissue modulus. The Young's

102 modulus for the encapsulated soft tissue was set to 0.2 MPa, and 0.49 for Poisson' ratio [20, 23, 103 24]. For easy modelling of complex geometries of the CRS socket, bone and encapsulated soft 104 tissue, three-dimensional 4-node tetrahedra (C3D4) mesh elements were assigned for all parts 105 and created by the finite element software package Abaqus (Dassault Systèmes, RI, USA). The 106 muscles, ligaments, tendons, subcutaneous fat and skin etc. were not segmented, but were 107 integrated as the encapsulated soft tissue. The element size was 3 mm for both the bone and 108 socket, and 5 mm for the encapsulated soft tissue which adopted from the study which performed 109 meshed convergence testing [25]. There was a total of 349, 828 elements in the model. The set 110 values of material properties and mesh types are summarized in Table 1.

111 Table 1. Material properties

Material	Young's modulus	Poisson's	Elements	Element type
	(MPa)	ratio		
Bone	15000	0.3	58,982	C3D4 ¹⁹
Encapsulated soft tissue	0.2	0.49	166,663	C3D4 ¹⁹
Socket	1500	0.3	124,183	C3D4 ¹⁹

112 Boundary and loading conditions

113 The interfaces between the femur and soft tissue were tied. The coefficient of friction between

the socket and soft tissue was assumed to be 0.4 [25,26].

115 Two conditions were simulated sequentially: (1) simulation of donning the prosthetic socket.

116 Before donning, the socket was placed underneath the residual limb with the upper inner

117 compression area just touching the residual limb (Figure 2a). The donning was simulated by

118 a 106 mm upward displacement of prosthetic socket along the z-axis with x and y-axis fixed.

The femoral head was fixed while the socket moved vertically upward until it reached the fully donned position. The upward displacement was kind of the donning force. The actual donning force was generated by the Abaqus software. After the socket fully donned, it maintained at that position.

(2) weight-bearing on the prosthetic socket and the residual limb. After the socket fully
donned, a simulated body weight load of 800N was applied on the femoral head while the
distal end of the socket was fixed (Figure 2b).

126 **Results**

127 Contact pressure and von Mises stress in the donning condition

The model predicted contact pressure distribution and von Mises stress are shown in Figure 3 and Figure 4 respectively. The maximum contact pressure and the maximum von Mises stress of the encapsulated soft tissue were 254.1 kPa and 227.7 kPa respectively. The residual limb was loaded primarily at the compression areas as indicated by the higher pressure distribution. In addition, there was a little pressure concentration on the residual limb corresponding to the upper brim of the CRS socket.

134 The maximum von Mises stresses of encapsulated soft tissue were concentrated in the proximal

region of the compression areas except for the anterior-lateral side where the von Mises stress

136 spread out from the compression center. The posterior-medial compression area appeared to have

137 the smallest maximum von Mises stress (186.8 kPa) among the four compression areas.

138 Contact pressure and von Mises stress in the donned condition with weight-bearing

139 The maximum contact pressure and maximum von Mises stress of encapsulated soft tissue were

found 218.5 kPa and 191.9 kPa respectively in the anterior-medial compression area (Figure 5
and Figure 6). The values were decreased by 14% for the maximum contact pressure and 15.5%
for the von Mises stress compared with the donning procedure.

143 Maximum Contact pressure and maximum von Mises Stress on different compression areas

144 The maximum contact pressure and the maximum von Mises stress of encapsulated soft tissue on

145 individual compression area are shown in table 2. From the donning to the weight-bearing

146 condition, the maximum contact pressure was decreased by 14.2%, 15.5%, 5.7%, 17.2% in the

147 anterior-medial, anterior-lateral, posterior-medial, and posterior-lateral sides respectively.

148 Corresponding maximum von Mises stress was also decreased by 16.2%, 19.8%, 7.0%, and

24.9%. Both contact pressure and von Mises stress were reduced the least in the posterior-lateralcompression area.

	1			1
	Contact pressure		von Mises stress	
Location	Donning	Weight-bearing	Donning	Weight-bearing
	(kPa)	(kPa)	(kPa)	(kPa)
Anterior-medial	254	218	228	191
Anterior-lateral	219	185	212	170
Posterior-medial	212	200	187	174
Posterior-lateral	204	169	201	151

151 Table 2. Maximum contact pressure and maximum von Mises stress on individual compress area

153 Discussion

154 The CRS prosthetic socket design was claimed to reduce the lost motion induced by soft tissue-155 socket interaction in the conventional prosthetic socket. However, the condition of the residual 156 limb under further compressions was not well understood. By simulating the donning and 157 weight-bearing responses, the stress and contact pressure of a transfermoral amputee's residual 158 limb utilizing the CRS socket were predicted. The maximum von Mises stress and the contact 159 pressure were both located on the anterior-medial side of the residual limb. The posterior-medial 160 compression area was the region which the value of the maximum contact pressure and 161 maximum von Mises stress decreased the least from donning to weight bearing. This may 162 indicate that the posterior-lateral compression area bore higher body weight during loading. A 163 previous study suggested that thicker soft tissue can absorb more impact force and energy [27]. 164 From the cross-sectional view of the subject's residual limb, the soft tissues (fat and muscles) 165 around the posterior-medial shaft of the femur was thicker than the other three locations (Figure 166 7). It is likely that this structural difference contributed to the location-dependent differences in 167 the pressure and stress distribution.

Socket interfacial pressure is an important factor which affects the comfortability of prosthesis user. The interfacial pressure has been studied by many researchers with different modalities to evaluate socket structure and function. Zhang's group [28] found the maximum normal stress in the donning procedure was less than 55.51 kPa, and the pre-stress was more evenly distributed for the conventional transfemoral prosthetic socket. In their study, the simulation of donning was created by applying 50N on the upper surface of the soft tissue. It was likely that this adding force was too small to cause force concentration and may not accurately reflect the donning

175 action. As donning is an action of putting the residual limb into the prosthetic socket, providing a 176 vertical displacement of the prosthetic socket seems to be a valid way to simulate the donning 177 action. Kahle and Highsmith [29] studied nine transfemoral amputees wearing IRC and brimless 178 socket designs. The maximum pressure was 254 kPa with a mean of 112 ± 80 kPa in the IRC 179 socket and 222 kPa with a mean of 109 ± 61 kPa in the brimless socket. Consistent with the 180 present results, they found the largest pressure and stress occurred in the medial-proximal aspect 181 of the socket, suggesting that high pressures are more likely to occur in this region. The largest 182 pressures of both sockets were even larger than the value (218 kPa) recorded in the present 183 study.

184 Colombo et al. [30] reported a 200 kPa maximum contact pressure on the transfermoral residual 185 limb surface which is slightly smaller than present findings. However, they evaluated the walking condition with several times of the body weight applied at the hip joint. Velez et al. [31] 186 187 found the maximum pressure during donning and loading with Quad and IRC socket designs was 188 151 kPa in one transfemoral amputee, about 30% smaller than the present study. The maximum 189 compression force in the CRS socket was much higher than the maximum pressure in 190 conventional socket designs. Nevertheless, it was also far less than the previous study of 191 transtibial amputee pressure tolerance and pain threshold [32]. It seems that further compression 192 of the CRS socket may be possible. However, possibility of blood vessel damage and skin break 193 should be evaluated further for patient using the CRS socket as well as under walking gait 194 condition.

195

Although 800 N vertical load was added at the femoral head, the maximum von Mises andthe maximum contact pressure were both smaller compared to the donning condition. While

body weight was applied, the vertical load would force the residual limb further into the socket. It might increase the residual limb contact area with the socket and distal end bearing which in turn helped the maximum von Mises stress and maximum contact pressure decreased from donning to weight bearing. This study utilized the upward displacement to simulate the donning procedure. Although it is more approach to the clinical scenario, the limitation is that the displacement driven upward force was generated by the computer which is uncontrollable and may cause a larger donning pressure.

205

The von Mises stress distribution pattern illustrated that stress was distributed along the middle portion of the anterior-lateral compression area of the residual limb. In contrast, stresses were concentrated at the upper portion for the other three compression areas. These concentrated stresses can be found internally or externally of the residual limb. Knowing the approximate location of stress concentration is enough regardless it is superficial or deep.

To improve the CRS socket design, the von Mises and the normal stresses should be more evenly distributed to enhance comfort. From the base of the inner CRS socket, the structure was depressed equally 15mm to achieve compression. With stress predicted, the socket structure can be modified to reduce the compression depth of upper parts of anterior-medial, posterior-medial, and posterior-lateral compression bars. After modification, stresses on the upper part of the residual limb would be reduced for better comfort.

This study did not exam the shear stress. However, we expected the shear stress elevation after removing of the upper brim of the socket. While the upper brim is removed, the pressure and shear stress previously taken by the upper brim of the conventional socket would shift to the lower part of prosthetic socket which causes shear stress elevation. It remains crucial to

evaluate shear stress of the residual limb wearing the CRS socket as excessive shear forcemay cause pressure ulcer.

223

224 A single case study incorporating simplified material properties is a limitation. Another 225 limitation is that the 800 N vertical load simulating weight bearing may not accurately reflect the 226 real loading of the hip joint. In vivo, the joint reaction force is not vertical, but occurs in three-227 dimensional [33]. The loading magnitude and direction of the hip joint are determined by the 228 angle of the femur head and muscle force. However, these parameters are difficult to measure 229 and vary between different persons. The FE results may not be accurately validated if we are 230 unable to measure the hip joint loading force and its direction. Our study simplified the load as 231 vertical, which was quite often used by previous FE prosthetic socket studies. The CRS socket is 232 a new transfemoral socket design. Our study is an essential starting point to understand basic 233 biomechanics of CRS socket design through simplified FE model.

234 Conclusion

In this study, the design of the CRS socket was based on 3D reconstructed geometry of the
residual limb. This approach of CRS socket design allowed assembly of the FE model to achieve
a more reliable FE prediction. The simulation results provide an initial look into the design and
optimization of the CRS socket structure. Further work is necessary to validate this process in a
larger sample.

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